mRNA Cancer Vaccine Collaboration and License Agreement

by and between

MODERNATX, INC.

and

MERCK SHARP & DOHME CORP.

April 17, 2018

This Amended and Restated mRNA Cancer Vaccine Collaboration and License Agreement (this "<u>Agreement</u>"), dated as of April 17, 2018 (the "<u>Amended Effective Date</u>"), is made by and between ModernaTX, Inc., a corporation organized and existing under the laws of Delaware ("<u>Moderna</u>"), and Merck Sharp & Dohme Corp., a corporation organized and existing under the laws of New Jersey ("<u>Merck</u>"). Each of Moderna and Merck may be referred to herein as a "<u>Party</u>" or together as the "<u>Parties</u>".

WHEREAS, Moderna and its Affiliates have developed expertise and technology useful for the research, development, manufacture, or commercialization of pharmaceutical products that function using mRNA;

WHEREAS, Moderna and its Affiliates are focused on the advancement of mRNA cancer vaccines that are based on formulated mRNA Constructs that encode for neoantigens or other antigens using mRNA Technology;

WHEREAS, Merck is a pharmaceutical company focused on researching, developing, manufacturing and commercializing innovative therapeutic products;

WHEREAS, Merck and Moderna previously entered into that certain PCV Collaboration and License Agreement dated as of June 28, 2016, as amended (the "Original Agreement" and such date, the "Effective Date") pursuant to which the Parties established a broad research and development collaboration pursuant to which Moderna would Research and Develop Collaboration PCV Products through proof of concept, and Merck would thereafter have the right to continue with Moderna in the Research, Development, Manufacture and Commercialization of Collaboration PCV Products; and

WHEREAS, the Parties now desire to amend and restate the Original Agreement in its entirety and replace the Original Agreement with this Agreement, to, among other things, expand the scope of the Collaboration to include SAVs in addition to PCVs.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. <u>DEFINITIONS</u>

The following terms and their correlatives will have the following meanings:

- 1.1 "2015 Collaboration Agreement" means that certain Master Collaboration and License Agreement, by and between Moderna and Merck, dated as of January 12, 2015, as amended or restated from time to time.
- 1.2 "2016 CSA" means that certain Pre-Clinical and Clinical Supply Agreement, by and between Moderna and Merck, dated on or about June 27, 2016, as amended or restated from time to time.
 - 1.3 "AAA" has the meaning set forth in Section 15.1(c).
- 1.4 "Act" means, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as such may be amended from time to

time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

- 1.5 "Additional Converted Program Research Activities" has the meaning set forth in Section 3.1(e)(i)(1).
- 1.6 "Additional Moderna PCV POC Term Study" has the meaning set forth in Section 3.3(d).
- 1.7 "<u>Additional Research Plan</u>" means a written plan setting forth the Collaboration Activities of the Parties with respect to any Additional Research Program and the budget therefor that is approved by both of the Parties.
 - 1.8 "Additional Research Program" has the meaning set forth in Section 4.1(b).
 - 1.9 "Additional Regulatory Costs" has the meaning set forth in the Financial Definitions Exhibit.
- 1.10 "Additional Study" means any Clinical Study (including any Phase IV Clinical Study) proposed by a Party pursuant to Section 4.4(a)(i) to be conducted during the Merck Participation Term for a given Program to Develop any Collaboration Product from such Program as a monotherapy or in combination with one or more Other Components beyond any Clinical Study(ies) contemplated by the then-current Joint Development Plan and Budget for the applicable Program.
 - 1.11 "Additional Study Proposal" has the meaning set forth in Section 4.4(a)(i).
- 1.12 "Adverse Event" per the International Conference on Harmonization (ICH), means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An Adverse Event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to such medicinal product.
- 1.13 "Affiliate" of a Person means any other Person which (directly or indirectly) is controlled by, controls or is under common control with such Person. A Person will be deemed to "control" another Person if it: (a) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, has other comparable ownership interest; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.
 - 1.14 "Agent Technology" means the Moderna Agent Technology and the Merck Agent Technology.
 - 1.15 "Agreement" has the meaning set forth in the Recitals.
 - 1.16 "Allowable Commercialization Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.17 "Allowable Development Costs" has the meaning set forth in the Financial Definitions Exhibit.
- 1.18 "<u>Amended Anticipated PCV POC Budget</u>" means Two Hundred Forty-Three Million Dollars (\$243,000,000), or such other amount as the Parties may mutually agree in the POC Plan for the PCV Program.
 - 1.19 "Amended Effective Date" has the meaning set forth in the Recitals.
 - 1.20 "Antitrust Clearance Date" has the meaning set forth in Section 14.1.
 - 1.21 [***]
 - 1.22 "Bankruptcy Code" has the meaning set forth in Section 10.5.
- 1.23 "Batch Records" means, with respect to a batch of product Manufactured, (a) batch records (including all attachments thereto), including pre-filtration Bioburden results, per process environmental monitoring reports, differential pressure alarm reports, CIP/SIP data, in-process CTU temperature charts, reports and details of major investigations, and reports and details of product related change controls, in English, and (b) any investigation or deviation reports (and details thereof) related to such product, in English, and (c) a release assay qualification summary report and a pre-campaign cleaning report, in English; in each case, for such batch.
- 1.24 "<u>Business Combination</u>" means, with respect to a Party (or its Affiliate), any of the following events: (a) any Third Party (or group of Third Parties acting in concert) acquires (including by way of a tender or

exchange offer or issuance by such Party (or its Affiliate)), directly or indirectly, beneficial ownership or a right to acquire beneficial ownership of shares of such Party (or its Affiliate) representing more than fifty percent (50%) of the voting shares (where voting refers to being entitled to vote for the election of directors) then outstanding of such Party (or its Affiliate); (b) such Party (or its Affiliate) consolidates with or merges into another corporation or entity which is a Third Party, or any corporation or entity which is a Third Party consolidates with or merges into such Party (or its Affiliate), in either event, pursuant to a transaction in which more than fifty percent (50%) of the voting shares of the acquiring or resulting entity outstanding immediately after such consolidation or merger is not held by the holders of the outstanding voting shares of such Party (or its Affiliate) immediately preceding such consolidation or merger; or (c) such Party (or its Affiliate) sells, transfers, leases or otherwise disposes of all or substantially all of the assets to which this Agreement relates to a Third Party.

- 1.25 "<u>Business Day</u>" means any day other than a Saturday or Sunday on which banking institutions in New York, NY are open for business.
- 1.26 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (a) the first Calendar Quarter of this Agreement shall commence on the Effective Date and end at the end of the Calendar Quarter in which the Effective Date occurs and (b) the last Calendar Quarter of this Agreement shall commence at the commencement of such Calendar Quarter and end on the expiration of the Term.
- 1.27 "<u>Calendar Year</u>" means each twelve (12) month period beginning on January 1st; provided, however, that (a) the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31 of the same year and (b) the last Calendar Year of this Agreement shall commence on January 1 of the Calendar Year in which this Agreement expires and end on the expiration of the Term.
 - 1.28 "Cash Losses" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.29 "Cash Profits" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.30 "Cash Profits or Losses" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.31 [***]
 - 1.32 "Cessation Transition Plan" has the meaning set forth in Section 10.10(b).
- 1.33 "<u>cGMP</u>" means the then-current good manufacturing practices, standards, guidelines and regulations promulgated and published by FDA, EMA or any other applicable Regulatory Authorities having jurisdiction over the Manufacture, Development or Commercialization of any product (and any precursor steps), as applicable, relating to the testing, manufacturing, processing, packaging, holding or distribution of drug substances and finished drugs including any standards, guidelines and regulations as promulgated by, as applicable: (a) the FDA under and in accordance with the U.S. Federal Food, Drug and Cosmetic Act and Title 21, Parts 210 and 211 of the U.S. Code of Federal Regulations, (b) the EMA and the EU Commission under European Directive 2003/94/EC, and/or (c) the ICH Harmonised Tripartite Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients (ICH Q7), as such standards, guidelines and regulations may be amended from time to time.
- 1.34 "Clinical Data" means all information with respect to a Collaboration Product made, collected or otherwise generated under or in connection with Clinical Studies for such Collaboration Product undertaken under the applicable POC Plan or Development Plan(s), including any data, reports and results with respect thereto.
- 1.35 "Clinical Initiation Criteria" means, with respect to a given Joint SAV Program (other than the KRAS Program), the criteria that are agreed upon by the Parties as part of, and set forth in, the POC Plan for such Joint SAV Program, which may be changed from time to time by written agreement of the Parties and which, among other data and information, will be used by the Parties to determine the suitability of an SAV for (a) the filing of an IND for such SAV and (b) the conduct of Phase I Clinical Studies with such SAV under such Joint SAV Program. The Clinical Initiation Criteria shall include criteria based upon [***].
- 1.36 "Clinical Quality Agreement" means a quality agreement entered into between the Parties with respect to the Manufacture of Collaboration Product for Development purposes during the Collaboration Term for the applicable Program, including pursuant to Section 6.2(d), 6.2(e) or **Exhibit K**.
- 1.37 "<u>Clinical Study</u>" means a clinical study (including a Post-Marketing Study or Phase IV Clinical Study) in humans the purpose of which is to obtain information regarding the product, including information

relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of the product, as applicable.

- 1.38 [***]
- 1.39 "CMC" means Chemistry and Manufacturing Controls, which includes (a) Manufacturing process development records for products, (b) all chemistry, Manufacturing and control procedures necessary for Manufacture of products, and (c) sourcing and testing of all raw materials and components used in the Manufacture of products.
- 1.40 "<u>Co-Promotion</u>" means those detailing and promotional activities (including performing sales calls) with respect to a Collaboration Product undertaken by or on behalf of either Party to encourage appropriate prescribing of such Collaboration Product in the U.S. in accordance with Section 8 and any Co-Promotion Agreement. When used as a verb, "to Co-Promote" means to engage in Co-Promotion, and "Co-Promoted" has a corresponding meaning.
 - 1.41 "Co-Promotion Agreement" has the meaning set forth in Section 8.5(b).
 - 1.42 "Code" has the meaning set forth in Section 5.4.
- 1.43 "<u>Collaboration</u>" means each of the programs for the Research, Development, Manufacture and Commercialization of mRNA Cancer Vaccines (including Collaboration Products) that is engaged in by or on behalf of one or more of the Parties under this Agreement during the applicable Collaboration Term.
- 1.44 "<u>Collaboration Activities</u>" means the activities conducted by or on behalf of one or more of the Parties or its Affiliates as part of the Collaboration.
 - 1.45 [***]
 - 1.46 "Collaboration Know-How" means [***].
- 1.50 "Collaboration Patents" means any and all Patents that claim or cover any of the Collaboration Know-How.
- 1.51 "Collaboration PCV Manufacturing Facility" means, with respect to the PCV Program, the Manufacturing facilities, or portion thereof, established by or on behalf of Moderna [***] for the PCV Program that is intended to be used for the Manufacture of Collaboration PCV Products for the PCV Program during the Collaboration Term for the PCV Program in accordance with this Agreement.
- 1.52 "Collaboration PCV Product" means, with respect to the PCV Program, any [***]. At either Party's request, the Parties will mutually identify the then-existing Collaboration PCV Products. [***] For the avoidance of doubt, Collaboration PCV Products shall exclude Collaboration SAV Products; provided, however, that a Collaboration PCV Product for [***].
- 1.53 "Collaboration Product" means any Collaboration PCV Product or Collaboration SAV Product, as applicable.
- 1.54 "Collaboration SAV Manufacturing Facility" means, with respect to a given Joint SAV Program, the Manufacturing facilities, or portion thereof, that are intended to be used for the Manufacture of Collaboration SAV Products for such Joint SAV Program during the Collaboration Term for such Joint SAV Program in accordance with this Agreement.
- 1.55 "Collaboration SAV Product" means, with respect to a given Joint SAV Program, any [***]. For the avoidance of doubt, Collaboration SAV Products shall exclude Collaboration PCV Products.
 - 1.56 "Collaboration Shared Neoepitope(s)" means, with respect to a given SAV Program, [***].
 - 1.57 "Collaboration Technology" means, [***].
- 1.58 "Collaboration Term" means, with respect to a given Program, the Internal SAV Program Term (if any), the POC Term, the Merck Participation Election Period, and, if Merck exercises the Merck Participation Election, the Merck Participation Term, in each case for such Program.
 - 1.59 "Combination Product" means:
- (a) a single pharmaceutical formulation [***] containing, as its active ingredients, both (i) a Collaboration Product or Financial PCV or Financial SAV, on the one hand, and (ii) one or more Other Component(s), on the other hand, or

(b) a combination therapy comprised of (i) a Collaboration Product or Financial PCV or Financial SAV, on one hand, and (ii) one or more Other Component(s), on the other hand, either when (1) priced and sold in a single package containing such multiple products, or (2) packaged separately but sold together for a single price,

in each case, including all dosage forms, formulations, presentations, and package configurations. Drug delivery vehicles, adjuvants and excipients will not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant or excipient is recognized by the FDA as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7).

- 1.60 "Commencement" means, together with all correlative meanings, [***] in a Clinical Study.
- 1.61 [***]
- 1.62 "Commercial Grant" means a grant by a Selling Party of a license or sublicense of the Merck Technology or Moderna Technology to a Third Party to Commercialize (which may also include Manufacture and Development to support any such Commercialization) any one or more Collaboration Products or Financial PCVs or Financial SAVs within one or more countries.
 - 1.63 "Commercial Liabilities" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.64 "Commercial Quality Agreement" has the meaning set forth in Section 6.3(b).
 - 1.65 "Commercial Supply Agreement" has the meaning set forth in Section 6.3(b).
- 1.66 "Commercialization" means any and all activities related to the import, export, transportation, storage, marketing, detailing, promotion, distribution, sale or other disposition and/or other approved use of a product in a country or region in the Territory, including: (a) strategic marketing, sales force detailing (including Co-Promotion), advertising, Medical Affairs, reimbursement and market access activities and market and product support; and (b) all customer support, Distribution Matters, invoicing and sales activities. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization, and "Commercialized" has a corresponding meaning. For clarity, Commercialization excludes any Research, Development or Manufacturing activities.
- 1.67 "<u>Commercialization Activities</u>" means, on a Collaboration Product-by-Collaboration Product basis, all global Commercialization activities undertaken with respect to such Collaboration Product.
- 1.68 "Commercially Reasonable Efforts" means with respect to the efforts to be expended by a Party with respect to any objective, [***].
- 1.69 "<u>Committee</u>" means the POC Committee, [***], Joint Steering Committee, Joint Development Committee, Joint Manufacturing Committee or Joint Commercialization Committee, or any other subcommittee, as applicable.
 - 1.70 "Competitive Infringement" has the meaning set forth in Exhibit J.
 - 1.71 "Competitive PCV Product" means[***].
 - 1.72 "Competitive SAV Product" means [***].
- 1.73 "Confidential CMC Data" means, with respect to a product, all [***] CMC-related data and information for such product.
 - 1.74 "Confidential CMC Documents" has the meaning set forth in Exhibit G.
 - 1.75 "Confidential Information" has the meaning set forth in Section 12.1(a).
 - 1.76 "Contracting Party" has the meaning set forth in Exhibit F.
- 1.77 "Control" or "Controlled" means, with respect to any Know-How, Patent or other intellectual property right, the possession (whether by ownership, license or sublicense, other than by a license, sublicense or other right granted (but not assignment) pursuant to this Agreement) by a Party (or its Affiliate) of the ability to assign or grant to the other Party the licenses, sublicenses or rights to access and use such Know-How, Patent or other intellectual property right as provided for in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense, or rights of access and use. Know-How, Patents or other intellectual property rights that are licensed to a Party or its Affiliates or jointly owned by a Party or its Affiliates, on the

one hand, and a Third Party, on the other hand, in each case pursuant to an In-License are not "Controlled" by such Party or its Affiliates for purposes of this Agreement unless and only after such agreement is included hereunder as an Included In-License pursuant to **Exhibit F**.

- 1.78 "Cost of Goods Sold" has the meaning set forth in the Financial Definitions Exhibit.
- 1.79 "Credit Against Profits Mechanism" has the meaning set forth in Exhibit D.
- 1.80 "<u>CTA</u>" means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a Clinical Study, which CTA may consist of, or include, an IND.
- 1.81 "Development" means any and all clinical drug development activities, Clinical Studies, statistical analysis and report writing, the preparation and submission of Regulatory Filings, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval for a product, and "Develop", "Developed" and "Developing" will have corresponding meanings. For clarity, Development excludes any Research, Commercialization or Manufacturing activities.
 - 1.82 "Development Costs" has the meaning set forth in the Financial Definitions Exhibit.
- 1.83 "Development Plan(s)" means, with respect to a Program, collectively, the Joint Development Plan and Budget and any Independent Additional Study Development Plan(s) for such Program.
 - 1.84 "Development Transition Plan" has the meaning set forth in Section 4.3(b).
 - 1.85 "DOJ" has the meaning set forth in Section 14.1.
 - 1.86 "<u>Directed</u>" means [***].
 - 1.87 "Direct Manufacturing Costs" shall be calculated consistent with GAAP and include [***].
 - 1.88 "Direct Marketing Expenses" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.89 "Disclosing Party" has the meaning set forth in Section 12.1(a).
 - 1.90 "Dispute Proposal" has the meaning set forth in Section 15.1(c).
 - 1.91 "Disputes" has the meaning set forth in Section 15.1(a).
 - 1.92 "Distribution Expenses" has the meaning set forth in the Financial Definitions Exhibit.
- 1.93 "<u>Distribution Matters</u>" means all issues and decisions regarding the distribution of products, including decisions as to whether and with wholesalers and distributors, if any, to contract, and the terms of contracts with such wholesalers and distributors.
 - 1.94 "Distributor" means a Third Party [***].
- 1.95 "<u>DMF</u>" means any drug master file, biologics master file (types 2, 3, 4, and 5) or For Further Manufacturing Use (FFMU) BLA, as applicable, filed with the FDA, and any equivalent filing in other countries or regulatory jurisdictions, including active substance master files submitted to the EMA.
 - 1.96 "Effective Date" has the meaning set forth in the Recitals.
- 1.97 "EMA" means the Regulatory Authority known as the European Medicines Agency and any successor agency thereto.
- 1.98 "<u>Equity Agreement</u>" means the Series H Preferred Stock Purchase Agreement, dated as of the Amended Effective Date, by and among Moderna Therapeutics, Inc. and the investors listed therein.
 - 1.99 "ex-U.S. Antitrust Filing" has the meaning set forth in Section 15.19.
 - 1.100 "Exclusions Lists" has the meaning set forth in Section 1.403.
- 1.101 "Executive Officer" means, for Moderna, [***], and for Merck, [***]. Either Party may change its Executive Officer upon written notice to the other Party, provided that such replacement individual has decision-making authority on behalf of such Party in respect of this Agreement.
- 1.102 "Expert" means a person with no less than [***] of pharmaceutical industry experience and expertise having occupied at least one senior position within a large pharmaceutical company relating to

commercialization and/or licensing but excluding any current or former employee or consultant of either Party or its Affiliates. Such person shall be fluent in the English language.

- 1.103 "Expert Committee" has the meaning set forth in Exhibit C.
- 1.104 "FDA" means the United States Food and Drug Administration and any successor agency thereto.
- 1.105 [***]
- 1.106 [***]
- 1.107 "Financial Definitions Exhibit" means Exhibit B.
- 1.108 "Financial PCV" has the meaning set forth in the Financial Definitions Exhibit.
- 1.109 "Financial SAV" has the meaning set forth in the Financial Definitions Exhibit.
- 1.110 "First Commercial Sale" means, with respect to any Collaboration Product or a Financial PCV or Financial SAV in a country, the first commercial sale by a Selling Party to a Third Party on arm's length terms for end use or consumption of such Collaboration Product or a Financial PCV or Financial SAV, as the case may be, in such country after all required Regulatory Approvals for commercial sale of the applicable Collaboration Product or a Financial PCV or Financial SAV have been obtained in such country. Sales prior to receipt of Regulatory Approval for such Collaboration Product or a Financial PCV or Financial SAV, such as so-called "treatment IND sales", "named patient sales", and "compassionate use sales" shall not be construed as a First Commercial Sale.
 - 1.111 "FTC" has the meaning set forth in Section 14.1.
- 1.112 "FTE" means the equivalent of a full-time scientific or technical person's work time over a twelve (12) month period (including normal vacation, sick days and holidays) devoted to, and directly related to, conducting activities under this Agreement, in accordance with this Agreement, based on [***] person-hours or greater per year. In the event that an individual devotes less than such full time to conducting activities under this Agreement in accordance with this Agreement during such twelve (12) month period, then for purposes of this Agreement, such individual shall only count as a portion of an FTE which shall be determined by dividing the number of full days during the applicable twelve (12) month period devoted to, and directly related to, conducting activities under this Agreement in accordance with this Agreement by the total number of working days during such twelve (12) month period. No individual may be charged at greater than one (1) FTE in a given Calendar Year.
- 1.113 "<u>FTE Costs</u>" means, the actual FTEs employed by Moderna, Merck or their respective Affiliates or Sublicensees in the conduct of any activities under this Agreement multiplied by the FTE Rate, which represents [***].
- 1.114 "FTE Rate" means [***] per one (1) full FTE per full twelve (12) month Calendar Year; provided, that, starting [***], such rate shall adjust [***] of each Calendar Year by an amount equal to the change, if any, in [***]. Notwithstanding the foregoing, for any Calendar Year during the Term that is less than a full year, the above referenced rate shall be proportionately reduced to reflect such portion of such full Calendar Year.
- 1.115 "GAAP" means U.S. generally accepted accounting principles or International Financial Reporting Standards, consistently applied, as designated and used by the applicable Party.
 - 1.116 "General PCV" means [***], but excluding any General SAV.
 - 1.117 "General SAV" means [***], but excluding any General PCV.
 - 1.118 "Global Commercialization Budget" has the meaning set forth in Section 8.4(b).
- 1.119 "Global Commercialization Plan" means, with respect to a Collaboration Product, a written plan that describes the plans for the Commercialization of such Collaboration Product in the Territory, including [***]. Each Global Commercialization Plan will be updated from time to time in accordance with Section 8.4(c).
- 1.120 "Good Clinical Practice" or "GCP" means the applicable then-current Good Clinical Practices as such term is defined from time to time by the FDA or other relevant Regulatory Authority having jurisdiction over the development, manufacture or sale of products pursuant to its regulations, guidelines or otherwise, as applicable.

- 1.121 "Good Laboratory Practice" or "GLP" means the applicable then-current standards for laboratory activities for pharmaceuticals (including biologicals) or vaccines, as applicable, as set forth in the Act, together with any similar standards of good laboratory practice as are required by any Regulatory Authority having jurisdiction over the applicable activity.
 - 1.122 "Gross Profit" has the meaning set forth in the Financial Definitions Exhibit.
- 1.123 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder.
- 1.124 "<u>HSR Filing</u>" means any filing with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the subject matter of this Agreement, together with all required documentary attachments thereto.
 - 1.125 "Human Materials" has the meaning set forth in Section 5.2.
 - 1.126 "IAS Costs" has the meaning set for in the Financial Definitions Exhibit.
 - 1.127 "IAS Party" has the meaning set forth in Section 7.1(b).
 - 1.128 [***]
 - 1.129 [***]
 - 1.130 [***]
- 1.131 "<u>In-License</u>" means a Moderna Pre-Existing In-License, Moderna New In-License or a Merck In-License.
 - 1.132 "In-License Upfront Payment" has the meaning set forth in Section 2(a) of Exhibit F.
 - 1.133 "Included In-License" means an Included Moderna In-License or an Included Merck In-License.
- 1.134 "<u>Included In-License IP</u>" means Patents and Know-How in-licensed by a Party from a Third Party pursuant to an Included In-License, including any extensions or expansions of the scope thereof.
- 1.135 "Included In-License Payments" means, with respect to a Contracting Party and an Included In-License, any amounts paid or payable during the Term by such Contracting Party under such Included In-License that are or were incurred by or on behalf of such Contracting Party or its Affiliates as a result of (a) [***], (b) the grant of [***], (c) the grant or exercise [***] or (d) [***], in each case ((a)-(d)), under and in accordance with the terms of this Agreement, but excluding in all cases [***]; provided, however, that the Parties will agree on [***].
 - 1.136 "Included Merck In-License" has the meaning set forth in Section 1(c) of Exhibit F.
- 1.137 "<u>Included Moderna In-License</u>" means an Included Moderna New In-License, an Included Moderna Pre-Existing In-License or an Included Permitted In-License.
 - 1.138 "Included Moderna New In-License" has the meaning set forth in Section 1(b)(ii) of Exhibit F.
 - 1.139 "Included Moderna Pre-Existing In-License" has the meaning set forth in Section 1(a) of Exhibit F.
 - 1.140 "Included Permitted In-License" has the meaning set forth in Section 1(d) of Exhibit F.
 - 1.141 [***]
- 1.145 "IND" means an Investigational New Drug Application filed with the FDA pursuant to 21 C.F.R. §312 before the commencement of human clinical trials involving a product, including all amendments and supplements to such application, or any equivalent filing with any Regulatory Authority outside the United States.
- 1.146 "IND-Enabling Studies" means, for a given SAV Program, the non-clinical pharmacology studies (including pharmacokinetic and toxicology studies) identified in the POC Plan for such SAV Program that are intended to be performed prior to filing an IND/CTA with respect to the SAVs that are being Researched for such SAV Program under the POC Plan.
 - 1.147 "Indemnification Claim Notice" has the meaning set forth in Section 13.6(c).
 - 1.148 "Indemnified Party" has the meaning set forth in Section 13.6(c).

- 1.149 "Independent Additional Study" has the meaning set forth in Section 4.4(a)(ii).
- 1.150 "Independent Additional Study Development Plan" has the meaning set forth in Section 4.4(a)(ii).
- 1.151 "Indirect Manufacturing Costs" shall be calculated consistent with GAAP and include [***].
- 1.152 "Indirect Marketing Expenses" has the meaning set forth in the Financial Definitions Exhibit.
- 1.153 "Individualized Neoepitope(s)" means [***].
- 1.154 "<u>Initial PCV POC Program Funding Amount</u>" means Two Hundred Million Dollars (\$200,000,000).
- 1.155 "<u>Initiation</u>" of a Program means, (i) with respect to the PCV Program, [***], (ii) with respect to the KRAS Program, [***], (iii) with respect to any Internal SAV Program, [***] and (iv) with respect to any other Joint SAV Program, [***].
- 1.156 "<u>Internal SAV Program</u>" means the Research by a Party or its Affiliates of SAVs Directed against a given Target(s) under the Collaboration in accordance with an Internal SAV Program Plan for such Target(s), which the other Party [***] in accordance with Section 3.1(d)(i).
- 1.157 "<u>Internal SAV Program Plan</u>" means a written plan that has been prepared by the Party conducting an Internal SAV Program.
- 1.158 "<u>Internal SAV Program Term</u>" means, with respect to a given Internal SAV Program, the period commencing on [***].
- 1.159 "<u>IP Committee</u>" means the intellectual property advisory committee as more fully described in Paragraph 1.1 of **Exhibit J**.
- 1.160 "<u>ISP Party</u>" means the Party conducting a given Internal SAV Program pursuant to the applicable Internal SAV Program Plan.
 - 1.161 "Issuing Party" has the meaning set forth in Section 12.3(c).
 - 1.162 "Joint Commercialization Committee" or "JCC" has the meaning set forth in Section 2.7.
 - 1.163 "Joint Development Committee" or "JDC" has the meaning set forth in Section 2.5.
 - 1.164 "Joint Development Plan and Budget" has the meaning set forth in Section 4.3(c)(i).
 - 1.165 "Joint Development Program" has the meaning set forth in Section 4.1(c).
 - 1.166 "Joint Development Study" has the meaning set forth in Section 4.4(a)(i).
- 1.167 "<u>Joint Know-How</u>" means all Collaboration Know-How within [***] that is jointly owned by the Parties in accordance with Section 11.4.
 - 1.168 "Joint Manufacturing Committee" or "JMC" has the meaning set forth in Section 2.6(a).
- 1.169 "<u>Joint Patents</u>" means all Collaboration Patents within [***] that are jointly owned by the Parties in accordance with Section 11.4.
- 1.170 "Joint SAV Program" means the collaborative Research, Development and Manufacture by the Parties or their respective Affiliates of SAVs (including Collaboration SAV Products) Directed against a given SAV Target(s) in accordance with the POC Plan for such SAV Target(s), and if Merck exercises the applicable Merck Participation Election and pays the Participation Election Payment, the further Research of SAVs (including Collaboration SAV Products) Directed against such SAV Target(s) in accordance with an Additional Research Plan, and the Development, Manufacture and Commercialization of Collaboration SAV Products Directed against such SAV Target(s) by or on behalf of one or more of the Parties under the Collaboration in accordance with this Agreement. [***]
 - 1.171 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 2.4.
 - 1.172 "Joint Technology" means all Joint Know-How and Joint Patents.
 - 1.173 "Keytruda" means Merck's human pharmaceutical product Keytruda® (pembrolizumab).
- 1.174 "Know-How" means all non-public technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills,

techniques, procedures, experiences, ideas, designs, drawings, assembly procedures, Software, computer programs, apparatuses, specifications, data, results and materials, including: biological, chemical, vaccine-related, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays, and biological methodology, in all cases, whether or not copyrightable or patentable, in written, electronic or any other form now known or hereafter developed.

- 1.175 "Knowledge" means with respect to the matter in question, the knowledge of any [***].
- 1.176 "KRAS" means [***].
- 1.177 "KRAS POC Program" has the meaning set forth in Section 3.1(b).
- 1.178 "KRAS Program" means the Research, Development and Manufacture of SAVs (including Collaboration SAV Products) Directed against KRAS in accordance with the POC Plan for KRAS, and if Merck exercises the applicable Merck Participation Election and pays the applicable Participation Election Payment, the further Research of SAVs (including Collaboration SAV Products) Directed against KRAS in accordance with an Additional Research Plan, and the Development, Manufacture and Commercialization of Collaboration SAV Products Directed against KRAS by or on behalf of one or more of the Parties under the Collaboration in accordance with this Agreement.
 - 1.179 "KRAS Transition Date" has the meaning set forth in Section 3.4(c)(ii).
 - 1.180 "KRAS Transition Plan" has the meaning set forth in Section 3.4(c)(ii).
- 1.181 "<u>Law</u>" or "<u>Laws</u>" means all laws, statutes, enactments, acts of legislature, rules, regulations, orders, judgments, guidelines, policies, directions, directives, or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision of any jurisdiction which are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates in carrying out the activities hereunder is subject, including the Act and GLPs, GCPs and cGMPs.
- 1.182 "<u>Lead Regulatory Party</u>" means, for a given Program, the POC Lead Regulatory Party or the Merck Participation Term Lead Regulatory Party, as applicable.
 - 1.183 [***]
 - 1.184 [***]
 - 1.185 [***]
 - 1.186 "Losses" has the meaning set forth in Section 13.6(a).
- 1.187 "Manufacturing" means the production, manufacture, synthesis, processing, filling, formulating, finishing, packaging, labeling, shipping and holding of product or any intermediate thereof (including with respect to a PCV, receipt of patient samples, sequencing, identifying and analyzing tumor specific mutations (e.g., using sequencing or genomics tools)), process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control. "Manufacturing" refers to both pre-clinical and clinical Manufacturing for Research and Development, and Manufacturing for Commercialization. "Manufacture" and "Manufactured" will have corresponding meanings. For clarity, "Manufacturing" excludes Research, Development or Commercialization activities.
 - 1.188 "Manufacturing Capacity Forecast" has the meaning set forth in Section 6.2(g)(i).
 - 1.189 "Manufacturing Costs" has the meaning set forth in the Financial Definitions Exhibit.
- 1.190 "Manufacturing Subcontractor" means, with respect to Merck, any Third Party that, as a contract manufacturer (for example, as of the Amended Effective Date, the Third Parties listed on **Exhibit L-1**) of Merck or any of its Affiliates, may Manufacture the applicable cGMP Collaboration Product in connection with a technology transfer pursuant to this Agreement or the PCV Clinical Supply Agreement, the SAV Clinical Supply Agreement, Commercial Supply Agreement, [***] (as applicable), which Third Party is designated by Merck and is reasonably acceptable to Moderna (and in all cases those listed on **Exhibit L-1** are deemed acceptable); provided that Moderna may only determine that a Third Party selected by Merck to act as a contract manufacturer of Merck (or its Affiliate) is not reasonably acceptable [***] if (a) such Third Party manufacturer or its Affiliate is a biotech or pharmaceutical company [***] that Researches, Develops or Commercializes (i)

- [***] (for example, as of the Amended Effective Date, the Third Parties listed on **Exhibit L-2**), or (ii) [***] (for example, as of the Amended Effective Date, the Third Parties listed on **Exhibit L-2**), or (b) with respect to Third Party manufacturing in [***], Moderna has reasonable concerns [***] relating to [***].
- 1.191 "Material(s)" means any tangible chemical or biological material, including any compounds, DNA and RNA (modified and unmodified), mRNA Constructs, polypeptides, clones, cells, plasmids, lipids, vectors, receptors, any other nucleic acids, proteins, peptides and any expression product, progeny, derivative or other improvement thereto, along with any tangible chemical or biological material embodying any Know-How.
- 1.192 "Medical Affairs" means, with respect to a product, the performance of activities with respect to: continuing medical education therefor; development, publication and dissemination of publications; exhibiting and presenting at seminars and conventions; conducting health economic studies; conducting speakers programs; conducting appropriate activities involving opinion leaders; engaging medical science liaisons and conducting medical science liaison activities; disease education to health care professionals and consumers; conducting advisory board meetings or other consultant programs; and establishing clinical consumer and patient registries.
 - 1.193 "Medical Affairs Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.194 "Merck" has the meaning set forth in the Recitals.
 - 1.195 "Merck Acquisition" has the meaning set forth in Section 10.8(d)(ii).
 - 1.196 "Merck Acquisition Program" has the meaning set forth in Section 10.8(d)(ii).
 - 1.197 "Merck Agent" means any [***] Controlled by Merck or its Affiliates (but not [***]).
 - 1.198 "Merck Agent Technology" has the meaning set forth in Section 11.3.
- 1.199 "Merck Background Know-How" means, on a Program-by-Program basis, subject to Section 10.12, any and all Know-How Controlled by Merck or its Affiliates (a) as of the date of Initiation of such Program, or (b) as to which Merck or its Affiliates obtains Control during the Collaboration Term for such Program, in each case ((a)-(b)) that [***], excluding [***] Merck's rights in any Collaboration Know-How.
- 1.200 "Merck Background Patents" means, on a Program-by-Program basis, subject to Section 10.12, those Patents that are Controlled by Merck or its Affiliates (a) as of the date of Initiation of such Program, or (b) as to which Merck or its Affiliates obtains Control during the Collaboration Term for such Program, in each case ((a)-(b)) that claim or cover the Merck Background Know-How for such Program, excluding in each case ((a) and (b)) Merck's rights in any Collaboration Patents.
- 1.201 "Merck Background Technology" means Merck Background Know-How and Merck Background Patents.
 - 1.202 "Merck Business Combination Program" has the meaning set forth in Section 10.8(d)(i).
 - 1.203 "Merck Cessation Election" has the meaning set forth in Section 10.10.
 - 1.204 [***]
 - 1.205 [***]
 - 1.206 "Merck General Patents" means Merck Background Patents, excluding [***].
 - 1.207 "Merck In-License" has the meaning set forth in Section 1(c) of Exhibit F.
 - 1.208 "Merck Indemnitees" has the meaning set forth in Section 13.6(b).
- 1.209 "Merck Internal SAV Program" means an Internal SAV Program being conducted by Merck or its Affiliates.
 - 1.210 [***]
 - 1.211 "Merck Non-Participation" has the meaning set forth in Section 3.7(a).
 - 1.212 "Merck Participation Election" has the meaning set forth in Section 3.5(b).
- 1.213 "Merck Participation Election Date" means, with respect to the PCV Program or a given Joint SAV Program, [***].
 - 1.214 "Merck Participation Election Notice" has the meaning set forth in Section 3.5(c).

- 1.215 "Merck Participation Election Period" means, with respect to the PCV Program or a given Joint SAV Program, the period commencing on the date of Initiation of such Program and ending upon the earliest of [***].
- 1.216 "Merck Participation Term" means, for the PCV Program or a given Joint SAV Program, the period commencing on the Merck Participation Election Date for such Program and ending upon [***].
- 1.217 "Merck Participation Term Lead Regulatory Party" means [***] with respect to the PCV Program or any Joint SAV Program, unless otherwise agreed to by the Parties in writing with respect to a given Program.
 - 1.218 "Merck Patents" means the Merck General Patents and the [***].
 - 1.219 [***]
 - 1.220 "Merck Program Director" has the meaning set forth in Section 2.2.
 - 1.221 [***]
 - 1.222 [***]
 - 1.223 "Merck Reimbursement Cap" has the meaning set forth in Exhibit E.
 - 1.224 "Merck Representatives" has the meaning set forth in Exhibit G.
 - 1.225 [***]
 - 1.226 "Merck SAV Program Costs" means, [***].
 - 1.227 [***]
- 1.228 "Merck Technology" means collectively, Merck Background Technology and Merck's interest in Collaboration Technology.
 - 1.229 "Moderna" has the meaning set forth in the Recitals.
- 1.232 "Moderna Agent" means any [***] Controlled by Moderna or its Affiliates (but not Collaboration Products).
 - 1.233 "Moderna Agent Technology" has the meaning set forth in Section 11.2.
- 1.234 "Moderna Background Know-How" means, on a Program-by-Program basis, subject to Section 10.12, any and all Know-How Controlled by Moderna or any of its Affiliates (a) as of the date of Initiation of such Program, including [***], or (b) as to which Moderna or any of its Affiliates obtains Control during the Collaboration Term for such Program, in each case ((a)-(b)) that [***], excluding [***] Moderna's rights in any Collaboration Know-How.
- 1.235 "Moderna Background Patents" means, on a Program-by-Program basis, subject to Section 10.12, those Patents that are Controlled by Moderna or any of its Affiliates [***] that claim or cover the Moderna Background Know-How for such Program, excluding [***] Moderna's rights in any Collaboration Patents.
- 1.236 "<u>Moderna Background Technology</u>" means Moderna Background Know-How and Moderna Background Patents.
 - 1.237 "Moderna Business Combination Program" has the meaning set forth in Section 10.7(e)(i).
- 1.238 "Moderna CMC Information" means, with respect to the PCV Program or a Joint SAV Program under this Agreement, the Confidential CMC Data of Moderna or its Affiliates with respect to a product that is Researched, Developed, Manufactured and/or Commercialized under the PCV Program or such Joint SAV Program.
 - 1.242 "Moderna Commercialization Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.243 "Moderna Costs Report" has the meaning set forth in **Exhibit E**.
 - 1.244 "Moderna Development Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.245 [***]
 - 1.246 "Moderna General Patents" means [***].
 - 1.247 "Moderna Indemnitees" has the meaning set forth in Section 13.6(a).

- 1.248 "Moderna Internal SAV Program" means an Internal SAV Program being conducted by Moderna or its Affiliates.
 - 1.249 "Moderna New In-License" has the meaning set forth in Section 1(b)(i) of Exhibit F.
 - 1.250 "Moderna Net Profits" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.251 [***]
 - 1.252 "Moderna Patents" means the Moderna General Patents, [***] and the [***].
 - 1.253 [***]
- 1.254 "<u>Moderna Pre-Existing In-License</u>" means, a license or other agreement between Moderna or its Affiliates and a Third Party in effect as of [***] pursuant to which a Third Party grants Moderna (or its Affiliates) a license under any Patents or Know-How that are necessary or reasonably useful for the Research, Development, Manufacture or Commercialization of mRNA Cancer Vaccines. The Moderna Pre-Existing In-License(s) shall be set forth on <u>Schedule 1.254</u>.
- 1.264 "Moderna Technology" means collectively, Moderna Background Technology and Moderna's interest in Collaboration Technology.
 - 1.265 "mRNA-5671" means mRNA-5671 as described in the POC Plan for the KRAS Program.
 - 1.266 "mRNA Cancer Vaccine" means any PCVs and/or SAVs, as applicable.
 - 1.267 "mRNA Cancer Vaccine Technology" means any [***].
 - 1.268 "mRNA Construct" means [***].
- 1.269 "<u>mRNA-PCV Field</u>" means Research, Development, Manufacture or Commercialization of any PCV.
- 1.270 "mRNA-SAV Field" means Research, Development, Manufacture or Commercialization of any SAV.
 - 1.271 "mRNA Technology" means [***].
- 1.272 "NDA" means a new drug application or a biologics license application (a "BLA"), including all supplements and amendments thereto and all necessary documents, data, and other information concerning a product, required for Regulatory Approval of the product as a pharmaceutical product by the FDA or an equivalent application to the equivalent agency in any other country or group of countries (*e.g.* the marketing authorization application (MAA) in the EU).
- 1.273 "Net Residual Amount" means the difference between (a) the Upfront Payment and (b) the POC Program Costs for the PCV Program incurred as of the earlier of (i) [***], or (ii) [***].
- 1.274 "Net Sales" means the gross invoice price (not including [***]) of a Collaboration Product or Financial PCV or Financial SAV sold by a Selling Party to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received:

wherein the foregoing actual deductions incurred in (a) through (g) shall be determined in a manner as [***], including such Financial PCV or Financial SAV or Collaboration Product, and for the sake of clarity, where any charge or allowance as described above in this Section 1.274 shall be counted once only. [***] With respect to a Financial PCV or Financial SAV or Collaboration Product that is sold as a Combination Product, Net Sales of such Financial PCV or Financial SAV or Collaboration Product shall be calculated in accordance with **Exhibit C** and shall not include the Relative Commercial Value of any Other Component of such Combination Product in accordance with **Exhibit C**.

- 1.275 "New In-License" means a Moderna New In-License or a Merck In-License.
- 1.276 "Non-Commercial Combination Activity" means [***].
- 1.277 "Non-IAS Party" has the meaning set forth in Section 7.1(b).
- 1.278 "Non-Participation PCV Net Profit Share" has the meaning set forth in Exhibit E.

- 1.279 "Non-Participation SAV Net Profit Share" has the meaning set forth in Exhibit E.
- 1.280 "Officials" has the meaning set forth in Section 5.5.
- 1.281 "Original Agreement" has the meaning set forth in the Recitals.
- 1.282 "Other Component" means any therapeutically or prophylactically active ingredients other than a PCV or SAV. For clarity, an Other Component may include one or more of the following: Merck Agent, Moderna Agent, Third Party Agent or [***].
 - 1.283 "Other Operating Income/Expense" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.284 "Other SAV POC Program" has the meaning set forth in Section 3.1(c)(iv).
 - 1.285 "Out-of-Pocket Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.286 "P&L" has the meaning set forth in Exhibit D.
 - 1.287 "Participation Election Payment" has the meaning set forth in Section 9.3(a)(ii).
 - 1.288 "Parties" has the meaning set forth in the Recitals.
 - 1.289 "Party" has the meaning set forth in the Recitals.
- 1.290 "<u>Patent</u>" means (a) a patent or a patent application, (b) any additions, priority applications, divisions, continuations, and continuations-in-part of any of the foregoing and (c) all patents issuing on any of the foregoing patent applications, together with all invention certificates, substitutions, reissues, reexaminations, registrations, supplementary protection certificates, confirmations, renewals and extensions of any of (a), (b) or (c), and foreign counterparts of any of the foregoing.
 - 1.291 "Patent and Trademark Expenses" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.292 "Patent Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.293 "Payment" has the meaning set forth in Section 5.5.
 - 1.294 "PCV" means [***].
 - 1.295 "PCV Cessation Net Profit Share" has the meaning set forth in Exhibit E.
 - 1.296 "PCV Clinical Supply Agreement" has the meaning set forth in Section 6.2(d).
 - 1.297 "PCV Participation Election Payment" has the meaning set forth in Section 9.3(a)(i).
 - 1.298 "PCV POC Program" has the meaning set forth in Section 3.1(a).
 - 1.299 "PCV POC Term" has the meaning set forth in Section 3.2(a)
- 1.300 "PCV Program" means the Research, Development and Manufacture of PCVs (including Collaboration PCV Products) in accordance with the POC Plan for PCVs, and if Merck exercises the applicable Merck Participation Election, the further Research of PCVs (including Collaboration PCV Products) in accordance with an Additional Research Plan, and the Development, Manufacture and Commercialization of Collaboration PCV Products by or on behalf of one or more of the Parties under the Collaboration in accordance with this Agreement. For clarity, the PCV Program shall be separate from each SAV Program.
 - 1.301 [***].
 - 1.302 "Permitted In-License" has the meaning set forth in Section 1(d) of Exhibit F.
 - 1.303 [***]
- 1.304 "Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
 - 1.305 "Pharmacovigilance Agreement" has the meaning set forth in Section 7.3.
- 1.306 "Phase I Clinical Study" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).
- 1.307 "Phase II Clinical Study" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).

- 1.308 "Phase III Clinical Study" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).
- 1.309 "<u>Phase IV Clinical Study</u>" means (i) any human clinical trial (other than a Phase I Clinical Study, Phase II Clinical Study or Phase III Clinical Study) in any country which is conducted on a product after Regulatory Approval of such product has been obtained from an appropriate Regulatory Authority, and includes clinical trials conducted voluntarily after Regulatory Approval for enhancing marketing or scientific knowledge of an approved indication or (ii) any REMS/RMP related study of a product after Regulatory Approval.
- 1.310 "<u>Plans</u>" means, with respect to a given Program, the Internal SAV Program Plan, the POC Plan, the Joint Development Plan and Budget and the Global Commercialization Plan for such Program.
 - 1.313 "POC Committee" has the meaning set forth in Section 2.3(a).
- 1.314 "<u>POC Data Package</u>" means, with respect to a given Program, the data package of data and information to be generated and collected under a POC Plan for such Program, which data package will in any event include: [***]; provided that with respect to an SAV POC Program, [***].
 - 1.315 "POC Lead Regulatory Party" means, for a given POC Program, [***].
 - 1.316 [***]
 - 1.317 "POC Plan" has the meaning set forth in Section 3.3(a).
 - 1.318 "POC Pharmacovigilance Agreement" has the meaning set forth in Section 3.4(m).
 - 1.319 "POC Program" has the meaning set forth in Section 3.1(c)(iv).
- 1.320 "<u>POC Program Costs for the PCV Program</u>" means, with respect to the PCV Program, the internal costs (*i.e.*, FTE Costs) and Out-of-Pocket Costs actually incurred by or on behalf Moderna (or its Affiliates) and that are [***] to the conduct of the POC Plan for the PCV Program, including:

With respect to the foregoing, any internal costs shall be calculated based on the number of FTEs used to perform the applicable activity multiplied by the FTE Rate.

- 1.321 "POC Term" has the meaning set forth in Section 3.2(b).
- 1.322 "Post-Marketing Study" means a non-human pre-clinical study or human Clinical Study of a product initiated after receipt of Regulatory Approval for such product in a country or territory, which is required by the Regulatory Authority in such country or territory to maintain the Regulatory Approval for such product in such country or territory.
 - 1.323 "Pre-Existing Restriction" means [***].
- 1.324 "<u>Pre-GLP Tox Commitment Date</u>" means, with respect to a given Internal SAV Program, the earlier of (a) the date of the ISP Party's selection of a Lead SAV Candidate for such Internal SAV Program, or (b) the effective date of expiration or termination of the SAV Research Term.
- 1.325 "<u>Pre-GLP Tox Data Package</u>" means, with respect to a given Internal SAV Program, the data package of data and information to be generated and collected for such Internal SAV Program, which data package will in any event include [***].
 - 1.326 "Pre-GLP Tox Election" has the meaning set forth in Section 3.1(d)(iv).
- 1.327 "<u>Pre-GLP Tox Election Date</u>" means, with respect to a given Internal SAV Program, the date of the Pre-GLP Tox Election Notice for such Internal SAV Program.
 - 1.328 "Pre-GLP Tox Election Notice" has the meaning set forth in Section 3.1(d)(v).
- 1.329 "<u>Pricing Matters</u>" means all issues and decisions regarding (a) price, price terms and other contract terms with respect to Collaboration Product sales, including discounts, rebates, other price concessions and service fees to payors and purchasers and (b) reimbursement programs applicable to a Collaboration Product.
 - 1.330 "Primary POC PCV Funding Amount" has the meaning set forth in Section 3.4(g)(i)(2).
- 1.331 "Product Specific Manufacturing Variances" has the meaning set forth in the Financial Definitions Exhibit.

- 1.332 "Profit & Loss Share" has the meaning set forth in Section 9.3(b).
- 1.333 "Profitability Date" has the meaning set forth in the Financial Definitions Exhibit.
- 1.334~ "Program" means the PCV Program or any SAV Program (including the KRAS Program), as applicable.
 - 1.335 "Program Directors" has the meaning set forth in Section 2.2.
- 1.336 "Promotional Materials" means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave-behind items, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings and sites and broadcast advertisements intended for use or used by or on behalf of either Party or their respective Affiliates in connection with any promotion of a Collaboration Product.
- 1.337 "Prosecution and Maintenance" means, with regard to a particular Patent or claim within a Patent, the preparation, filing, prosecution and maintenance of such Patent or claim, as well as re-examinations, reissues and the like with respect to such Patent or claim, together with the conduct of interferences, the defense of oppositions and other similar proceedings with respect to such Patent or claim. The term "Prosecute and Maintain" shall have a corresponding meaning.
 - 1.338 "Providers" has the meaning set forth in Section 5.2.
- 1.339 "Qualification Standards" means the customary, reasonable standards and criteria to be applied [***].
- 1.340 "Quality Agreements" means the Clinical Quality Agreement(s) and the Commercial Quality Agreement(s).
 - 1.341 [***]
 - 1.342 "Receiving Party" has the meaning set forth in Section 12.1(a).
 - 1.343 "Reconciliation Report" has the meaning set forth in **Exhibit D**.
- 1.344 "Registrational Study" means, with respect to the United States, a Clinical Study of a product on sufficient numbers of patients that is designed to establish that such product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with such product in the dosage range to be prescribed, and to support Regulatory Approval of such product or label expansion of such product, as described under 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent clinical trial.
- 1.345 "<u>Regulatory Approval</u>" means, with respect to a country or extra-national territory, any and all approvals (including NDAs), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such extra-national territory, including any pricing or reimbursement approvals.
- 1.346 "Regulatory Authority" means any national (*e.g.*, the FDA), supra-national (*e.g.*, the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction in the world, involved in the granting of Regulatory Approval or otherwise involved in regulating the Research, Development, Manufacture or Commercialization of a product.
- 1.347 "Regulatory Filing" means any submission to a Regulatory Authority, including all applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals), together with any related correspondence and documentation submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to a product and all data contained in any of the foregoing, including all INDs, NDAs, CTAs, regulatory drug lists, advertising and promotion documents, Clinical Data, Adverse Event files and complaint files, and include any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto.
- 1.352 "<u>Research</u>" means activities related to the design, discovery, identification, research, pre-clinical development, preclinical toxicology studies, profiling, characterization, improvement or optimization of a product. For clarity, "Research" excludes Development, Commercialization or Manufacturing activities. The term "Researched" has a corresponding meaning.

- 1.353 [***]
- 1.354 "Reviewing Party" has the meaning set forth in Section 12.3(c).
- 1.355 "Right of Reference" means the "right of reference" defined in 21 CFR 314.3(b), including, with respect to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Filings (and any data contained therein) filed with such Regulatory Authority with respect to such Party's product, only to the extent necessary for the conduct of Research, Development, Manufacturing or Commercialization activities for such product in such country or as otherwise expressly permitted or required under this Agreement to enable the other Party to exercise its rights or perform its obligations hereunder.
- 1.356 "<u>Safety Issue</u>" means, with respect to a given Collaboration Product or Other Component used in combination with such Collaboration Product: [***].
- 1.357 "SAV" means a messenger RNA-based therapeutic cancer vaccine intended to treat multiple patients and [***], including [***] but excluding PCVs.
 - 1.358 "SAV Cessation Net Profit Share" has the meaning set forth in Exhibit E.
 - 1.359 "SAV Clinical Supply Agreement" has the meaning set forth in Section 6.2(e).
- 1.360 "SAV IND Data Package" means, for a given Joint SAV Program (other than the KRAS Program), an information package regarding the SAVs for such Joint SAV Program that is submitted by Moderna to Merck following completion of the IND-Enabling Studies for the SAVs for such Joint SAV Program, which includes [***].
 - 1.361 "SAV Participation Election Payment" has the meaning set forth in Section 9.3(a)(ii).
 - 1.362 "SAV POC Program" has the meaning set forth in Section 3.1(c)(iv).
 - 1.363 "SAV POC Term" has the meaning set forth in Section 3.2(b).
- 1.364 "<u>SAV Program</u>" means (a) a Joint SAV Program or (b) an Internal SAV Program. For clarity, a given SAV Program will be separate from each other SAV Program, and each SAV Program shall also be separate from the PCV Program. If agreed to by the Parties, a given SAV Program may include more than one Target.
- 1.365 "SAV Research Term" means the period from the Amended Effective Date until the earlier of [***].
 - 1.366 [***]
- 1.367 "SAV Target" means (a) for the KRAS Program, KRAS, or (b) for any other Joint SAV Program, any Target(s) (other than KRAS) that the Parties mutually agree to include in such Joint SAV Program pursuant to the POC Plan for such Joint SAV Program.
 - 1.368 "SAV Target Notice" has the meaning set forth in Section 3.1(c)(i).
 - 1.369 "SEC" has the meaning set forth in Section 12.3(b).
 - 1.370 "Selling Expenses" has the meaning set forth in the Financial Definitions Exhibit.
- 1.371 "Selling Party" means with respect to a Party, such Party and its Affiliates and Sublicensees, except as otherwise provided in **Exhibit D** or **Exhibit E**.
 - 1.372 [***]
- 1.373 "Serious Adverse Event" or "SAE" means any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or, is a congenital anomaly/birth defect. Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or development of drug dependency or drug abuse or transmission of an infectious agent via a medicinal product.

- 1.374 "Shared Collaboration Costs" has the meaning set forth in the Financial Definitions Exhibit.
- 1.375 "Shared Commercialization and Related Manufacturing Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.376 "Shared Costs Report" has the meaning set forth in **Exhibit D**.
- 1.377 "<u>Shared Development and Related Manufacturing Costs</u>" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.378 "Shared Neoepitope(s)" means [***].
 - 1.379 "Shared Losses" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.380 "Shared Profits" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.381 "Shared Profits or Losses" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.382 "Significant Third Party" has the meaning set forth in Section 15.3.
- 1.383 "Software" means any and all computer programs, operating systems, applications, firmware, middleware, or software of any nature, whether operational, under development or inactive including all object code, source code, comment code, algorithms, tools, build, underlying components thereof, menu structures and arrangements, icons, operational instructions, scripts, commands, syntax, screen designs, reports, designs, concepts, technical manuals, test scripts, user manuals and other documentation therefor, whether in machine-readable form, programming language or any other language or symbols, and whether stored, encoded, recorded or written on disk, tape, film, memory device, paper or other media of any nature and all databases necessary or appropriate to operate any such computer programs, operating systems, applications, firmware, middleware, or software.
 - 1.384 "[***]" means [***].
 - 1.385 "Special Arbitration" has the meaning set forth in Section 15.1(c).
- 1.386 "<u>Sublicense Income</u>" means all consideration (including upfront payments, license fees, royalties and milestone payments) [***] by a Selling Party [***], net of out-of-pocket expenses of a Selling Party incurred in connection with such [***].
- 1.387 "<u>Sublicensee</u>" means any Person that is granted a sublicense as permitted by Section 10.3, either directly by a Party or indirectly by any other Sublicensee (including any Affiliate that is granted a sublicense hereunder but excluding, for clarity, any Distributors).
- 1.388 "Supply Agreement" means any supply agreement entered into by the Parties pursuant to Section 6 (including the PCV Clinical Supply Agreement, SAV Clinical Supply Agreement and any Commercial Supply Agreement). For clarity, the 2016 CSA is not a Supply Agreement.
- 1.389 "<u>Supply Failure</u>" means, with respect to the given PCV Clinical Supply Agreement, SAV Clinical Supply Agreement, Commercial Supply Agreement or **Exhibit K**, the meaning given to such term in such PCV Clinical Supply Agreement, SAV Clinical Supply Agreement, Commercial Supply Agreement or **Exhibit K**, as applicable, for an event or circumstance, [***].
 - 1.390 "<u>Target</u>" means [***].
- 1.391 "<u>Tax</u>" and "<u>Taxation</u>" means any form of tax or taxation, levy, duty, charge or withholding (including any related fine, penalty, addition to tax, surcharge or interest) imposed by, or payable to, a governmental authority.
 - 1.392 "Technical Failure" means with respect to a given Joint SAV Program, [***].
 - 1.393 "Term" has the meaning set forth in Section 14.1.
 - 1.394 "Territory" means worldwide.
 - 1.395 "Testing Costs" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.396 "Third Party" means any Person other than Moderna, Merck and their respective Affiliates.
- 1.397 "<u>Third Party Agent</u>" means any clinical-stage compound or marketed product controlled by a Third Party (but not any [***]).

- 1.398 "Third Party Claims" has the meaning set forth in Section 13.6(a).
- 1.399 "Transparency Report" has the meaning set forth in Section 3.4(k)(vii).
- 1.400 "<u>United States</u>" or "<u>U.S.</u>" means the United States of America, including its territories and possessions, the District of Columbia and Puerto Rico.
 - 1.401 "U.S. GAAP Standard Cost" has the meaning set forth in the Financial Definitions Exhibit.
 - 1.402 "Upfront Payment" has the meaning set forth in Section 9.1.
- 1.403 "Violation" means, with respect to a Party, such Party or any of its officers or directors or any other personnel of such Party (or other permitted agents of such Party performing activities hereunder) has been:
 (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov/exclusions/authorities.asp); (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or listed as having an active exclusion in the System for Award Management (http://www.sam.gov); or (c) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (a), (b) and (c) collectively the "Exclusions Lists").

2. COLLABORATION OVERVIEW; GOVERNANCE

- 2.1 <u>Overview of Collaboration</u>. The Parties intend and have agreed to undertake the Collaboration under this Agreement with the primary goal to Research, Develop, Manufacture and Commercialize Collaboration Products in accordance with the Collaboration with the goal of expanding and enhancing the value of such Collaboration Products, consisting, in general, of the following major components:
- (a) a broad program to be conducted during the POC Term for the PCV Program for the Research and Development of PCVs (including Collaboration PCV Products), pursuant to which Moderna will conduct Research and Development efforts with Merck's participation with respect to such PCVs and establish Manufacturing capabilities for Collaboration PCV Products, as described in the POC Plan for the PCV Program and further detailed in Section 3:
- (b) a broad program to be conducted during the POC Term for the KRAS Program, pursuant to which the Parties will conduct Research and Development efforts with respect to SAVs Directed against KRAS (including Collaboration SAV Products Directed against KRAS) and identify Manufacturing capacity for such Collaboration SAV Products, as described in the POC Plan for the KRAS Program and further detailed in Section 3;
- (c) if during the SAV Research Term, the Parties do not agree to collaborate on one or more additional Targets, then a Party and its Affiliates may conduct an Internal SAV Program, pursuant to which such Party and its Affiliates may conduct Research efforts with respect to one or more SAVs Directed against such Target, as described in the Internal SAV Program Plan for such Internal SAV Program and further described in Section 3.1(d);
- (d) if during the SAV Research Term, the Parties mutually agree to collaborate on one or more additional SAV Targets (other than KRAS) in accordance with Section 3.1(c), a broad program to be conducted during the POC Term for such Joint SAV Program, pursuant to which the Parties will conduct Research and Development efforts with respect to such SAVs Directed against such SAV Target (including Collaboration SAV Products Directed against such SAV Target) and identify Manufacturing capacity for such Collaboration SAV Products, as described in the POC Plan for such Joint SAV Program and further detailed in Section 3;
- (e) for each given Program, Merck will have the right during the Merck Participation Election Period for such Program to exercise the Merck Participation Election for such Program to further participate with Moderna in the further Research, Development, Manufacture and Commercialization of mRNA Cancer Vaccines (including Collaboration Products) with respect to such Program, and to share equally the costs and benefits of, such Research, Development, Manufacture and Commercialization, subject to and in accordance with this Agreement;

- (f) for each given Program, if Merck exercises the Merck Participation Election for such Program, then, subject to Merck paying the Participation Election Payment for such Program in accordance with Section 9.3(a), during the Merck Participation Term for such Program:
- (i) the Parties will conduct further Research and Development of mRNA Cancer Vaccines (including Collaboration Products) for such Program through Regulatory Approval, with the activities to be jointly funded by the Parties in accordance with the terms of this Agreement; provided, however, that [***];
- (ii) Merck shall have the sole right to Commercialize the Collaboration Products from such Program in the Territory (subject to Moderna's right to engage in Co-Promotion activities in the United States under and in accordance with Sections 8.5 and 8.6 and any Co-Promotion Agreement(s));

- (iii) the Parties will participate in profits or losses arising from the Commercialization of such Collaboration Products, all as detailed and pursuant to Section 9; and
- (iv) each Party will grant appropriate cross-licenses to the other Party to Research, Develop, Manufacture and Commercialize such Collaboration Products pursuant to Section 10.

(g) [***].

- (i) During the SAV Research Term, the Parties may review and discuss the available Clinical Data that is generated in the course of Developing Collaboration PCV Products to determine whether [***].
- (1) If, during the SAV Research Term, [***], then the Parties may mutually agree to amend the applicable Plan to [***] in accordance with the Plan for such SAV Program.
- (2) If, during the SAV Research Term, [***], and the Parties wish to conduct Collaboration Activities for such [***], then the Parties may mutually agree to initiate a new SAV Program with respect to such [***] in accordance with Section 3.1(c).

(3) [***]

- (ii) From time to time after the end of the SAV Research Term and during any remaining portion of the Collaboration Term for the PCV Program, the Parties may review and discuss the available Clinical Data that is generated in the course of Developing Collaboration PCV Products to determine whether [***]. During the discussion referenced above, a Party shall disclose to the other Party if such Party (or any of its Affiliates) is engaged in a pre-existing *bona fide* active and sustained research, development or commercialization program (alone or with one or more Third Parties) on any [***] based on [***].
- (1) If, after the end of the SAV Research Term and during any remaining portion of the Collaboration Term for the PCV Program, a pre-existing *bona fide* active and sustained research, development or commercialization program with respect to an [***] based on [***], then following the disclosure pursuant to clauses (ii) above in which the existence of such pre-existing program became known to both Parties, each Party shall [***].
- (2) If, after the end of the SAV Research Term and during any remaining portion of the Collaboration Term for the PCV Program, such [***], then the Parties may mutually agree to amend the applicable Plan to incorporate the Research, Development, Manufacture and Commercialization of [***] associated with [***] in accordance with the Plan for such [***].
- (3) If, after the end of the SAV Research Term and during any remaining portion of the Collaboration Term for the PCV Program, no such pre-existing program exists [***], at the written request of either Party, then any [***]s based on any such [***] shall automatically be treated [***], for so long as one or both of the Parties [***].

2.2 <u>Collaboration Management</u>. Promptly after the Effective Date, each Party will appoint a person who will oversee day-to-day contact between the Parties for all matters related to the management of the Collaboration Activities in between meetings of the Committees and will have such other responsibilities as the Parties may agree in writing after the Effective Date. One person will be designated by Merck (the "<u>Merck Program Director</u>") and one person will be designated by Moderna (the "<u>Moderna Program Director</u>") and together they will be the "<u>Program Directors</u>". Each Party may replace its Program Director at any time by notice in writing to the other Party. Any Program Director may designate a substitute to temporarily perform the functions of that Program Director by written notice to the other Party. Each Program Director also may serve as a representative of its respective Party on one or more Committees. The initial Program Directors will be:

For Moderna: [***]

For Merck: [***]

2.3 POC Committee.

- (a) Formation and Membership. Pursuant to the Original Agreement, the Parties have established a joint committee to oversee the POC Programs (the "POC Committee"), comprised of [***] representatives of Moderna (or its Affiliate) and [***] representatives of Merck (or its Affiliate). Each POC Committee member will be a senior development leader or have similar experience and expertise as a senior development leader. Each Party may replace its representatives on the POC Committee at any time upon written notice to the other Party. With the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), each Party may invite non-voting employees and consultants to attend meetings of the POC Committee, subject to their agreement to be bound to the same extent as a permitted subcontractor under Section 10.4.
- (b) Meetings. While in existence, the POC Committee will meet [***] (or more frequently as may be determined by the POC Committee) and may hold meetings in person or by audio or video conference as determined by the POC Committee, but at a minimum, [***] of such meetings each Calendar Year will be in person (which in-person meeting will be held at one of Moderna's U.S. facilities, and the other held at Merck's U.S. facilities). Meetings of the POC Committee will be effective only if at least [***] representative of each Party is present or participating. Each Party will be responsible for all of its own expenses of participating in the meetings. The Parties will endeavor to schedule meetings of the POC Committee at least [***] months in advance. The POC Committee will determine the POC Committee operating procedures, which shall in all cases be consistent with the terms of this Agreement, and will codify these operating procedures in the written minutes of the first meeting (or subsequent meetings as such procedures are updated). The POC Committee will prepare and circulate a meeting agenda prior to each such meeting. For the purposes of this Section 2, "agenda" will include any relevant background materials. The Parties will alternate in preparing written minutes of such meeting, and the preparing Party will circulate such minutes within [***] days after such meeting. The Parties will agree on the minutes of each meeting promptly, but in no event later than the next meeting of the POC Committee. Each Party will designate one (1) of its [***] representatives who is empowered by such Party to make decisions regarding issues within the purview of the POC Committee as set forth below in Section 2.3(c) to act as the co-chair of each POC Committee. The co-chairs will be responsible for overseeing the activities of its POC Committee members consistent with the responsibilities set forth in Section 2.3(c).
- (c) Responsibilities. The POC Committee will discuss the Parties' performance of Collaboration Activities under the Internal SAV Program Plans and POC Plans. The POC Committee may form project teams to oversee any day-to-day activities necessary to execute the POC Plans. Without limiting the generality of the foregoing, within such scope, the POC Committee will have the following responsibilities:
- (i) discuss an ISP Party's performance of any Internal SAV Program under an Internal SAV Program Plan;
 - (ii) review each Party's performance of Collaboration Activities under the POC Plans;
- (iii) review any proposed modifications or amendments to a given POC Plan (including the Data Sharing and Sample Testing Schedule included therein);
- (iv) review and discuss any Additional Moderna PCV POC Term Studies conducted in accordance with Section 3.3(d);
- (v) resolve any disputes related to the Additional Moderna PCV POC Term Study contemplated in Section 3.3(d);

(vi) prioritize and oversee execution of specific activities to be performed under each POC

Plan;

- (vii) review and discuss amendments to the KRAS Transition Plan (provided that any amendments to the KRAS Transition Plan must be mutually agreed to by the Parties in writing) and oversee the activities to be performed for the transition of the KRAS Program (including transfer of the IND) under the POC Plan and KRAS Transition Plan for the KRAS Program;
- (viii) review data, reports or other information submitted by either Party with respect to Collaboration Activities under each Internal SAV Program Plan or POC Plan;
 - (ix) review and discuss any actual or potential Safety Issue or Technical Failure;
 - (x) review and discuss any Pre-GLP Tox Data Package for a given Internal SAV Program;

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- (xi) review and discuss any SAV IND Data Package for a given Joint SAV Program;
- (xii) form such other subcommittees or project teams as the POC Committee may deem appropriate (including any project teams to oversee the day-to-day activities necessary to execute the POC Plans) and oversee the activities of any subcommittees or project teams formed by the POC Committee, including by receiving and reviewing reports and other information submitted by those subcommittees or project teams (if applicable); *provided*, that any such subcommittee or project team may make recommendations to the POC Committee but may not be delegated POC Committee decision-making authority;

(xiii) [***];

- (xiv) coordinate and oversee the Manufacturing activities under a POC Plan with respect to PCVs (including Collaboration PCV Products) under the applicable Programs in the Territory, including CMC matters:
- (xv) review and discuss Manufacturing activities under a POC Plan with respect to SAVs (including Collaboration SAV Products) under the applicable Joint SAV Program in the Territory, including CMC matters;
- (xvi) discuss and resolve all disputes referred to the POC Committee by any subcommittee or project teams established by the POC Committee;
- (xvii) review proposed publications regarding the results of the Collaboration Activities proposed to be published in accordance with Section 12.2; and
 - (xviii) attempt to resolve any disputes relating to this Agreement on an informal basis.
- (d) Decision-making. The [***] POC Committee representatives of each Party will collectively have one (1) vote (i.e., all representatives of a Party vote as a single block). The POC Committee members will use diligent efforts to reach agreement on all matters. If, despite such efforts, agreement on a particular matter cannot be reached by the POC Committee within [***] days after the POC Committee first considers such matter (or such shorter time as may be reasonable in the circumstances), then upon the written request of a Party, such matter will be referred to the Executive Officers (or their designees, which designee is required to have decision-making authority on behalf of such Party), who will attempt in good faith to resolve such dispute by negotiation and consultation for a [***] day period following receipt of such written notice. If, despite such efforts, agreement on a particular matter cannot be reached by the Executive Officers within such [***] day period, then with respect to the applicable POC Program (i) if such matter relates to [***] such matter shall be determined by Moderna, in good faith and its sole discretion after due and reasonable consideration of Merck's position, (ii) if such matter relates to [***], such matter shall be determined by Merck, in good faith and its sole discretion after due and reasonable consideration of Moderna's position [***] (iv) for any other matter, such matter shall be resolved in accordance with the provisions of Section 15.1(c); provided that the Amended Anticipated PCV POC Budget (including any component thereof) may not be modified without the written consent of the Parties.

- (e) *POC Committee Term*. The POC Committee will cease to exist upon the later of (i) the expiration or termination of all Merck Participation Election Periods or (ii) the expiration of the SAV Research Term.
- 2.4 <u>Joint Steering Committee</u>. Upon the first exercise of a Merck Participation Election, then within thirty (30) days after the Merck Participation Election Date, the Parties will establish a joint steering committee (the "<u>Joint Steering Committee</u>" or "<u>JSC</u>"). During the Merck Participation Term for a given Program, the JSC will oversee and facilitate Research activities under any Additional Research Program and the Development, Manufacturing and Commercialization of mRNA Cancer Vaccines (including Collaboration Products) for such Program. For clarity, the JSC will not have any responsibilities regarding, or oversight of, activities under the POC Plan for a given Program.
- (a) Composition of the Joint Steering Committee. The Joint Steering Committee shall be comprised of [***] representatives of Merck and [***] representatives of Moderna. Each Party may change its representatives to the Joint Steering Committee from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Collaboration Activities. With the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), each Party may invite non-voting employees and consultants to attend meetings of the Joint Steering Committee, subject to their agreement to be bound to the same extent as a permitted subcontractor under Section 10.4. The JSC may change its size from time to time by mutual consent of its members; provided that the JSC will consist at all times of an equal number of representatives of each of Merck and Moderna. Each Party will designate one of its representatives who is empowered by such Party to make decisions regarding issues within the purview of the Joint Steering Committee to act as the co-chair of the Joint Steering Committee. The co-chairs will be responsible for overseeing the activities of its Joint Steering Committee members consistent with the responsibilities set forth in this Section 2.4.
- (b) Function and Powers of the Joint Steering Committee. During the Merck Participation Term for a given Program, the Joint Steering Committee shall have general strategic oversight of the Collaboration for such Program, and shall confer regarding the status of the Additional Research Plans and the Development Plans and the Research, Development, Manufacture and Commercialization of mRNA Cancer Vaccines (including Collaboration Products) for such Program. Without limiting the generality of the foregoing, the JSC shall have the following specific responsibilities during the Merck Participation Term for a given Program:
- (i) review and discuss the Joint Development Plan and Budget for such Program and all amendments thereto, and approve any such amendments for the Joint Development Plan and Budget for the PCV Program and annual budget updates for the Joint Development Plan and Budget for any Program in accordance with Section 4.3(c)(ii), including to determine the resources and activities allocated by each Party thereto (which resources and activities will be set forth in the Joint Development Plan and Budget for such Program);
 - (ii) review and approve the Development Transition Plan for such Program;

(iii) review and comment on any Independent Additional Study Development Plan for such

(iv) review and approve the Global Commercialization Plan, Global Commercialization Budget and global Commercialization strategy for such Program pursuant to Section 8.3;

(v)[***];

Program;

(vi) review, discuss and coordinate the Parties' scientific presentation and publication strategy relating to the Collaboration Products in the Territory for such Program in accordance with Section 12.2;

(vii) [***]

(viii) review and approve any Additional Research Program(s) for such Program proposed by either Party;

(ix) oversee Research activities conducted pursuant to any Additional Research Plan for such Program;

- (x) review and discuss any actual or potential Safety Issue with respect to any Collaboration Product or any Other Component used in a Combination Product;
- (xi) provide guidance to the JDC, JMC or JCC and attempt to resolve issues for such Program presented to it by any other Committee; and
- (xii) perform such other functions as may be expressly delegated to the JSC pursuant to this Agreement.
- (c) Joint Steering Committee Decision-Making. Decisions of the Joint Steering Committee shall be made unanimously with each Party having one (1) vote (*i.e.*, all representatives of a Party must vote as a single block). The Joint Steering Committee members will use diligent efforts to reach agreement on all matters. If, despite such efforts, agreement on a particular matter cannot be reached by the Joint Steering Committee within [***] days after the Joint Steering Committee first considers such matter (or such shorter time as may be reasonable in the circumstances), then upon the written request of a Party, such matter will be referred to the Executive Officers (or their designees, which designee is required to have decision-making authority on behalf of such Party), who will attempt in good faith to resolve such dispute by negotiation and consultation for a [***] day period following receipt of such written notice. If, despite such efforts, agreement on a particular matter cannot be reached by the Executive Officers within such [***] day period, then the matter shall be resolved in accordance with the provisions of Section 15.1(c); provided, that:
- (i) [***], such matter shall be determined by Merck, in good faith and its sole discretion after due and reasonable consideration of Moderna's position;

- (ii) [***], such matter shall be determined by Moderna, in good faith and its sole discretion after due and reasonable consideration of Merck's position;
- (iii) [***], such matter shall be determined by Merck, in good faith and its sole discretion after due and reasonable consideration of Moderna's position;
- (iv) [***], then such matter shall be determined by Moderna, in good faith and its sole discretion after due and reasonable consideration of Merck's position;
- (v) [***], such matter shall be determined by Merck, in good faith and its sole discretion after due and reasonable consideration of Moderna's position; provided, however, (A) decisions with respect to [***] shall be in accordance with [***] (B) with respect to the [***], Merck shall [***];
- (vi) [***], such matter shall be determined by Merck, in good faith and its sole discretion after due and reasonable consideration of Moderna's position; and
- (vii) the budget within a Joint Development Plan and Budget for the applicable Program, Global Commercialization Budget or the budget within an Additional Research Plan may not be increased without the written consent of the Parties.
- (d) Joint Steering Committee Meetings. The Joint Steering Committee shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less than [***] per Calendar Quarter, unless the Parties mutually agree in writing to a different frequency, with the location for such meetings alternating between Moderna and Merck facilities (or such other location as may be determined unanimously by the Joint Steering Committee members). Alternatively, the Joint Steering Committee may meet by means of teleconference, videoconference or other similar communications equipment. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.
- (e) *Joint Steering Committee Agendas*. The co-chairs of the Joint Steering Committee shall be responsible for distributing an agenda for each Joint Steering Committee meeting at least [***] days in advance of such meeting. Each Party shall have the right to request that the chairs include any appropriate matter (*i.e.*, additional topics) on the agenda, which requests shall be accommodated by the chairs.
- (f) Joint Steering Committee Minutes. The co-chairs shall be responsible for generating and issuing reasonably detailed minutes of each Joint Steering Committee meeting that reflect material decisions made and action items identified at such meeting, and will circulate such minutes to the Joint Steering Committee representatives of each Party for review within [***] days after such meeting. Any corrections or comments to such minutes must be provided to the co-chair within [***] days after the draft minutes are issued, who shall

- 2.5 <u>Joint Development Committee or JDC</u>. Upon the first exercise of a Merck Participation Election, then within [***] days after the Merck Participation Election Date, the Parties will establish a joint development committee (the "<u>Joint Development Committee</u>" or "<u>JDC</u>"). During the Merck Participation Term for a given Program, the JDC will oversee the conduct of the Development of Collaboration Products. For clarity, the JDC will not have any responsibilities regarding, or oversight of, activities under the POC Plan for a given Program.
- (a) Composition of the JDC. The JDC shall comprise [***] representatives of Merck and [***] representatives of Moderna. Each Party may change its representatives to the JDC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have expertise and operational responsibilities for Development and/or registration of pharmaceutical products. With the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), each Party may invite non-voting employees and consultants to attend meetings of the JDC, subject to their agreement to be bound to the same extent as a permitted subcontractor under Section 10.4. The JDC may change its size from time to time by mutual consent of its members; provided that the JDC will consist at all times of an equal number of representatives of each of Merck and Moderna. The JDC shall be chaired by a representative of Merck. The chair shall have the responsibilities set forth in Section 2.5(e), but shall have no additional powers or rights beyond those held by the other JDC representatives.
- (b) Function and Powers of the JDC. During the Merck Participation Term for a given Program, without limiting the generality of this Section 2.5, the JDC shall oversee and facilitate the conduct of the Development of Collaboration Products during the Merck Participation Term for such Program, including to:
- (i) monitor and oversee the Development activities under the Development Plan, including timely sharing and discussion of any material results or events relating to such Development activities and discussion of any anticipated cost overruns;
- (ii) oversee the conduct of and monitor progress of any Clinical Studies under the Joint Development Plan and Budget for such Program;
- (iii) decide whether and when to initiate or discontinue any Clinical Study under the Joint Development Plan and Budget for such Program;
- (iv) facilitate the flow of information between the Parties with respect to the Development of Collaboration Products for such Program;
- (v) discuss and review the overall strategy regarding Regulatory Approval of Collaboration Products in the Territory for such Program;
- (vi) provide a forum for discussion of any regulatory related activities and maintenance of INDs or CTAs for Collaboration Products and initial Regulatory Approvals for Collaboration Products for such Program;
 - (vii) review the Development Transition Plans for such Program;
- (viii) coordinate with the JMC regarding enrollment for Clinical Studies for Collaboration Products, including the forecast for Manufacturing capacity and the applicable enrollment rate;

- (ix) discuss any Additional Study(ies) proposed by either Party for such Program; and
- (x) until the formation of the JCC, discuss, when available to Merck, the applicable and relevant components of the initial Global Commercialization Plan for such Program; provided that for clarity, the JDC will not oversee the Commercialization activities with respect to Collaboration Products, and such Commercialization activities shall be under the purview of the JCC, as, and to the extent, applicable.
- (c) *Joint Development Committee Decision-Making*. Decisions of the Joint Development Committee shall be made unanimously with each Party having one vote (*i.e.*, all representatives of a Party must vote as a single block). In the event that the Joint Development Committee cannot or does not, after good faith efforts

during a period of not more than [***] days, reach agreement on an issue that comes before the JDC and over which the JDC has oversight, then such matter shall be raised to the JSC for resolution in accordance with Section 2.4(c).

- (d) *JDC Meetings*. The JDC shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than [***] per Calendar Quarter, with the location for such meetings alternating between Moderna and Merck facilities (or such other location as may be determined unanimously by the JDC members). Alternatively, the JDC may meet by means of teleconference, videoconference or other similar communications equipment. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.
- (e) *JDC Agendas*. The chair of the JDC shall be responsible for distributing an agenda for each committee meeting at least [***] days in advance of such meeting. Each Party shall have the right to request the chair to include any matter on the agenda, which requests shall be accommodated by the chair.
- (f) JDC Minutes. The chair shall be responsible for generating and issuing reasonably detailed minutes of each JDC meeting, which shall include a summary of any actions agreed at the meeting and will circulate such minutes to the JDC representatives of each Party for review within [***] days after such meeting. Any corrections or comments to such minutes must be provided to the chair within [***] days after the draft minutes are issued, who shall then issue the approved (or, if no comments are provided within such [***] day period, deemed approved) minutes in final form to the JDC representatives of each Party.
- 2.6 <u>Joint Manufacturing Committee or JMC</u>. Upon the exercise of the Merck Participation Election for the first Program, then within [***] days after the Merck Participation Election Date, subject to the oversight of, and without limiting the authority of, the Joint Steering Committee, the Parties will establish a committee to oversee and facilitate the Manufacturing of Collaboration Products for the Programs. For clarity, the JMC will not have any responsibilities regarding, or oversight of, activities under the POC Plan for a given Program.

- (a) Composition of the Joint Manufacturing Committee. The joint manufacturing committee (the "Joint Manufacturing Committee" or "JMC") shall comprise [***] representatives of Merck and [***] representatives of Moderna. Each Party may change its representatives to the JMC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with Manufacturing activities. With the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), each Party may invite non-voting employees and consultants to attend meetings of the JMC, subject to their agreement to be bound to the same extent as a permitted subcontractor under Section 10.4. The JMC may change its size from time to time by mutual consent of its members; provided that the JMC will consist at all times of an equal number of representatives of each of Merck and Moderna. The JMC shall be chaired by a representative of [***]. The chair shall have the responsibilities set forth in Section 2.6(e) but shall have no additional powers or rights beyond those held by other JMC representatives.
- (b) Function and Powers of the JMC. Without limiting the generality of this Section 2.6, the JMC shall oversee and facilitate the Manufacturing of Collaboration Products for a Program during the Merck Participation Term for such Program, including to:
- (i) coordinate and oversee the Manufacturing activities under this Agreement with respect to Collaboration Products in the Territory in accordance with any Supply Agreement (as applicable), including CMC matters;
- (ii) discuss and coordinate with the JDC to allocate appropriate amounts from the applicable budgets to Manufacturing activities;
 - (iii) [***]
- (iv) coordinate with the JDC regarding enrollment for Clinical Studies for Collaboration Products under the applicable Programs, including [***] and the applicable enrollment rate;
- (v) coordinate with the JCC regarding Manufacturing of Collaboration Products under the applicable Programs for Commercialization, including [***];
 - (vi) [***]; and

(vii) discuss, coordinate and plan for Manufacturing technology transfers as set forth in Section 6.2(f), a Supply Agreement, [***] (as applicable).

- (c) *Joint Manufacturing Committee Decision-Making*. Decisions of the Joint Manufacturing Committee shall be made unanimously with each Party having one vote (*i.e.*, all representatives of a Party must vote as a single block). In the event that the Joint Manufacturing Committee cannot or does not, after good faith efforts during a period of not more than [***] days, reach agreement on an issue that comes before the JMC and over which the JMC has oversight, then such matter shall be raised to the JSC for resolution in accordance with Section 2.4(c).
- (d) *JMC Meetings*. The JMC shall meet [***], or more frequently as the Parties may agree, in accordance with a schedule established by mutual written agreement of the Parties, with the location for such meetings alternating between Moderna and Merck facilities (or such other location as may be determined unanimously by the JMC members). Alternatively, the JMC may meet by means of teleconference, videoconference or other similar communications equipment. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.

- (e) *JMC Agendas*. The chair of the JMC shall be responsible for distributing an agenda for each JMC meeting at least [***] days in advance of such meeting. Each Party shall have the right to request the chair to include any appropriate matter on the agenda, which requests shall be accommodated by the chair. The chair shall be responsible for generating and issuing minutes, in accordance with Section 2.6(f), of each JMC meeting, which shall include a summary of any actions agreed at the meeting.
- (f) *JMC Minutes*. The chair shall be responsible for generating and issuing reasonably detailed minutes of each JMC meeting, which shall include a summary of any actions agreed at the meeting and will circulate such minutes to the JMC representatives of each Party for review within [***] days after such meeting. Any corrections or comments to such minutes must be provided to the chair within [***] days after the draft minutes are issued, who shall then issue the approved (or, if no comments are provided within such [***] day period, deemed approved) minutes in final form to the JMC representatives of each Party.
- 2.7 <u>Joint Commercialization Committee or JCC</u>. Upon the first exercise of a Merck Participation Election, then within [***] days after the Merck Participation Election Date, subject to the oversight of, and without limiting the authority of, the Joint Steering Committee, the Parties hereby establish a joint commercialization committee (the "<u>Joint Commercialization Committee</u>" or "<u>JCC</u>"). During the Merck Participation Term for a given Program, the JCC will oversee and facilitate the Commercialization of Collaboration Products for such Program as follows:
- (a) Composition of the JCC. The JCC shall comprise [***] representatives of Merck and [***] representatives of Moderna. Each Party may change its representatives to the JCC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with Commercialization activities. With the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), each Party may invite non-voting employees and consultants to attend meetings of the JCC, subject to their agreement to be bound to the same extent as a permitted subcontractor under Section 10.4. The JCC may change its size from time to time by mutual consent of its members; provided that the JCC will consist at all times of an equal number of representatives of each of Merck and Moderna. The JCC shall be chaired by a representative of [***]. The chair shall have the responsibilities set forth in Section 2.7(e) but shall have no additional powers or rights beyond those held by other JCC representatives.
- (b) Function and Powers of the JCC. During the Merck Participation Term for a given Program, without limiting the generality of this Section 2.7, the JCC shall have the following specific responsibilities for such Program:
 - (i) review and comment on the global Commercialization strategy for such Program;

- (iii) as necessary, periodically request a review of the overall commercial strategy for such Program, and request Merck prepare and submit an updated global Commercialization strategy for such Program for review by the JCC;
- (iv) discuss the Commercialization activities under the Global Commercialization Plan for such Program;
- (v) facilitate the flow of information between the Parties with respect to the Commercialization of Collaboration Products for such Program;
- (vi) review and discuss strategies with respect to Medical Affairs and Pricing Matters for Collaboration Products in the Territory for such Program to the extent not prohibited by applicable Law; and
- (vii) [***], coordinating Co-Promotion in the U.S. in accordance with the terms and conditions of this Agreement and the Co-Promotion Agreement for such Program.
- (c) Joint Commercialization Committee Decision-Making. Decisions of the Joint Commercialization Committee shall be made unanimously with each Party having one vote (i.e., all representatives of a Party must vote as a single block). In the event that the Joint Commercialization Committee cannot or does not, after good faith efforts during a period of not more than [***] days, reach agreement on an issue that comes before the JCC and over which the JCC has oversight, then such matter shall be raised to the JSC for resolution in accordance with Section 2.4(c).
- (d) *JCC Meetings*. The JCC shall meet [***], provided that as of and after the beginning of the Calendar Year immediately preceding the anticipated First Commercial Sale of a Collaboration Product, the JCC shall meet [***] per Calendar Quarter, or more frequently as the Parties may agree, in accordance with a schedule established by mutual written agreement of the Parties, with the location for such meetings alternating between Moderna and Merck facilities (or such other location as may be determined unanimously by the JCC members). Alternatively, the JCC may meet by means of teleconference, videoconference or other similar communications equipment. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.
- (e) *JCC Agendas*. The chair of the JCC shall be responsible for distributing an agenda for each JCC meeting at least [***] days in advance of such meeting. Each Party shall have the right to request the chair to include any matter on the agenda, which requests shall be accommodated by the chair.
- (f) JCC Minutes. The chair shall be responsible for generating and issuing reasonably detailed minutes of each JCC meeting, which shall include a summary of any actions agreed at the meeting, and will circulate such minutes to the JCC representatives of each Party for review within [***] days after such meeting. Any corrections or comments to such minutes must be provided to the chair within [***] days after the draft minutes are issued, who shall then issue the approved (or, if no comments are provided within such [***] day period, deemed approved) minutes in final form to the JCC representatives of each Party.

- 2.8 <u>Authority</u>. Notwithstanding the foregoing, each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the applicable Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Committee will have the power to (a) amend, modify or waive compliance with this Agreement, (b) alter, increase or expand the Parties' rights or obligations under this Agreement beyond those explicitly set forth in this Agreement, (c) determine that a Party has fulfilled any obligations under this Agreement or that a Party has breached any obligation under this Agreement, (d) make a decision that is expressly stated to require the Parties' mutual agreement or a decision for which Merck or Moderna have final decision making authority, (e) change the Collaboration Activities in any manner that would alter the fundamental objectives of the Collaboration Activities as described herein, or (f) impose additional costs or expenses on either Party beyond those explicitly set forth in this Agreement. Any dispute between the Parties regarding the issues set forth in this Section 2.8 will be resolved pursuant to the procedures set forth in Section 15.1.
- 2.9 <u>Interactions Between the Committees and Personnel.</u> The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that may be involved in administering such Party's activities under this Agreement. The JSC shall establish procedures to facilitate

communications between the JSC and the relevant internal committee, team or board of each of the Parties in order to maximize the efficiency of the JSC and the performance of the Parties of their respective obligations under this Agreement.

2.10 <u>Amendment and Restatement</u>. The Parties hereby agree and acknowledge that this Agreement amends and restates the Original Agreement in its entirety and the Original Agreement is replaced with, and superseded by, this Agreement; provided that, for the avoidance of doubt, any activities conducted under the Original Agreement shall be deemed to have been conducted under this Agreement.

3. PROGRAMS AND MERCK PARTICIPATION ELECTIONS

3.1 Overview of Programs.

(a) <u>PCV POC Program</u>. Subject to and in accordance with the terms of this Agreement, during the POC Term for the PCV Program, Moderna will undertake Research and Development and such other activities as set forth in the POC Plan for the PCV Program with the goal of Researching and Developing PCVs (including Collaboration PCV Products) through the conduct of preclinical studies and Clinical Studies with monotherapy PCVs (including Collaboration PCV Products) and Collaboration PCV Products in combination with Keytruda to create the POC Data Package for the PCV Program, all as more fully set forth in the POC Plan for the PCV Program (the "<u>PCV POC Program</u>"). For clarity, as of the Amended Effective Date, Moderna consents to [***] in accordance with the POC Plan for the PCV Program; provided, however, that notwithstanding the foregoing, [***].

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(b) <u>KRAS POC Program</u>. Subject to and in accordance with the terms of this Agreement and the KRAS Transition Plan, during the POC Term for the KRAS Program, the Parties will undertake Research and Development and such other activities as set forth in the POC Plan for the KRAS Program with the goal of Researching and Developing SAVs (including Collaboration SAV Products) Directed against KRAS through the conduct of preclinical studies and Clinical Studies with monotherapy SAVs (including Collaboration SAV Products) Directed against KRAS and Collaboration SAV Products in combination with Keytruda to create the POC Data Package for the KRAS Program, all as more fully set forth in the POC Plan for the KRAS Program (the "<u>KRAS POC Program</u>"). For clarity, (i) the Parties acknowledge and agree that, as of the Amended Effective Date, [***], and (ii) Moderna consents to [***].

(c) Other SAV Programs.

- (i) During the SAV Research Term, to the extent that either Party wishes to conduct Research and Development for SAVs Directed against a Target (or multiple Targets), other than KRAS, that is not the subject of a then existing SAV Program, then such Party shall provide written notice to the other Party of each proposed Target(s) to be included in a proposed SAV Program, which notice shall set forth [***] any Moderna Pre-Existing In-Licenses, Moderna New In-Licenses or Merck In-Licenses, as applicable, relating to such proposed Target(s) (an "SAV Target Notice"). Notwithstanding the foregoing, an SAV Target Notice may not include [***].
- (ii) If the Parties mutually agree in writing to the inclusion of a proposed Target(s), [***], then (A) each such Target shall become an "SAV Target," (B) the Parties shall conduct a "Joint SAV Program" for such SAV Target(s), and (C) the Parties shall promptly thereafter mutually prepare and approve in writing a POC Plan for a Joint SAV Program for such SAV Target(s). Such POC Plan for such Joint SAV Program shall contain such other information as set forth in and be consistent with Section 3.3(b). For the avoidance of doubt, the Parties may agree to multiple separate POC Plans for multiple Joint SAV Programs pursuant to this Section 3.1(c)(ii).
- (iii) If the non-proposing Party does not approve the inclusion of a proposed Target in an SAV Target Notice, [***], it shall notify the proposing Party thereof in writing within [***] days of receipt of the applicable SAV Target Notice. During the SAV Research Term, if Moderna [***] declines in writing to participate in a program for a Target(s) that is proposed by Merck pursuant to an SAV Target Notice pursuant to Section 3.1(c)(i), then Merck may elect, upon written notice to Moderna within [***] after Moderna declines to participate in such program, to [***] (provided that [***]).
- (iv) During the POC Term for a given Joint SAV Program, subject to and in accordance with the terms of this Agreement, the Parties will undertake Research and Development and such other activities as set forth in the applicable POC Plan for such Joint SAV Program (other than the KRAS Program, which is

covered by the provisions of Section 3.1(b) above) with the goal of Researching and Developing SAVs (including Collaboration SAV Products) Directed against such SAV Target under such POC Plan through the conduct of preclinical studies and Clinical Studies with [***] SAVs (including Collaboration SAV Products) Directed against such SAV Target and, [***] (each, an "Other SAV POC Program", and together with the KRAS POC Program, each an "SAV POC Program"). The PCV POC Program, KRAS POC Program and each Other SAV POC Program shall each be referred to herein as a "POC Program".

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(d) Internal SAV Programs.

(i) During the SAV Research Term, if a non-proposing Party reasonably declines in writing to participate in a program for a Target(s) that is proposed pursuant to an SAV Target Notice in accordance with Section 3.1(c)(iii), or fails to respond in writing to the proposing Party within [***] days of receipt of the applicable SAV Target Notice, then the proposing Party may elect, in its sole discretion, to provide written notice, within [***] days after the date that the non-proposing Party declines in writing to participate (or fails to respond, as applicable), to the non-proposing Party to conduct an Internal SAV Program for such proposed Target(s), and (A) upon the date of such written notice, the proposing Party shall conduct an "Internal SAV Program" for such Target(s) and shall be the "ISP Party" for such Internal SAV Program, (B) the ISP Party shall promptly thereafter (and in any event within [***] days) prepare in writing and provide to the non-ISP Party an Internal SAV Program Plan for such Internal SAV Program consistent with the SAV Target Notice, with the goal of Researching SAVs Directed against such Target(s) under the Internal SAV Program Plan through the selection of a Lead SAV Candidate, and (C) the Parties shall promptly discuss in good faith and agree upon the definition of [***] to be set forth in the Internal SAV Program Plan for such Internal SAV Program, [***].

(ii) The ISP Party for such Internal SAV Program, [***], will undertake Research and such other activities as set forth in the applicable Internal SAV Program Plan for such Internal SAV Program to generate information to prepare the Pre-GLP Tox Data Package for such Internal SAV Program. If Merck is the ISP Party for such Merck Internal SAV Program, Moderna will Manufacture and supply SAVs (including mRNA Constructs therefor) Directed against the applicable Target(s) for such Merck Internal SAV Program, all in accordance with the supply terms set forth in **Exhibit N**. An ISP Party may terminate its Internal SAV Program for any reason upon [***] days written notice to the non-ISP Party. If an ISP Party does not actively conduct its Internal SAV Program [***], then the ISP Party shall provide prompt written notice to the non-ISP Party of such discontinuation [***], and as of the date of such written notice, [***].

(iii) During the Internal SAV Program Term for a given Internal SAV Program, the Parties shall present and review, via the POC Committee, the status of the Research activities for such Internal SAV Program and the data generated thereunder. Upon [***], the ISP Party will promptly (and in any event within [***] days) prepare and provide to the non-ISP Party the Pre-GLP Tox Data Package for such Internal SAV Program. After the delivery of the Pre-GLP Tox Data Package and for the remainder of the Internal SAV Program Term for such Internal SAV Program, the ISP Party shall, as reasonably requested by the non-ISP Party, meet with the non-ISP Party to discuss such Pre-GLP Tox Data Package and any questions of the non-ISP Party with respect thereto, including providing the non-ISP Party with certain additional information as the non-ISP Party may reasonably request to assist with interpretation of such Pre-GLP Tox Data Package.

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(iv) On an Internal SAV Program-by-Internal SAV Program basis, the ISP Party hereby grants to the non-ISP Party, during the Internal SAV Program Term for a given Internal SAV Program, the exclusive right, exercisable at the non-ISP Party's sole discretion in accordance with Section 3.1(d)(v) below, to elect to continue, in collaboration with the ISP Party, the Research, Development, Manufacture and Commercialization of mRNA Cancer Vaccines (including Collaboration Products) for such Internal SAV Program (and the Target(s) thereunder) as a Joint SAV Program, and to exercise the licenses set forth in Section 10.1(a)(ii) or 10.2(a)(ii) (as applicable) with respect to such mRNA Cancer Vaccines (including Collaboration Products) for such Internal SAV Program as a Joint SAV Program, in each case, solely under the terms and conditions set forth in this Agreement (each such election, a "Pre-GLP Tox Election"). During the Internal SAV Program Term for a given Moderna Internal SAV Program, Merck may terminate its Pre-GLP Tox Election for such Moderna Internal SAV Program upon written notice to Moderna. In the event that Merck terminates its Pre-GLP Tox Election for a given Moderna Internal SAV Program, then the consequences set

forth in Section 3.1(d)(vi) shall apply with respect to such Moderna Internal SAV Program (*mutatis mutandis*); provided, however, [***].

(v) On an Internal SAV Program-by-Internal SAV Program basis, the non-ISP Party may elect to exercise the Pre-GLP Tox Election for a given Internal SAV Program by delivering to the ISP Party written notice of such exercise at any time during the Internal SAV Program Term for such Internal SAV Program (each, a "Pre-GLP Tox Election Notice"). Commencing on the Pre-GLP Tox Election Date for a given Internal SAV Program, (A) each Target(s) for such Internal SAV Program shall become an "SAV Target", (B) such Internal SAV Program shall be converted into a "Joint SAV Program" and (C) the Parties shall engage in such Joint SAV Program for such SAV Target(s) in accordance with Section 3.1(c)(ii), including preparing a POC Plan for such Joint SAV Program as soon as reasonably practicable (and in any event within [***] days) after such Pre-GLP Tox Election Date.

(vi) For a given Moderna Internal SAV Program, if Moderna delivers a Pre-GLP Tox Data Package for such Moderna Internal SAV Program and Merck does *not* exercise the Pre-GLP Tox Election for such Moderna Internal SAV Program during the Internal SAV Program Term, then, upon written notice to Merck within [***] days after the Pre-GLP Tox Commitment Date for such Moderna Internal SAV Program, Moderna shall be entitled to [***], Development, Manufacturing and Commercialization program for the Target(s) for such Moderna Internal SAV Program *outside* the Collaboration and without any further compensation to Merck, and (A) each such Target shall be deemed a Released Target and the Moderna Internal SAV Program shall be deemed terminated for purposes of this Agreement, (B) the licenses set forth in Section 10.1(d) may not be exercised by Merck with respect to such Released Target(s) and (C) the exclusivity provisions set forth in Sections 10.7(c) and 10.8(b) shall terminate with respect to the Released Target(s) and the provisions set forth in Sections 10.7(d)(iv) and 10.8(c)(iv) shall terminate with respect to the Collaboration Shared Neoepitope(s) under such Moderna Internal SAV Program, [***].

(vii) For a given Merck Internal SAV Program, if Merck delivers a Pre-GLP Tox Data Package for such Merck Internal SAV Program and Moderna does *not* exercise the Pre-GLP Tox Election for such Merck Internal SAV Program during the Internal SAV Program Term, then Merck may elect upon written notice to Moderna within [***] days after the

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Pre-GLP Tox Commitment Date for such Merck Internal SAV Program to either (1) convert such Merck Internal SAV Program to a "Joint SAV Program" and each such Target to an "SAV Target"; provided that (x) Merck will be [***]; provided, however, that at the request of Merck, the Parties will [***], or (2) terminate such Merck Internal SAV Program upon written notice to Moderna, provided that if Merck elects to exercise its rights under this clause (2), then (A) each Target for such Merck Internal SAV Program [***], (B) the licenses set forth in [***], (C) in such case, [***]terminate with respect to such Merck Internal SAV Program [***], (D) any outstanding purchase orders for mRNA Constructs to be delivered by Moderna to Merck in accordance with the supply terms set forth in **Exhibit N** will terminate with respect to such Merck Internal SAV Program, and (E) Merck shall have no further rights under **Exhibit J** with respect to such Merck Internal SAV Program.

(e) Clinical Studies Under a POC Plan for a Joint SAV Program.

(i) Selection of Collaboration Products for IND Enabling Studies.

(1) For any given Internal SAV Program that converts to a Joint SAV Program in accordance with Section 3.1(d), if either Party has reasonably identified [***], then, at the request of such Party, the Parties, via the POC Committee, will discuss whether to conduct such activities. If the Parties mutually agree that the conduct of such additional pre-clinical Research activities is reasonably likely to [***], the Parties will amend the applicable POC Plan to include such Research activities and any [***] (the "Additional Converted Program Research Activities"), and the Parties will reasonably agree as to which Party should conduct the Additional Converted Program Research Activities. If the Parties do not mutually agree to amend the POC Plan for such Joint SAV Program to include such Additional Converted Program Research Activities during the [***] following the POC Committee's discussion, then (A) [***] (B) a Party may, [***].

(2) During the POC Term for a given Joint SAV Program, the Parties shall discuss in good faith and mutually agree on the specific SAV(s) under such Joint SAV Program that will be the subject of the IND-Enabling Studies under the POC Plan for such Joint SAV Program. As of the Amended Effective Date, the Parties acknowledge and agree that (A) the IND-Enabling Studies for the KRAS Program have been

completed [***], and (B) mRNA-5671 is a Collaboration SAV Product Directed against KRAS for the KRAS Program and will be the subject of Clinical Studies under the POC Plan for the KRAS Program.

(ii) Clinical Studies.

(1) (I) From time to time prior to the completion of the IND-Enabling Studies for a given Joint SAV Program, the Parties may review, and may mutually agree to update, in good faith, the Clinical Initiation Criteria for such Joint SAV Program based on reasonable scientific rationale. Following completion of IND-Enabling Studies for a given Joint SAV Program, the Party that conducted such IND-Enabling Studies will promptly prepare and provide the other Party with the SAV IND Data Package for such Joint SAV Program. Within [***] days after the date of delivery of the SAV IND Data Package for such Joint SAV Program, the POC Committee will review and discuss the SAV IND Data Package for such Joint SAV Program, including determining if the Clinical Initiation Criteria has been met for such Joint SAV Program (provided if there is disagreement as to [***], such disagreement shall be referred to Section 15.1(c) for resolution (which the Parties agree shall be conducted within [***] days or such other period of time as agreed to by the Parties)).

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(II) Promptly (but in any event within [***] days following the determination as to whether the Clinical Initiation Criteria has been met for such Joint SAV Program (regardless of whether or not the Clinical Initiation Criteria were met), the Parties shall meet to discuss if the Parties desire to continue to progress such Joint SAV Program into Clinical Studies under the POC Plan. Subject to the provisions of this Section 3.1(e)(ii), the Parties must mutually agree to advance such Joint SAV Program into Clinical Studies under the POC Plan for such Joint SAV Program prior to commencing the first Clinical Study under the POC Plan; provided, however [***]. If the Parties mutually agree to advance such Joint SAV Program into Clinical Studies, then Merck shall use Commercially Reasonable Efforts to file an IND or CTA for such Program in accordance with the POC Plan as soon as reasonably practicable after the date of such agreement.

(III) If, within [***] days following the meeting of the Parties pursuant to clause (II) above, the Parties do not mutually agree to advance such Joint SAV Program into Clinical Studies under the current POC Plan for such Joint SAV Program, then the Parties may continue for a period of [***] days to discuss in good faith alternatives to continue the Research and Development of SAVs (and Collaboration SAV Products) under such Joint SAV Program, which alternatives may include, if mutually agreed to by the Parties, [***]. If the Parties do not mutually agree to amendments to the then current POC Plan within such [***] day period or such longer time as mutually agreed to by the Parties, then the matter shall be referred to Section 15.1(c) for resolution (which the Parties agree shall be conducted within [***]or such other period of time as agreed to by the Parties).

(IV) Notwithstanding anything herein to the contrary, the Parties acknowledge and agree that this Section 3.1(e)(ii) shall not apply to the KRAS Program.

(2) In the event that the Parties mutually agree in writing not to advance a given Joint SAV Program into Clinical Studies under the POC Plan for such Joint SAV Program, then the POC Term for such Joint SAV Program shall terminate [***] days after the Parties' decision in writing (which shall in any event be within [***] days after the date of delivery of the SAV IND Data Package) not to commence Clinical Studies for such Joint SAV Program.

(3) In the event that an SAV IND Data Package is delivered to Merck and Moderna wishes to advance a given SAV for a Joint SAV Program under the POC Plan for such Joint SAV Program (as notified by Moderna to Merck in writing simultaneously with the delivery of the SAV IND Data Package), but Merck does not agree to advance such SAV into Clinical Studies under such POC Plan, then (A) [***] (B) [***], in each case ((A) and (B)), [***] after Merck's decision in writing not to commence Clinical Studies for such Joint SAV Program. In the event that Merck does not agree in writing to commence Clinical Studies for such Joint SAV Program within [***].

Clinical Studies under the POC Plan, and (D) Moderna determines in good faith that there is [***] and notifies Merck thereof during the POC Committee discussion pursuant to Section 3.1(e)(ii), then [***]

(5) In the event that (A) an SAV IND Data Package is delivered to Merck, (B) as part of the POC Committee discussion pursuant to Section 3.1(e)(ii), Merck wishes to advance a given Joint SAV Program into Clinical Studies under the POC Plan for such Joint SAV Program, (C) as part of the POC Committee discussion pursuant to Section 3.1(e)(ii), Moderna does not agree to advance a given Joint SAV Program into Clinical Studies under the POC Plan for such Joint SAV Program, and (D) Moderna [***], then Merck may [***] pursuant to this Section 3.1(e)(ii)(5), then the following shall apply:

a. Merck shall [***]b. Moderna shall [***];c. [***]d. [***]e. [***]

Notwithstanding anything herein to the contrary, the Parties acknowledge and agree that this Section 3.1(e)(ii) shall not apply to the KRAS Program.

- (iii) Non-Commencement or Suspension of Clinical Studies for Safety Issue under POC
 Plan for a Joint SAV Program by Lead Regulatory Party. Notwithstanding anything to the contrary herein or in the applicable POC Plan for a given SAV POC Program, if the Lead Regulatory Party reasonably believes that there is a Safety Issue for such SAV POC Program, then the Lead Regulatory Party will immediately (and in any event within [***] Business Days after the date the Lead Regulatory Party determines there is a Safety Issue) provide written notice to the other Party of such Safety Issue for such Program, following which [***]. In all cases, the Lead Regulatory Party shall have the right to cease or suspend the conduct of a given Clinical Study for a given SAV POC Program if the Lead Regulatory Party reasonably believes there is a Safety Issue.
- (iv) <u>Suspension of SAV Program for Technical Failure</u>. For a given SAV Program, the Parties may suspend the conduct of activities under such SAV Program upon mutual written agreement that there is a Technical Failure with respect to the SAVs for such SAV Program, subject to the consequences in Section 3.2(b).

3.2 POC Term.

(a) Subject to this Agreement, unless (i) earlier terminated by mutual written agreement of the Parties, or (ii) extended by mutual written agreement of the Parties, the term of the PCV POC Program will commence on the Effective Date and expire upon the earliest of [***] ("PCV POC Term"); [***].

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- (b) Subject to this Agreement (including Section 3.2(c)), unless (i) earlier terminated by mutual written agreement of the Parties, or (ii) extended by mutual written agreement of the Parties, the term of a given SAV POC Program will commence on the date of Initiation of such Joint SAV Program (provided that for clarity, with respect to the KRAS Program, the term shall commence on the Amended Effective Date) and expire upon the earliest of [***] (each, an "SAV POC Term" for the applicable Joint SAV Program, and together with the PCV POC Term, each, a "POC Term").
- (c) Notwithstanding anything to the contrary contained herein, in the event that Merck delivers the Merck Participation Election Notice for a given Program in accordance with this Agreement, then the POC Term for such Program shall automatically continue until [***].

3.3 POC Plan.

(a) *Initial POC Plan*. Each POC Program shall be conducted in accordance with a plan (and with respect to the PCV Program, in accordance with a budget) that has been prepared and mutually agreed to by the Parties for such POC Program (each, a "POC Plan"). The amended POC Plan for the PCV Program, [***], is attached hereto as **Exhibit A-1**, and the POC Plan, [***], for the KRAS Program is attached hereto as **Exhibit A-2**. The initial POC Plan for each Joint SAV Program (other than the KRAS Program) shall be prepared by the Parties in accordance with Sections 3.1(c) and 3.1(d)(iv). A given POC Plan may be amended or updated, to the extent applicable, pursuant to Section 3.3(c). For clarity, each POC Plan may, if applicable, include a schedule

for data sharing and sample testing (a "<u>Data Sharing and Sample Testing Schedule</u>") for the applicable POC Program. In addition, Moderna will use Commercially Reasonable Efforts, at its sole cost and expense, to conduct the experiments set forth on **Exhibit A-3**, unless otherwise agreed by the Parties in writing, and all Know-How conceived, discovered, developed or otherwise made by or on behalf of a Party or any of its Affiliates or permitted subcontractors of any of the foregoing (solely or jointly by or on behalf of a Party or any of its Affiliates or permitted subcontractors of any of the foregoing) in the course of performing such experiments shall be Moderna Background Know-How, and [***].

- (b) Scope. Each POC Plan shall set forth [***]. Each POC Plan for a Joint SAV Program shall set forth the anticipated tasks and responsibilities of each Party throughout the applicable POC Program, it being understood that, except as otherwise specifically set forth in such POC Plan, Moderna shall be responsible for non-clinical activities and Manufacturing (including CMC development, with input from Merck) of SAVs (including Collaboration SAV Products) under such POC Plan, and supply of Moderna Agents for use in such Clinical Studies under such POC Plan, and Merck will be responsible for the preparation and filing of INDs and CTAs for, and the conduct of, the Phase I Clinical Study and Phase II Clinical Study of Collaboration SAV Products and supply of Keytruda and Merck Agents for use in such Clinical Studies under such POC Plan. The Parties generally anticipate that the POC Plan for a given POC Program may include the following activities for such POC Program:
- (c) Preparation and Amendment of a POC Plan. Each of Merck and Moderna will have the right to propose modifications or amendments to a POC Plan; provided that any modifications or amendments to any POC Plan that are proposed by either Party will be subject to review by the POC Committee and written approval by the Parties [***]; provided that neither Party may [***]. With respect to any amendment to the POC Plan for the PCV Program, such amendment shall also include a budget to the extent set forth in Section 3.4(g)(iii). [***]
- (d) Additional Moderna PCV POC Term Study. In addition to the Research and Development activities set forth in the POC Plan for the PCV Program, following [***], for a given Collaboration PCV Product, based on [***] that is sufficient to enable the Parties to proceed to a Registrational Study for such Collaboration PCV Product, [***], until the expiration of the Merck Participation Election Period for the PCV Program, Moderna shall be entitled to conduct a Registrational Study for such Collaboration PCV Product (the "Additional Moderna PCV POC Term Study"), subject to the following terms and conditions: (i) Moderna shall [***]; (ii) Merck shall [***]; (iii) Moderna may not [***], (v) Merck shall have the right to [***], (vi) the performance of the Additional Moderna PCV POC Term Study shall not [***], (vii) to the extent that there are any [***], (viii) if Merck exercises the Merck Participation Election for the PCV Program, then [***], (ix) if Merck does not exercise the Merck Participation Election for the PCV Program, then [***], and (x) Moderna shall provide Merck [***].

3.4 POC Program Performance.

- (a) *Efforts*. The Parties have agreed to engage in POC Programs on the terms and conditions set forth in this Agreement, under the oversight of the POC Committee and in accordance with the applicable POC Plans.
- (b) *PCV Program*. Unless otherwise agreed to by the Parties or otherwise explicitly set forth in the POC Plan for the PCV Program, (i) Moderna will be responsible for performing and conducting the PCV Program in accordance with the POC Plan for the PCV Program (including the Manufacture of PCVs (including Collaboration PCV Products), in

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accordance with **Exhibit K**, [***]), including [***], and for generating the POC Data Package for the PCV Program, and (ii) Merck shall be solely responsible for Manufacturing and supplying all Keytruda necessary for any Clinical Studies involving Collaboration PCV Product(s) in combination with Keytruda, in accordance with the supply terms set forth on **Exhibit K**.

(c) KRAS Program.

(i) Unless otherwise agreed to by the Parties or otherwise explicitly set forth in the POC Plan for the KRAS Program, (A) Moderna will be responsible for Manufacturing and supply of mRNA-5671 in accordance with **Exhibit K**, and (B) Merck shall be responsible for (x) after the KRAS Transition Date, the conduct of the Phase I Clinical Study and Phase II Clinical Study for mRNA-5671, including [***], and (y) supply of Keytruda for use in such Clinical Studies under such POC Plan.

- (ii) KRAS Transition Plan. As of the Amended Effective Date, the initial written plan for the transition of Development activities from Moderna to Merck for the KRAS Program (the "KRAS Transition Plan") is set forth on Schedule 3.4(c)(ii). The KRAS Transition Plan may be reviewed by and amended by mutual written agreement of the Parties. Each Party will use Commercially Reasonable Efforts to perform the obligations assigned to it under the KRAS Transition Plan in accordance with the timelines set forth therein. All costs and expenses incurred in connection with the conduct of the KRAS Transition Plan shall be borne by the Party incurring such cost or expense. The date upon which activities set forth in the KRAS Transition Plan are complete shall be the "KRAS Transition Date".
- (d) Other Joint SAV Programs. Unless otherwise agreed to by the Parties or otherwise explicitly set forth in the applicable POC Plan, for any given Joint SAV Program (other than the KRAS Program), (i) Moderna shall be solely responsible for performing and conducting the activities assigned to Moderna for such Joint SAV Program in accordance with the applicable POC Plan (including (A) [***]), and (ii) Merck shall be solely responsible for performing and conducting the activities assigned to Merck for such Joint SAV Program in accordance with the applicable POC Plan, including [***].
- (e) *Diligence*. Each Party shall use its Commercially Reasonable Efforts to perform and conduct each POC Program in accordance with the applicable POC Plan (including any applicable timelines set forth therein) and the terms of this Agreement and to achieve the goals and deliverables set forth in each POC Plan, including, for Moderna, [***]. Subject to the foregoing and the terms and conditions of this Agreement (including compliance with the applicable POC Plan), each Party (and not the POC Committee) shall be responsible for managing its own Research and Development efforts within the scope of the activities for a POC Program pursuant to the applicable POC Plan and making decisions with respect to its day-to-day conduct in support of such Research and Development efforts. For clarity, to the extent the Parties do not agree to commence some or all of the Development activities involving [***], this Section 3.4(e) shall not apply to such Development activities involving [***].
- (f) Personnel and Resources. Each Party shall dedicate to each POC Program appropriate resources and allocate personnel with an appropriate level of education, experience and training in Researching and Developing mRNA Cancer Vaccines (including Collaboration Products) for such POC Program in order to perform its activities as part of the applicable POC Program efficiently and expeditiously, which resources and personnel shall be consistent with the applicable POC Plan.

(g) Costs for the POC Plan for the PCV Program.

- (i) Subject to Section 3.4(g)(iii) and Section 3(a) of **Exhibit F**, unless otherwise agreed to by the Parties in writing, costs and expenses incurred in the conduct of the POC Plan for the PCV Program (including all POC Program Costs for the PCV Program) will be borne solely by Moderna; provided, however, that, subject to the remainder of this Section 3.4(g), [***]:
- (1) Up to [***] of the Initial PCV POC Program Funding Amount shall be allocated for activities set forth under the [***], and in the event that the costs and expenses to be incurred in connection with the completion of the activities set forth in the [***] exceed the [***], then [***] shall be responsible for and directly cover any excess costs or expenses up to [***]; provided, however, that (A) in the event that the costs and expenses to be incurred in connection with the completion of the activities set forth under the [***] are reasonably expected to exceed the amount in the [***], then [***] may, at its sole discretion, elect to directly cover any such excess costs or expenses; provided that if [***] does not elect to provide for additional funding for activities set forth under the [***], the Parties shall use good faith efforts to reach agreement on a reasonable solution with respect to such activities set forth under the [***], including the funding thereof and, if the Parties are unable to reach agreement, the [***]; and (B) in the event that the costs and expenses incurred in connection with the completion of the activities set forth under the [***] are less than the [***], then any remaining amount will be [***]. If Merck exercises the Merck Participation Election for the PCV Program, then as of the Merck Participation Election Date at Merck's election, (i) [***] of any of the costs incurred by or on behalf of Moderna (or its Affiliates) under this Section 3.4(g)(i)(1) that are in excess of the [***] but less than the amount set forth in the [***] will be (1) [***], or (2) [***]; provided that if Merck does not exercise the Merck Participation Election for the PCV Program, then [***].
- (2) Up to [***] of the Initial PCV POC Program Funding Amount shall be allocated for all Collaboration Activities set forth under the [***]; provided, however, that, in the event that the costs and expenses to be incurred in connection with the performance of such Collaboration Activities under the [***],

[***] shall be solely responsible for and cover any excess costs or expenses up to the amount in the [***]. In the event that the costs and expenses to be incurred in connection with the performance of such Collaboration Activities are reasonably expected to exceed [***], [***] may, at its sole discretion, elect to directly cover any such excess costs or expenses, and [***] shall continue to [***]; provided, further, that if [***] does not elect to provide for additional funding for such Collaboration Activities, the Parties shall use good faith efforts to reach agreement on a reasonable solution with respect to such Collaboration Activities, including the funding thereof and, if the Parties are unable to reach agreement, the [***]. If Merck exercises the Merck Participation Election for the PCV Program, then as of the Merck Participation Election Date at Merck's election, (i) [***] of any of the costs incurred by or on behalf of Moderna (or its Affiliates) under this Section 3.4(g)(i)(2) that are in excess of the [***] but less than the amount set forth in the [***] will be (1) [***], or (2) [***]; provided that if Merck does not exercise the Merck Participation Election for the PCV Program, then [***].

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(3) Up to [***] of the Initial PCV POC Program Funding Amount may be allocated for [***] solely to the extent the costs and expenses of the Collaboration Activities set forth in the POC Plan for the PCV Program attached hereto as of the Amended Effective Date [***] are less than [***]. With respect to such difference up to the [***], the Parties will endeavor to agree in good faith on [***]. However, if the Parties are unable to so agree, then, in accordance with Section 3.3(c), [***].

(ii) Subject to Section 3.4(g)(iii) and Section 3(a) of **Exhibit F**, unless otherwise agreed to by the Parties in writing, costs and expenses incurred in the conduct of the portion of the POC Plan for the PCV Program involving [***] will be borne solely by [***]; provided that, once the Parties mutually agree to commence Development activities involving the [***] under the PCV POC Program, in the event that there are any amounts from the [***] that have not been used or allocated for use in accordance with the POC Plan for the PCV Program, the costs and expenses of such activities shall be funded from such remaining amounts; subject to the following:

(1) Up to [***] of the [***] shall be allocated for Collaboration Activities set forth under the amended POC Plan for the PCV Program (as attached hereto as of the Amended Effective Date) for the portion of the PCV Program involving [***]; provided, however, that, in the event that the costs and expenses to be incurred in connection with the performance of such Collaboration Activities are reasonably expected to exceed the [***], [***] may, at its sole discretion, elect to directly cover any such excess costs or expenses, and [***] shall continue to [***]; provided, further, that if [***] for such Collaboration Activities, the Parties shall use good faith efforts to reach agreement on a reasonable solution with respect to such Collaboration Activities, including the funding thereof and, if the Parties are unable to reach agreement, [***].

(iii) In the event that the Parties mutually agree in writing to amend the POC Plan for the PCV Program for additional activities [***], as part of the amendment to the POC Plan for the PCV Program, the Parties shall also mutually agree in writing on a budget for the conduct of such activities. With respect to such activities, the Parties shall [***]; provided that, with respect to activities related to the [***] shall be responsible for all costs and expenses for such activities up to the [***]. Notwithstanding the foregoing, in the event that there are amounts from the [***], as applicable, that have not been used or allocated for use in accordance with the POC Plan for the PCV Program, then prior to the Parties [***], the costs and expenses of such activities shall be funded from the remaining portions of the [***], as applicable.

Notwithstanding anything to the contrary contained herein, unless otherwise agreed to by the Parties in writing, [***] shall be solely responsible for any and all costs and expenses relating to Research involving the [***] and none of such costs or expenses shall count against the [***].

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(h) Costs for the POC Plans for the Joint SAV Programs.

(i) Subject to Section 3(a) of **Exhibit F**, Section 3.1(e)(ii)(5) and this Section 3.4(h), unless otherwise agreed to by the Parties in writing, each Party shall bear and be responsible for the costs and expenses incurred by or on behalf of such Party (or its Affiliates) in the conduct of each POC Plan for the applicable Joint SAV Program.

(ii) For any Merck Internal SAV Program that converts into a Joint SAV Program in accordance with Section 3.1(d)(v), and for which Moderna conducts IND-Enabling Studies and Merck

subsequently initiates a Clinical Study for a Collaboration SAV Product for such Joint SAV Program, then within [***] days after [***].

- (iii) For any Merck Internal SAV Program that converts into a Joint SAV Program in accordance with Section 3.1(d)(vii), if Merck subsequently exercises the Merck Participation Election for such Joint SAV Program, then an amount equal to [***] of the amount of the costs that are incurred by or on behalf of Merck [***] shall be [***].
- (i) *Records*. Each Party will maintain, or cause to be maintained, records of its activities under each POC Program in sufficient detail and in good scientific manner appropriate for scientific, Patent and regulatory purposes, that will properly reflect all work performed therein, for a period consistent with such Party's record retention policies, but in no event less than required by applicable Laws. Subject to Section 6.1(e), each Party will have the right to reasonably request a copy of the other Party's records for the applicable POC Program upon providing reasonable rationale for needing such records.
- (j) *Reports*. Each Party shall provide to the POC Committee reasonable progress updates at each Calendar Quarter meeting of the POC Committee on the status of the POC Program activities conducted by such Party, including [***]. For clarity, all such reports shall be considered Confidential Information of both Parties. Each Party agrees that it will also provide updates from time to time between such meetings as the other Party may reasonably request.
 - (k) Regulatory Matters. For a given POC Program, during the applicable POC Term:
- (i) The POC Lead Regulatory Party shall be primarily responsible for regulatory matters with respect to the Collaboration Products in connection with the performance of the applicable POC Program. The POC Lead Regulatory Party shall ensure that all directions from any Regulatory Authority, ethics committees or institutional review boards with jurisdiction over any Clinical Studies are followed. Further, the POC Lead Regulatory Party shall ensure that all necessary approvals, licenses, registrations or authorizations (including any IND or CTA) from any Regulatory Authority, ethics committees or institutional review boards with jurisdiction over the Clinical Study are obtained prior to initiating performance of such Clinical Study.
- (ii) Subject to POC Committee oversight on the overall regulatory strategy for the Collaboration Products, including oversight of the initial IND or CTA filings for a given Collaboration Product, the POC Lead Regulatory Party shall have primary responsibility with respect to submitting Regulatory Filings for the applicable Collaboration Products (other than DMFs) and all communications with, and submissions to, Regulatory Authorities in connection with such Collaboration Products, with the other Party's support and input, which

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support shall be provided by the other Party upon reasonable request by the POC Lead Regulatory Party [***]. The POC Lead Regulatory Party shall also be responsible for all routine maintenance of all INDs or CTAs (other than DMFs) for the applicable Collaboration Products. Without limiting the foregoing, Moderna shall provide such information and assistance as Merck may reasonably request in connection with the completion of and submission of, and maintenance of, Regulatory Filings (other than DMFs), including INDs and CTAs, and responses to inquiries from Regulatory Authorities, provided that (A) to the extent Moderna CMC Information is [***] or (B) in the event disclosure of Moderna CMC Information [***], Merck will notify Moderna [***], provided further that in the event that the Parties are unable to agree [***], then such matter shall be referred to the Executive Officers (or their designees), and if the Executive Officers (or their designees) are unable to agree on such course of action within such time frame, then [***]. In the event additional Moderna CMC Information not currently contained within regulatory documents [***], the Parties shall mutually agree [***]. Moderna will be reasonable [***].

(iii) If Moderna is the POC Lead Regulatory Party for any Clinical Studies involving Keytruda, Moderna shall act as the sponsor of such Clinical Study under its existing IND or CTA for the applicable Collaboration Product and have a Right of Reference to the IND or CTA of Keytruda; provided, however, that in no event shall Moderna file an additional IND or CTA for any Clinical Study involving Keytruda unless required by Regulatory Authorities to do so. If a Regulatory Authority requests an additional IND or CTA for a Clinical Study involving Keytruda, the Parties shall meet and mutually agree on an approach to address such requirement. Merck shall provide reasonable support and input to enable Moderna to prepare and file an amendment solely to the extent required.

(iv) The POC Lead Regulatory Party shall, subject to applicable Law, (1) allow subject matter experts from the other Party to [***], (2) through the POC Committee, allow the other Party a reasonable opportunity to review and comment upon all material Regulatory Filings (other than DMFs or portions of such Regulatory Filings containing Moderna CMC Information) to Regulatory Authorities for the applicable Collaboration Products, and the POC Lead Regulatory Party [***], (3) [***], and (4) promptly provide to individuals in the other Party's regulatory group copies of any material correspondence or other documents received from Regulatory Authorities with respect to the applicable Collaboration Products. In all cases, Merck shall have the right (but not the obligation) to participate in any discussions with a Regulatory Authority regarding matters related to Keytruda or any Merck Agent. In all cases, Moderna shall have the right (but not the obligation) to participate in any discussions with a Regulatory Authority regarding matters related to [***].

(v) If Moderna is the POC Lead Regulatory Party for any Clinical Studies involving Keytruda, Merck shall provide to Moderna, as necessary, a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the Right of Reference for Keytruda. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to a Moderna Agent, Merck Agent or Keytruda, as applicable. Merck shall authorize the FDA and other applicable Regulatory Authorities to cross-reference the applicable Merck INDs and CTAs for Keytruda to provide data access to Moderna sufficient to support conduct of any Clinical Study sponsored by Moderna involving Keytruda. If Merck's IND or CTA is not available in a given country, Merck will file its CMC data with the applicable Regulatory Authority for such country, referencing Moderna's IND or CTA as appropriate (however, Moderna shall have no right to directly access the CMC data for Keytruda).

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(vi) If Moderna is the POC Lead Regulatory Party for any Clinical Studies involving Keytruda, Moderna shall (a) track and collect financial disclosure information from all "clinical investigators" involved in any Clinical Studies involving Keytruda and (b) prepare and submit the certification or disclosure of the same in accordance with all applicable Law, including Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. Prior to the initiation of clinical activities under any Clinical Study sponsored by Moderna involving Keytruda, the Parties shall determine, in writing, whether Moderna shall track and collect separate certification or disclosure forms for each of Merck and Moderna or one (1) "combined" certification or disclosure form for both Merck and Moderna. For purposes of this Section 3.4(k)(vi), the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

(vii) With respect to any annual reporting period in which Moderna is not an entity that is required to make a Transparency Report under applicable Law, Moderna will: (a) notify Merck, in writing, within [***] days after the commencement of such reporting period that Moderna is not so required; and (b) during such reporting period Moderna will track and provide to Merck data regarding "indirect" payments or other transfers of value by Moderna to such health care professionals to the extent such payments or other transfers of value were required, instructed, directed or otherwise caused by Merck pursuant to this Agreement in the format requested by Merck and provided on a basis to be agreed upon by both Parties. Moderna represents and warrants that any data provided by Moderna to Merck pursuant to part (b) above will be complete and accurate to the best of Moderna's knowledge. With respect to any such annual reporting period in which Moderna is required to make a Transparency Report under applicable Law, Moderna will provide to Merck, in writing, Moderna's point of contact for purposes of receiving information from Merck pursuant to this Section 3.4(k)(vii), along with such contact's full name, email address, and telephone number. Moderna may update such contact from time to time by notifying Merck in writing pursuant to Section 15.15. Where applicable, Merck will provide to such Moderna contact all information regarding [***] provided for use in a Clinical Study required for such reporting. In the event that the [***] provided pursuant to this Section 3.4(k)(vii) changes, Merck shall notify Moderna of such revised value and the effective date thereof. For purposes of this Section 3.4(k)(vii), "Transparency Report" means a transparency report in connection with reporting payments and other transfers of value made to health care professionals, including investigators, steering committee members, data monitoring committee members, and consultants in connection with a Clinical Study in accordance with reporting requirements under applicable Law, including the Physician Payment Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, or a Party's applicable policies.

(viii) Moderna shall be responsible for filing all DMFs for Collaboration Products during the POC Term and in connection therewith the provisions of Section 7.2(b) shall apply *mutatis mutandis*.

(1) Ownership of Regulatory Filings.

- (i) For a given POC Program, the POC Lead Regulatory Party or its Affiliates shall own, maintain, file and hold in its name, all Regulatory Filings (other than DMFs), including INDs or CTAs, for the applicable Collaboration Products. The POC Lead Regulatory Party shall provide the POC Committee with regular updates regarding the status of Regulatory Filings and correspondences for the applicable Collaboration Products, and such Regulatory Filings and correspondences shall be reviewed by the POC Committee. If Merck pays the Participation Election Payment for a given Program, Moderna shall assign and transfer ownership of all relevant INDs or CTAs and Regulatory Filings (other than DMFs) then held by Moderna (or any of its Affiliates) for Collaboration Products for such Program to Merck in accordance with Section 4.3(b).
- (ii) The Parties agree and acknowledge that Moderna has filed an IND for a Clinical Study for mRNA-5671 under the KRAS Program prior to the Amended Effective Date, and such IND shall be transferred to Merck in accordance with the KRAS Transition Plan. Notwithstanding the foregoing, in all cases, [***].
- (1) In addition to the provisions of Section 12 and other provisions of this Agreement regarding treatment of Moderna CMC Information, Merck recognizes that maintaining the confidentiality of [***], requires a higher level of vigilance than certain other Confidential Information, and agrees to (x) maintain in confidence the [***] with the same degree of care that Merck uses to protect its own like sensitive information and (y) without limiting Section 3.4(k)(ii), strictly limit the use and disclosure of any such [***] solely for the purpose of preparing, filing and maintaining Regulatory Filings and maintaining Regulatory Approvals and related quality purposes with respect to the applicable Collaboration Product and no other purpose.
- (m) Adverse Event Reporting. For a given POC Program, during the applicable POC Term, the POC Lead Regulatory Party shall be responsible for maintaining the global safety database for the Collaboration Products from such POC Program and reporting all Adverse Events related to the clinical activities under such POC Program to the appropriate Regulatory Authorities in the countries in which the applicable Collaboration Products are being Developed, in accordance with the applicable Laws of the relevant countries and Regulatory Authorities. Without limiting the foregoing, upon the other Party's request, and for the PCV Program if Merck exercises the Merck Participation Election for the PCV Program, in all cases prior to IND/CTA transfer, the POC Lead Regulatory Party shall provide copies of any Serious Adverse Event and applicable non-serious Adverse Event reports with respect to any Collaboration Products from such Program and any details related thereto in accordance with Section 4.3(b)(ii). Within [***] days prior to the Commencement of any Clinical Studies for any Collaboration Products during the applicable POC Term, the Parties will execute a pharmacovigilance agreement or update to the current pharmacovigilance agreement ("POC Pharmacovigilance Agreement") to ensure the exchange of relevant safety data within appropriate timeframes and in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The POC Pharmacovigilance Agreement will include [***]. Such guidelines and procedures shall be in accordance with, and enable the Parties and their respective Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities. [***]

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(i) [***]

(ii) [***]

(n) Sample Testing.

- (i) For the PCV Program, Moderna shall provide samples of biological material collected from subjects participating in a Clinical Study performed under the POC Plan for the PCV Program, including blood and/or tissue samples, to Merck as specified in the applicable protocol or as agreed to by the POC Committee.
- (ii) For a given Program, the Parties shall conduct testing on such samples in accordance with the Data Sharing and Sample Testing Schedule (if set forth in the applicable POC Plan) and the applicable protocol. Solely to the extent intended to be shared between the Parties, as specified on the Data Sharing and

Sample Testing Schedule in the applicable POC Plan, the Party conducting the sample testing shall provide to the other Party the results of such sample testing in electronic form, or other mutually agreeable alternate form, on the timelines specified in the Data Sharing and Sample Testing Schedule or as otherwise mutually agreed. [***]

3.5 Merck Participation Election Rights.

- (a) *POC Data Package*. Promptly following the expiration of the POC Term for a given SAV POC Program, Merck will provide Moderna with the information listed in [***] of the definition of POC Data Package in Section 1.314 for such SAV POC Program that is generated by or on behalf of Merck or its Affiliates in the course of conducting Collaboration Activities for such SAV POC Program. In addition, in no event more than [***] days following the earlier of (x) the completion of the Collaboration Activities set forth in the POC Plan for such POC Program and (y) the expiration of the POC Term for such POC Program, Moderna shall provide the POC Data Package for such Program to Merck; provided, however, (A) to the extent Merck has [***] (B) with respect to the PCV Program, to the extent the Parties do not mutually agree to undertake Development activities set forth in the POC Plan for the PCV Program involving the [***] pursuant to Section 3.1(a), Moderna shall not be required to include any information regarding [***] in the POC Data Package. After the delivery of the POC Data Package and for the remainder of the Merck Participation Election Period for the applicable Program, Moderna shall, as reasonably requested by Merck, meet with Merck to discuss such POC Data Package and any questions of Merck with respect thereto, including [***].
- (b) Grant of Merck Participation Election. On a Program-by-Program basis, Moderna hereby grants to Merck during the Merck Participation Election Period for a given Program the exclusive right, exercisable at Merck's sole discretion, to continue, in collaboration with Moderna, the Research, Development, Manufacture and Commercialization of mRNA Cancer Vaccines (including Collaboration Products) for such Program, and to exercise the licenses set forth in Section 10.1(c) with respect to such mRNA Cancer Vaccines (including Collaboration Products) for such Program, in each case, solely under the terms and conditions set forth in this Agreement (each, a "Merck Participation Election").

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- (c) Merck Participation Election Period, Participation Election. On a Program-by-Program basis, Merck may elect to exercise the Merck Participation Election for a given Program by delivering to Moderna written notice of exercise at any time during the Merck Participation Election Period for such Program (each, a "Merck Participation Election Notice"). Commencing on the Merck Participation Election Date for a given Program, the Parties shall engage in the Joint Development Program for such Program in accordance with Section 4. For the avoidance of doubt, Merck may deliver the Merck Participation Election Notice for one or more Programs (or no Programs) at its discretion, and such determination may be made by Merck on a Program-by-Program basis.
- (d) *Net Residual Amount*. Following the Merck Participation Election for the PCV Program, the Net Residual Amount (if any) will be fully committed towards future Shared Collaboration Costs incurred by or on behalf of the Parties (or their Affiliates) during the Merck Participation Term for the PCV Program; provided, however, that notwithstanding the foregoing, if Merck exercises the Merck Participation Election for the PCV Program prior to the completion of the activities set forth in the then-current POC Plan for the PCV Program, within [***] days after the Merck Participation Election Date for the PCV Program, Moderna will provide Merck with [***] and, unless the Parties otherwise agree, such Net Residual Amount will be fully committed towards [***], and the remainder shall be fully committed towards future Shared Collaboration Costs for the PCV Program incurred by or on behalf of the Parties (or their Affiliates) during the Merck Participation Term for the PCV Program.
- 3.6 [***] Notwithstanding anything herein to the contrary, in the event that the [***] is incorporated [***] in a given Program, the following terms and conditions of this Agreement as they apply to [***] as incorporated [***] for such Program will be modified as follows:

3.7 Non-Exercise of Merck Participation Election.

- (a) Effects. For a given Program (other than for an Internal SAV Program), if:
- (i) Merck does not exercise the Merck Participation Election for such Program during the Merck Participation Election Period for such Program;

- (ii) [***]
- (iii) [***]
- (iv) [***], a "Merck Non-Participation"), then:
- (A) if for the PCV Program, the Merck Participation Election Period, the POC Term, the Collaboration Term and the Collaboration shall terminate solely for the PCV Program, and all Collaboration PCV Products then in existence will be treated as "PCVs" under this Agreement thereafter (other than for purposes of this Section 3.7(a)); provided that [***];
- (B) if for a Joint SAV Program, the Merck Participation Election Period, the POC Term, the Collaboration Term and the Collaboration shall terminate solely for such Joint SAV Program and all Collaboration SAV Products then in existence from such Program will be treated as "SAVs" under this Agreement thereafter (other than for purposes of this Section 3.7(a));
- (C) Merck shall no longer have any licenses or other rights under this Agreement (except [***]) to Research, Develop, Manufacture and Commercialize any Collaboration Products from such Program under this Agreement;
 - (D) Sections 10.7 and 10.8 shall terminate with respect to such Program [***];
- (E) (I) If Merck had initiated activities to conduct a Clinical Study under the applicable Joint SAV Program, Merck will prepare and provide to Moderna [***].
- (II) If Merck had Commenced a Clinical Study under the applicable Joint SAV Program [***];
 - (F)[***];
 - (G)[***];

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(H) Moderna will make the payments set forth in Section 9.2 and **Exhibit E** in connection with (1) Moderna Net Profits allocated to sales of any Financial PCVs, or (2) Moderna Net Profits allocated to sales of any Financial SAVs up to an aggregate amount equal to [***];

- (I) [***]
- (J) [***]; and
- (K) in all cases, if Moderna is conducting a Clinical Study involving Keytruda, the provisions of Section 3.4(m) shall apply *mutatis mutandis*. For purposes of clause (H)(2) of this Section 3.7, within [***] after the date of the Merck Non-Participation for a given Joint SAV Program, Merck shall provide to Moderna [***]. Additionally, in the event of a Merck Non-Participation for the PCV Program, then subject to the remainder of this Section 3.7, during [***] period following the effective date of the Merck Non-Participation for the PCV Program, [***].

[***]

In the event that Merck exercises the Merck Non-Participation with respect to a Joint SAV Program before the date of [***], then (1) Merck shall, [***].

In addition, the Parties' rights and obligations under [***] shall terminate in full with respect to such Program [***]. In addition, on a Program-by-Program basis, if, as of the date of the Merck Non-Participation for such Program, a Party is granting a sublicense to the other Party under an Included In-License for such Program, and such sublicense under such Included In-License survives the Merck Non-Participation for such Program pursuant to this Section 3.7(a), then, (i) the Party receiving such sublicense under such Included In-License shall [***] and (ii) such Party's rights under such Included In-License will be subject to the terms of such Included In-License; provided that in each case of (i) and (ii), the licensor Party promptly informs the other Party of any [***].

(b) Remaining Activities under the POC Plan for the PCV Program. If (i) Merck exercises the Merck Non-Participation for the PCV Program and (ii) the activities set forth in the then-current POC Plan for

the PCV Program are not completed prior to the expiration or termination of the PCV POC Term, then Moderna will retain the Net Residual Amount (if any) and will use the Net Residual Amount for the continued Research, Development, Manufacture or Commercialization of PCVs (including any Collaboration PCV Products then in existence).

4. ADDITIONAL RESEARCH PROGRAM AND JOINT DEVELOPMENT PROGRAM

4.1 Overview.

(a) *General*. If Merck exercises the Merck Participation Election for a given Program, during the Merck Participation Term for such Program, the Parties shall mutually conduct a Research and Development program with the goal of furthering the Research and Development of mRNA Cancer Vaccines (including Collaboration Products) for such Program and conducting Clinical Studies with the goal of obtaining Regulatory Approvals for one or more Collaboration Products for such Program all subject to and in accordance with this Agreement.

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(b) Additional Research Programs. During the Merck Participation Term for a given Program, the Parties may conduct one or more Additional Research Programs focused on advancing the Research and Manufacturing of mRNA Cancer Vaccines (including Collaboration Products) for such Program, subject to and in accordance with the terms of this Agreement and the applicable Additional Research Plan (each, an "Additional Research Program").

(c) Clinical Studies.

(i) During the Merck Participation Term for a given Program, the Parties shall conduct Clinical Studies of Collaboration Products from such Program either as a monotherapy or in combination with Other Components, including as a part of clinical development partnerships with Third Parties by either Party or its Affiliates, subject to and in compliance with this Agreement (including the exclusivity provisions hereunder) and the applicable Joint Development Plan and Budget for the applicable Program (the "Joint Development Program" for such Program), as well as Independent Additional Studies for such Program pursuant to Section 4.4 in compliance with this Agreement (including the exclusivity provisions hereunder). In all cases, the Merck Participation Term Lead Regulatory Party shall have the right to cease or suspend the conduct of a given Clinical Study if the Merck Participation Term Lead Regulatory Party reasonably believes there is a Safety Issue.

(ii) If the Merck Participation Term Lead Regulatory Party suspends the conduct of a Clinical Study for a given Joint SAV Program as a result of a Safety Issue, then the Merck Participation Term Lead Regulatory Party shall provide immediate (and in any event within [***] Business Days of the determination by the Lead Regulatory Party of such Safety Issue) written notice to the other Party of such determination, and the Parties will discuss in good faith whether to initiate a new Joint Development Plan and Budget to resolve the Safety Issue for such Joint SAV Program. If the Parties mutually agree upon a new Joint Development Plan and Budget for such Joint SAV Program, then the Parties will perform the Collaboration Activities (including any nonclinical studies or Clinical Studies) under the new Joint Development Plan and Budget for such Joint SAV Program in accordance with this Agreement. If the Merck Participation Term Lead Regulatory Party provides written notice of a Safety Issue for such Joint SAV Program, and as a result thereof the Parties do not recommence Collaboration Activities to resolve the Safety Issue under such Joint Development Plan and Budget (or amended Joint Development Plan and Budget) for a period of [***], then upon the expiration of such [***] period, then Merck will be deemed to have exercised the Merck Cessation Election for such Joint SAV Program pursuant to Section 10.10. For clarity, if Merck proposes a reasonable Joint Development Plan and Budget to resolve such Safety Issue within such [***] period, (A) Moderna shall [***] and (B) the preparation and initiation of activities under such Joint Development Plan and Budget shall be deemed [***].

- (a) General. During the Merck Participation Term for a given Program, in the event that a Party proposes to conduct an Additional Research Program for such Program, then such Party shall propose the Additional Research Program to the JSC and such Party will prepare an Additional Research Plan for such Additional Research Program, setting forth such activities and budget therefor and, solely to the extent the Parties mutually agree and approve such Additional Research Plan, [***], the Parties shall conduct such Additional Research Program in accordance with the terms of this Agreement and such Additional Research Plan. All costs and expenses incurred by or on behalf of the Parties (or their Affiliates) in connection with the conduct of any Additional Research Program(s) shall be considered Allowable Development Costs. The Parties acknowledge and agree that Research activities under an Additional Research Plan may be [***].
- (b) Additional Research Plans. Either Party may propose at any meeting of the JSC amendments to any Additional Research Plan. Notwithstanding the foregoing, at a minimum, no later than [***] days prior to the start of a given Calendar Year, the Parties shall propose an updated budget for any ongoing studies or Manufacturing activities under any then-current Additional Research Plans for the Additional Research Programs for the upcoming Calendar Year for the JDC's review and JSC's approval. Additional Research Plans that incorporate Manufacturing activities (e.g., process development) for Collaboration Products should also be presented to the JMC for review and comment.
- (c) Efforts. The Parties will conduct each Additional Research Program on the terms and conditions set forth in this Agreement, under the oversight of the JDC, JSC, and JMC, as applicable, and in accordance with the applicable Additional Research Plan. Each Party shall use its respective Commercially Reasonable Efforts to perform the activities allocated to it pursuant to the applicable Additional Research Plan for a given Additional Research Program in accordance with the terms of this Agreement and within the timelines set forth in such Additional Research Plan, and to achieve the goals and deliverables set forth in such Additional Research Plan. Subject to the foregoing and the terms and conditions of this Agreement (including compliance with the applicable Additional Research Plan), each Party (and not the Joint Steering Committee) shall be responsible for managing its own Research and Manufacturing efforts within the scope of the activities allocated to it pursuant to the applicable Additional Research Plan for a given Additional Research Program and for making decisions with respect to its day-to-day conduct in support of such Research and Manufacturing efforts in connection therewith.

4.3 Joint Development Program.

(a) General. During the Merck Participation Term for a given Program, it is the expectation of the Parties that (i) Merck will be the Party solely responsible for conducting the clinical Development activities for the Collaboration Products under the Joint Development Plan and Budget for the applicable Program, (ii) with respect to the PCV Program, each Party will be solely responsible for conducting an Independent Additional Study proposed by such Party under the applicable Independent Additional Study Development Plan, (iii) with respect to a given Joint SAV Program, [***], (iv) subject to Section 6.2, Moderna will be responsible for conducting Manufacturing activities, including [***], under the Joint Development Plan and Budget for the applicable Program, and (v) Merck will be primarily responsible for pre-approval Commercialization activities (all subject to Section 8), in each case, unless the Parties otherwise agree.

- (b) Development Transition Plan. Promptly following the Merck Participation Election Date for a given Program, Moderna will prepare and provide to Merck a draft plan for the transition of any Development activities then being conducted by or on behalf of Moderna or its Affiliates from Moderna to Merck for such Program (including with respect to the PCV Program, Clinical Studies for Collaboration PCV Products) (a "Development Transition Plan"), which Development Transition Plan will be reviewed by the JDC and subject to the approval of the JSC. If and to the extent applicable, the Development Transition Plan will require Moderna to perform the following activities (provided that, for clarity, the Development Transition Plan shall not include any obligations for Moderna to provide to Merck any information or materials previously provided to Merck or to re-perform any activities that have already been transitioned to Merck), on the timeline set forth in the Development Transition Plan:
 - (i) transfer and assign to Merck or its designee [***];
 - (ii) transfer to Merck [***];
 - (iii) deliver to Merck copies of all [***];

(iv) (A) with respect to the PCV Program, to the extent it is determined pursuant to [***] that [***] should be [***], at Merck's request, reasonably assist Merck in [***] and (B) with respect to each Joint SAV Program, to the extent it is determined pursuant to [***] that [***] should be [***], at Merck's request, reasonably assist Merck in [***]; and

(v) deliver to Merck, in an electronic format (the form of which shall be agreed upon by the Parties), [***].

Each Party will use Commercially Reasonable Efforts to perform the obligations assigned to it under the Development Transition Plan in accordance with the timelines set forth therein. All costs and expenses incurred by or on behalf of the Parties (or their Affiliates) in connection with the conduct of the Development Transition Plan shall be considered Allowable Development Costs.

(c) Joint Development Plans.

(i) Within (x) [***] days after the Merck Participation Election Date for the PCV Program, or (y) subject to the last sentence of this Section 4.3(c)(i), [***] days after the date of the Merck Participation Election Notice for a given Joint SAV Program, the Parties shall agree on the Collaboration Activities of the Parties with respect to the applicable Joint Development Program and set forth such activities and a [***] year rolling budget therefor (such budget to be on a study-by-study or activity-by-activity basis) in a joint development plan (each, a "Joint Development Plan and Budget"), the initial draft of which shall be prepared by [***]. The purpose of the Joint Development Plan and Budget for the applicable Program is to set forth the specific Development activities to be performed by the Parties in support of such Joint Development Program, [***]. Each Joint Development Plan and Budget for the applicable Program shall set forth activities that are similar in nature to those contained in the applicable POC Plan. Notwithstanding anything herein to the contrary, if the Parties fail to mutually agree on a Joint Development Plan and Budget for a given Joint SAV Program within [***] days after

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the date of the Merck Participation Election Notice for such Joint SAV Program, then Moderna shall deliver written notice (together with an invoice) to Merck that the SAV Participation Election Payment for such Joint SAV Program is due and either (1) Merck may pay the SAV Participation Election Payment for such Joint SAV Program within [***] Business Days after receipt of such notice, and the Parties will continue to diligently work to mutually agree on a Joint Development Plan and Budget for such Joint SAV Program, or (2) if Merck does not make such payment under clause (1), then [***].

- (ii) Either Party may propose at any meeting of the JDC amendments to the Joint Development Plan and Budget for the applicable Program; provided, however, if such amendments involve an Additional Study or series of related Additional Studies, the inclusion of such Additional Study(ies) shall be in accordance with Section 4.4. Notwithstanding the foregoing, at a minimum, no later than [***] days prior to the start of a Calendar Year, the Parties shall propose an updated budget for any ongoing studies or activities under the then-current Joint Development Plan and Budget for the applicable Joint Development Program for the upcoming Calendar Year for the JDC's review and JSC's approval.
- (iii) The Parties have agreed to engage in the Joint Development Programs on the terms and conditions set forth in this Agreement, under the oversight of the JDC and JSC and in accordance with the applicable Development Plans. Each Party shall use its respective Commercially Reasonable Efforts to perform the activities allocated to it pursuant to the Development Plans [***] in accordance with the terms of this Agreement and within the timelines set forth in the Development Plans and [***], respectively, and to achieve the goals and deliverables set forth in the Development Plans and [***]. Subject to the foregoing and the terms and conditions of this Agreement (including compliance with the Development Plans and [***] and any applicable Clinical Supply Agreement), each Party (and not the JSC) shall be responsible for managing its own Development and Manufacturing efforts within the scope of the activities allocated to it pursuant to the Development Plans and [***] and for making decisions with respect to its day-to-day conduct in support of such Development efforts.

4.4 Additional Studies.

(a) Proposal of Additional Studies.

(i) To the extent that either Party wishes to conduct an Additional Study or related series of Additional Studies of a Collaboration Product (f^{***}) that is not set forth in the Joint Development Plan and

Budget for the applicable Program for the purpose of seeking Regulatory Approval for such Collaboration Product, such Party shall prepare a [***] year rolling Development plan and budget for such Additional Study(ies) and propose such Additional Study(ies) to the JDC. Such proposed Development plan and budget shall identify the applicable Collaboration Product, [***] (an "Additional Study Proposal"). Following receipt of the Additional Study Proposal from the proposing Party, the non-proposing Party shall have [***] days to decide whether or not to co-fund such Additional Study, and if such non-proposing Party elects to so co-fund, then such Additional Study will be considered a "Joint Development Study", and the Parties shall amend and update the Joint Development Plan and Budget for the applicable Program to include such Additional Study as a Joint Development Study as part of the Joint Development Program.

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- (ii) If the non-proposing Party fails to elect to co-fund a proposed Additional Study within such [***] day period, then (1) with respect to such proposed Additional Study for the PCV Program, [***] (2) with respect to a proposed Additional Study for a Joint SAV Program, [***], may independently conduct such Additional Study (an "Independent Additional Study") subject to the terms and conditions of this Section 4.4 and in accordance with such Additional Study Proposal (thereafter, an "Independent Additional Study Development Plan"); provided, however, that if (A) the Independent Additional Study would involve a Collaboration Product in combination with a Moderna Agent when Moderna is the non-proposing Party or a Merck Agent [***] when Merck is the non-proposing Party, then [***], or (B) the non-proposing Party reasonably and in good faith believes that [***], then the proposing Party shall [***].
- (b) *Costs*. The Party sponsoring or conducting an Independent Additional Study under an Independent Additional Study Development Plan shall be responsible for [***], in connection with such Independent Additional Study(ies) and such costs shall be borne in accordance with this Section 4.4 and **Exhibit D**.
- (c) *Recording of Costs*. All Development Costs pursuant to this Section 4.4 shall be recorded and reported consistent with **Exhibit D**. Each Party shall keep records associated with Development Costs incurred through performance of an Independent Additional Study Development Plan strictly separate from records associated with Development Costs incurred through performance of the applicable Joint Development Program.

4.5 Records, Reports, Resources.

- (a) *Personnel and Resources*. Each Party shall dedicate to the Additional Research Programs, Joint Development Programs and Independent Additional Studies (as applicable) appropriate resources and allocate personnel with an appropriate level of education, experience and training in Researching and Developing mRNA Cancer Vaccines (including Collaboration Products) for such Programs in order to achieve the objectives of the Additional Research Programs, Joint Development Programs and Independent Additional Studies (as applicable) efficiently and expeditiously, which resources and personnel shall be consistent with the Additional Research Plans or Development Plans (as applicable).
- (b) Research and Development Costs. Development Costs incurred in the conduct of the Additional Research Programs and Joint Development Programs will be borne in accordance with **Exhibit D**. Development Costs incurred in the conduct of the Independent Additional Study Development Plan(s) (as applicable) will be borne in accordance with **Exhibit D**.
- (c) *Records*. Each Party will maintain, or cause to be maintained, records of its activities under the Additional Research Programs, Joint Development Programs and Independent Additional Studies (as applicable) in sufficient detail and in good scientific manner appropriate for scientific, Patent and regulatory purposes, that will properly reflect all work performed therein, for a period consistent with such Party's record retention policies, but in no event less than required by applicable Laws. Each Party will have the right to reasonably request a copy of any such records upon providing reasonable rationale for needing such records; provided, however, Moderna shall have no right to directly access the CMC data for [***], and Merck shall have no right to directly access the CMC data for [***].

applicable) during the prior Calendar Quarter, which summary report shall include [***]. Each Party agrees that it will promptly respond to the other Party's reasonable questions regarding any of the other Party's reports. For clarity, all such reports shall be considered Confidential Information of each Party. Each Party shall also provide updates from time —to -time between such meetings as the other Party may reasonably request.

5. COMPLIANCE

5.1 General. Each Party shall conduct the Internal SAV Programs, POC Programs, Additional Research Programs, Joint Development Programs and Independent Additional Studies and other activities under the Internal SAV Program Plans, POC Plans, Additional Research Plans, Joint Development Plan and Budget for the applicable Program or Independent Additional Study Development Plans in compliance with all applicable Laws. Each Party shall promptly notify the other Party in writing of any deviations from applicable Laws, including, each if and to the extent applicable to the respective Party or its activities hereunder, the Act, the Anti-Kickback Statute (42 U.S.C. §1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. §1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA. In addition, each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any person debarred under United States law, including Section 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the Internal SAV Programs, POC Programs, Additional Research Programs, Joint Development Programs or Independent Additional Studies or other activities under the Internal SAV Program Plans, POC Plans, Additional Research Plans, Joint Development Plan and Budget for the applicable Program or Independent Additional Study Development Plans. Each Party shall notify the other Party in writing immediately if any such debarment occurs or comes to its attention, and shall, with respect to any person or entity so debarred promptly remove such person or entity from performing activities under the Internal SAV Programs, POC Programs, Additional Research Programs, Joint Development Program or Independent Additional Studies or other activities under the Internal SAV Program Plans, POC Plans, Additional Research Plans, Joint Development Plan and Budget for the applicable Program or Independent Additional Study Development Plans, function or capacity related thereto. Without limiting the foregoing, if animals are used in Research hereunder, the applicable Party will comply with the Animal Welfare Act and any other applicable Laws relating to the care and use of laboratory animals. Merck encourages Moderna to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care and treatment of such research animals. Any animals which are used in the course of the Internal SAV Programs, POC Programs, Additional Research Programs, Joint Development Programs or Independent Additional Studies or other activities under the Internal SAV Program Plans, POC Plans, Additional Research Plans, Joint Development Plan and Budget for the applicable Program or Independent Additional Study Development Plans, or products derived from those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes.

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5.2 <u>Use of Human Materials</u>. Without limiting the provisions of Section 5.1, if any human cell lines, tissue, human clinical isolates or similar human-derived materials ("<u>Human Materials</u>") are to be collected or used in the Internal SAV Programs, POC Programs, Additional Research Programs, Joint Development Program or Independent Additional Studies and other activities under the Internal SAV Program Plans, POC Plans, Additional Research Plans, Joint Development Plan and Budget for the applicable Program and Independent Additional Study Development Plans, the applicable Party represents and warrants (i) that it shall comply, with all applicable Laws relating to the collection and/or use of the Human Materials and (ii) that it has obtained or shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection or use of such Human Materials. Each Party shall provide documentation of such approvals and consents upon the other Party's request. The applicable Party further represents and warrants that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities ("<u>Providers</u>") who contributed the Human Materials, including any obligations of compensation to such Providers or any other Third Party for the intellectual property associated with, or commercial use of, the Human Materials for any purpose.

5.3 <u>Compliance with Corporate Policy</u>. Each Party acknowledges that the other Party's corporate policies require that business must be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the activities contemplated herein in a manner which is consistent with both law and good business ethics. Consistent with the 'Compliance Program Guidance for Pharmaceutical Manufacturers'

published by the Office of Inspector General, U.S. Department of Health and Human Services, each Party agrees to maintain a compliance program and policies and adequate internal audit program with respect to its detailing and other Commercialization activities in the United States pursuant to this Agreement containing all the elements described in such guidance document, as well as completing any required reporting to any Regulatory Authority. Each Party shall, promptly following the Effective Date, have in place and enforce, and at all times during the Term thereafter will have in place and will enforce, for its (and its Affiliates) employees, a code of conduct and compliance program, including as provided under each Party's respective corporate policies.

5.4 <u>Business Partner Code of Conduct</u>. Each Party endeavors to hold itself and its business partners to the highest performance, ethical and compliance standards, including basic human rights, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. In performing its duties under this Agreement, each Party acknowledges the value and importance of performance and ethical behavior in its performance under this Agreement. Without limiting any of Moderna's other obligations hereunder, Merck expects that Moderna will abide by the letter and spirit of Merck's Supplier Performance Expectations and Business Partner Code of Conduct (the "Code"), a copy of which is available at http://www.merck.com/about/how-we-operate/code-of-conduct/values.html, in its performance of this Agreement. Moderna is also expected to follow the Pharmaceutical Supply Chain Initiative (PSCI) principles, a copy of which is available at http://www.pharmaceuticalsupplychain.org/. In the event of a conflict or inconsistency between the Code and the express terms of this Agreement, this Agreement shall govern and prevail.

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- 5.5 Governments and International Public Organizations. Without limitation of the foregoing, each Party warrants that none of its employees, agents, officers or other members of its management are officials, officers, agents, representatives of any government or international public organization. Each Party agrees that it shall not make any payment, either directly or indirectly, of money or other assets, including the compensation derived from this Agreement (hereinafter collectively referred as a "Payment"), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "Officials") where such Payment would constitute a violation of any Law. In addition, regardless of legality, no Party shall make any Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of a Party's businesses.
- 5.6 No Authority. Each Party acknowledges that no employee of the other Party or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by such Party or its agents to any Third Party in violation of terms of this or any other provisions of this Agreement.
- 5.7 Exclusions Lists. Each Party certifies to the other Party that, as of the Effective Date and the Amended Effective Date, such Party has screened itself, and its officers and directors, against the Exclusions Lists and that it has informed the other Party whether such Party, or any of its officers or directors has been in Violation. After the execution of this Agreement, each Party shall notify the other Party in writing immediately if any Violation occurs or comes to its attention, and shall, with respect to any person or entity in Violation, promptly remove such person or entity from performing any Internal SAV Programs, POC Program, Joint Development Program, or and other activities hereunder, function or capacity related thereto.

6. MANUFACTURING AND SUPPLY

6.1 During POC Program.

(a) mRNA Cancer Vaccines and Collaboration Products. To the extent supply of mRNA Cancer Vaccines (including Collaboration Products) or mRNA Constructs (formulated or unformulated) is required to perform the activities under a POC Plan for a given Program, Moderna shall be solely responsible (except as set forth in the applicable POC Plan, Exhibit K, or as otherwise mutually agreed to by the Parties in writing) for Manufacturing such mRNA Cancer Vaccines (including Collaboration Products) or mRNA Constructs (formulated or unformulated) in accordance with such POC Plan for such Program and this Agreement and the supply terms set forth in Exhibit K or pursuant to Section 10.13, as applicable.

(b) *Keytruda*. To the extent supply of Keytruda is required to perform the Clinical Studies under a POC Plan for a given Program, Merck shall be solely responsible for supplying such requirements of Keytruda in accordance with such POC Plan for such Program, this Agreement and the supply terms set forth in **Exhibit K**.

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- (c) *Manufacturing Capabilities*. Pursuant to the POC Plan for a given Program [***], Moderna will [***] to establish [***] for use as part of such POC Plan (and the Development Plans, if applicable) for such Program, which will include [***], in accordance with the Development Plans (or POC Plans, if applicable) and this Agreement. [***]
 - (d) Inspections by Merck During POC Term.
- (i) During the SAV POC Term, to the extent Merck has not already conducted a quality audit and an EHS audit of the Collaboration SAV Manufacturing Facility(ies) identified by Moderna pursuant to Section 6.1(c) in the preceding [***] period, Merck shall have a reasonable opportunity to conduct a quality audit and EHS audit of such Collaboration SAV Manufacturing Facility(ies) prior to initiation of cGMP Manufacturing; provided, however, such [***] limitation shall not apply in the event that [***]. Quality audits under this Section may include an audit of [***].
- (ii) At least [***] days prior to the anticipated expiration of the POC Term for a given Program, Merck, in each such instance, shall have the right, during normal business hours [***] and with reasonable advance notice, to [***] with respect to the applicable Collaboration Products, solely for the purposes of assisting Merck in determining [***]; [***]. Moderna will support such [***] by Merck by making appropriate resources available to provide the information, data, and records, and to answer questions from Merck. In connection with such [***]. With respect to any SAV Program, if Merck identifies any audit observations in connection with any audits under this Section 6.1(d)(ii), the Parties will discuss in good faith suitable approaches for correcting such observations and will prepare a plan for correcting such observations for such SAV Program; [***].
- (iii) With respect to an SAV Program and an audit by Merck of Collaboration SAV Manufacturing Facility(ies) in accordance with Section 6.1(d)(i), if Merck identifies any audit observations, the Parties will discuss in good faith suitable approaches for correcting such observations and the Parties will prepare a plan for correcting such observations for such SAV Program, [***].
- (iv) Notwithstanding Section 6.1(d)(i) and Section 6.1(d)(iii), the Parties hereby acknowledge and agree that Merck has conducted, as of the Amended Effective Date, a quality audit and EHS audit with respect to the Collaboration SAV Manufacturing Facility(ies) designated to date for the Manufacture of Collaboration SAV Products for the KRAS Program. As of the Amended Effective Date, as set forth on Schedule 6.1(d)(iv), Moderna and Merck have agreed to the timing and scope of the required corrective actions resulting from such quality and EHS audits. [***] Merck acknowledges that the batches of mRNA-5671 Manufactured by Moderna in such Collaboration SAV Manufacturing Facility(ies) are suitable, as of the Amended Effective Date, for use in Clinical Studies for the KRAS Program, subject to [***].
- (e) Confidential CMC Documents. Notwithstanding anything in this Agreement to the contrary, during the POC Term for a given Program, except with respect [***], Moderna may redact from documents provided or made available to Merck or its Affiliates, and otherwise decline to disclose or provide Merck access to, Moderna CMC Information and proprietary manufacturing processes relating to Moderna CMC Information from such Program.

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6.2 Manufacture for Development During Merck Participation Term for a given Program.

(a) mRNA Cancer Vaccines and Collaboration Products. To the extent supply of mRNA Cancer Vaccines (including Collaboration Products) or mRNA Constructs (formulated or unformulated) is required to perform the activities under any Additional Research Plan for a given Program, Moderna shall be solely responsible (except as mutually agreed by the Parties in writing or as set forth in the applicable Joint Development Plan and Budget) for Manufacturing such mRNA Cancer Vaccines (including Collaboration Products) or mRNA Constructs (formulated or unformulated) in accordance with such Additional Research Plan for such Program and this Agreement.

- (b) Merck's Exercise of a Merck Participation Election for SAV Programs. Subject to the remainder of this Section 6.2(b), to the extent supply of Collaboration SAV Products (including mRNA Constructs therefor) is anticipated to be required to perform the activities under any Joint Development Plan and Budget, concurrent with Merck's review of Moderna's Manufacturing operations and the Parties' preparation of a plan for correcting observations for such SAV Program as set forth in Section 6.1(d)(ii), the Parties shall discuss in good faith and mutually agree on [***]. After receipt of [***], the Parties shall discuss in good faith [***]. After such joint discussion and evaluation, if the Parties are not able to agree [***], then [***] shall have the right to make the final determination [***]. For the avoidance of doubt, the discussions and determination as set forth in this Section 6.2(b) for an SAV Program may take place during the POC Term for such SAV Program as well as during the Merck Participation Term for such SAV Program. If the Parties mutually agree, or if [***], that [***], then [***] shall have a reasonable amount of time following such determination to [***].
 - (c) Merck's Exercise of a Merck Participation Election for the PCV Program.
- (i) With respect to the PCV Program, if Merck identifies any audit observations in connection with any audits under Section 6.1(d)(ii), the Parties will discuss in good faith suitable approaches for correcting such observations and, following the exercise of the Merck Participation Election for the PCV Program [***], will prepare a plan and a budget for correcting such observations for the PCV Program, any resulting corrective action plan and budget must [***], and Moderna shall have a reasonable amount of time following such consultation with, and approval by, Merck to make appropriate corrections. Moderna shall bear all of its own costs and expenses in connection with taking any such corrective actions in accordance with such plan and budget up to [***]. In the event that Moderna incurs costs and expenses in excess of [***] in connection with taking such corrective actions in accordance with such plan and budget, such excess costs shall be treated as Shared Collaboration Costs with respect to the PCV Program under Exhibit D.
- (ii) [***] Merck, [***], shall purchase from Moderna up to such capacity ([***]), Collaboration PCV Product for use in Development in connection with the performance of Collaboration Activities during the Merck Participation Term for the PCV Program until [***]. Following [***], upon [***] prior written notice to Moderna, [***].

- (d) PCV Clinical Supply Agreement and Clinical Quality Agreements. At least [***] days prior to the anticipated expiration of the POC Term for the PCV Program, the Parties shall initiate good faith discussions with respect to, and within [***] days after Merck exercises the Merck Participation Election for the PCV Program enter into, a supply agreement and a Clinical Quality Agreement with respect to the Manufacture of Collaboration PCV Products for Development purposes during the Merck Participation Term for the PCV Program (if and to the extent Merck exercises the Merck Participation Election), which supply agreement (the "PCV Clinical Supply Agreement") and Clinical Quality Agreement will include mutually agreed terms and conditions in accordance with Exhibit M, and shall otherwise include terms and conditions consistent with supply and quality agreements that are customary for agreements of this type which Merck utilizes with other non-affiliated Third Party manufacturers.
- (e) SAV Clinical Supply Agreement and Clinical Quality Agreements. At least [***] days prior to the anticipated expiration of the SAV POC Term for the first SAV Program for which [***], the Parties shall initiate good faith discussions with respect to, and within [***] days after Merck exercises the Merck Participation Election for such SAV Program, enter into a supply agreement and a Clinical Quality Agreement with respect to the Manufacture of Collaboration SAV Products for Development purposes during the Merck Participation Term for such SAV Program (if and to the extent Merck exercises the Merck Participation Election for a given SAV Program), which supply agreement (the "SAV Clinical Supply Agreement") and Clinical Quality Agreement will include mutually agreed terms and conditions in accordance with Exhibit M, and shall otherwise include terms and conditions consistent with supply and quality agreements that are customary for agreements of this type [***]. In the event that [***], the Parties may mutually agree to amend the existing SAV Clinical Supply Agreement to include Collaboration SAV Products from such subsequent SAV Program or enter into a new SAV Clinical Supply Agreement for such Collaboration SAV Products.
 - (f) [***]; Supply Failure; Selection of Alternative Supplier.
- (i) If ([***], then Merck would have the right to cause Moderna to effect, and Moderna shall effect a technology transfer in accordance with **Exhibit H** and the applicable Clinical Supply Agreement to Merck (or its Affiliate) or to a Manufacturing Subcontractor in order to permit Merck (or its Affiliate) or such Manufacturing Subcontractor to Manufacture the applicable Collaboration Product to meet Merck's

requirements for Development activities under the applicable Program under this Agreement. All costs and expenses incurred by or on behalf of the Parties (or their Affiliates) in connection with effecting such technology transfer in accordance with **Exhibit H** will be Shared Collaboration Costs. Without limiting the foregoing, Moderna shall keep Merck reasonably apprised [***]. Should a technology transfer as expressly set forth in this Section 6.2(f)(i) be required or determined pursuant to Section 6.2(f)(ii), then [***]. During any technology transfer for a Collaboration PCV Product [***]. Following a successful technology transfer to Merck (or its Affiliate) or to a Manufacturing Subcontractor in accordance with **Exhibit H**, Merck shall assume responsibility for the supply of Collaboration PCV Product for Development and Commercialization activities under the PCV Program, unless otherwise agreed to by the Parties in writing. During any technology transfer for a Collaboration SAV Product[***].

- (ii) Notwithstanding the terms of the SAV Clinical Supply Agreement, immediately upon [***], the Parties, through the JMC, will review and discuss [***]. If the Parties reasonably determine (based on the considerations above) that the best available course of action [***] is for Moderna to [***], Moderna will, with Merck's input, [***]. If the Parties determine that it is in the best interests of the applicable Program for [***], then Moderna [***], and in such case the Parties will prepare an appropriate plan for review by the JMC and approval by the Parties, including [***]. If the Parties determine that the best available remedy for ensuring that the foregoing requirements are met is some other approach, the Parties will prepare an appropriate plan to reflect such approach for review by the JMC and approval by the Parties, including [***]. Notwithstanding the preceding provisions of this Section 6.2(f)(ii), if the Parties cannot agree on the best available course of [***], the matter will be resolved in accordance with [***]. During the pendency of any such dispute resolution procedure, [***].
- (iii) If following a Supply Failure, there is a dispute as to the best approach for ensuring [***], then the costs and expenses incurred by or on behalf of a Party or its Affiliates in connection with [***], shall be considered [***].
 - (g) Management of Development Manufacturing Capacity.
- (i) With respect to the Collaboration Products (except for any Collaboration SAV Product for which Moderna is not responsible to supply [***]), Moderna, in consultation with Merck, shall prepare and maintain a quarterly forecast (each, a "Manufacturing Capacity Forecast") of the supply of such Collaboration Products, [***]. The Manufacturing Capacity Forecast for each applicable Program is to be updated [***]. The Manufacturing Capacity Forecast for each applicable Program is to be reviewed [***] by the JMC and used by the JMC in coordination with the JDC to inform plans for [***].
- (ii) Should the addition or amendment of a Clinical Study to the Manufacturing Capacity Forecast for a given Program result in the need to obtain additional Manufacturing capabilities (including [***], as determined by the JMC [***], the JMC shall jointly evaluate options to increase Manufacturing capabilities [***] with the goal of [***]. All [***] are subject to review by the JMC [***], with respect to Collaboration PCV Products, and [***], with respect to Collaboration SAV Products (provided that [***]); provided that no such [***] shall require a Party to establish [***] without such Party's prior written consent. Any disputed matter with respect to Collaboration SAV Products pursuant to this Section 6.2(g)(ii) will be resolved in accordance with [***].
- (h) To the extent there is a technology transfer pursuant to Section 6.2(f) as a result of [***], any costs and expenses associated with establishing [***] that are incurred by or on behalf of [***], including [***], shall be considered [***].
- (i) To the extent supply of Keytruda is required to perform the activities under a Development Plan, Merck shall be responsible for supplying such requirements of Keytruda in accordance with such Development Plan and the supply terms set forth on **Exhibit K**.
- (j) To the extent supply of a Merck Agent is required to perform the activities under a Development Plan, Merck shall be responsible for supplying such requirements of such Merck Agent in accordance with such Development Plan and the supply terms set forth on **Exhibit K**. To the extent supply of a Moderna Agent is required to perform the activities under a Development Plan, Moderna shall be responsible for supplying such requirements of such Moderna Agent in accordance with such Development Plan and the supply terms set forth on **Exhibit K**.

(k) To the extent supply of a Third Party Agent is required to perform the activities under a Development Plan, the Party who has contracted with such Third Party for such Third Party Agent shall be responsible for supplying such requirements of such Third Party Agent in accordance with such Development Plan.

6.3 Manufacture for Commercialization During Merck Participation Term for a given Program.

- (a) Manufacturing for Commercialization during Merck Participation Term for a given Program. With respect to a given Program, considering the forecasted commercial volume requirements for the applicable Collaboration Product, the Parties shall jointly evaluate options to [***]. Notwithstanding the foregoing, with respect to any Collaboration SAV Product, [***]. The [***] with respect to the PCV Program is subject to review by the JMC and approval by [***]; provided that if the Parties do not approve the [***] pursuant to this Section 6.3(a), such dispute will be resolved in accordance with [***] neither Party's plan [***]shall include a proposal requiring the other Party to [***]. The initial discussions regarding commercial supply of Collaboration SAV Products may take place at the same time discussions are taking place pursuant to Section 6.2, and if commercial supply may be sourced at the same time [***], then the selection criteria under Section 6.2(b) shall also include [***]. If there is a dispute regarding the Commercial Capacity Buildup Plan for a Joint SAV Program and the Parties resolve the dispute through [***], then the determination [***] and the Party responsible for [***] shall be responsible for payment of the costs and expenses incurred in [***]; provided that such Party shall be entitled to [***].
- (b) Commercial Supply Agreements and Commercial Quality Agreements. If Moderna [***], the Parties shall enter into a supply agreement and quality agreement with respect to Manufacture of the applicable Collaboration Product for commercial purposes, which supply agreement (the "Commercial Supply Agreement") and quality agreement (the "Commercial Quality Agreement") shall contain terms and conditions consistent with supply and quality agreements that are customary for agreements of this type that Merck utilizes with other non-affiliated Third Party manufacturers, including, [***].
- 6.4 <u>Allocation of Capacity</u>. Allocation of capacity for Collaboration Products among **Exhibit K**, the PCV Clinical Supply Agreement, SAV Clinical Supply Agreement and the Commercial Supply Agreement will be prioritized, in descending order of priority, as follows: [***].

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7. REGULATORY RESPONSIBILITIES DURING THE MERCK PARTICIPATION TERM FOR A GIVEN PROGRAM

7.1 Merck Participation Term Lead Regulatory Party.

(a) During the Merck Participation Term for a given Program, subject to Section 7.1(b), unless otherwise agreed to by the Parties in writing, [***] shall be the Lead Regulatory Party and primarily responsible for regulatory matters with respect to the applicable Joint Development Program and the Collaboration Products for such Program. Subject to JDC oversight on the overall regulatory strategy for the Collaboration Products for such Program, [***] shall have primary responsibility with respect to submitting Regulatory Filings (other than DMFs) for such Program. [***] shall be primarily responsible for all communications with, and submissions to, Regulatory Authorities in connection therewith, provided that [***] shall have a reasonable opportunity to review and comment on the subject matter of all material Regulatory Filings (other than DMFs) (including all material correspondence). At the reasonable request of [***], [***] shall prepare, or otherwise provide assistance in the preparation of, certain portions of Regulatory Filings ([***]) for such Program. In the event additional [***] not currently contained within regulatory documents [***], the Parties shall mutually agree on the [***]. Subject to Section 7.1(b), [***] shall also be responsible for all routine maintenance of all INDs or CTAs for Collaboration Products for such Program. [***] shall, subject to applicable Law, [***] shall provide such information and assistance as [***] may reasonably request in connection with the completion of and submission of and maintenance of Regulatory Filings for such Program, including applications for Regulatory Approvals, and responses to agency inquiries (which information [***] shall provide in a timely manner to respond to the agency), for such Collaboration Products for such Program, and the maintenance thereof. In the event [***] receives a request from a Regulatory Authority with respect to such Program for which disclosure of [***] will notify [***] promptly after receiving such request and the Parties shall discuss a course of action within a time frame consistent with the time period requested by such Regulatory Authority, provided that in the

event that the Parties are unable to agree on such course of action within such time frame, then such matter shall be referred to [***].

(b) During the Merck Participation Term for a given Program, notwithstanding Section 7.1(a), the Party sponsoring or conducting an Independent Additional Study under an Independent Additional Study Development Plan for such Program (the "IAS Party") shall be responsible for regulatory matters with respect to such Independent Additional Study for such Program and the Collaboration Products thereunder, including filing and maintaining the IND or CTA for the conduct of such Independent Additional Study and communications with, and submissions to, Regulatory Authorities in connection with such Independent Additional Study; provided, however, that if a Regulatory Authority requires that an Independent Additional Study be conducted under an IND or CTA held by the other Party (the "Non-IAS Party"), then the Parties shall discuss in good faith an alternative approach if reasonably available. The non-IAS Party shall provide other information and assistance as the IAS Party may reasonably request in connection with the completion of and submission of INDs or CTAs for Independent Additional Studies for such Program; provided, however, Moderna shall have no right to directly access the CMC data for [***]. In addition to the foregoing, if [***]; provided that, if the applicable Regulatory Authority requires [***]. Without limiting the foregoing, the Parties agree to grant each other such Rights of Reference as are necessary, and to otherwise cooperate in good faith, to enable the conduct of Independent Additional Studies in accordance with the terms of this Agreement, including to with respect to submission of Regulatory Filings, applications for Regulatory Approvals and the maintenance thereof.

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7.2 Ownership of Regulatory Filings.

- (a) Subject to Section 7.1(b) and Section 7.2(b), during the Merck Participation Term for a given Program, all applications for Regulatory Approval, the Regulatory Approvals, and other Regulatory Filings (other than DMFs) (including all INDs and CTAs) relating to the applicable Collaboration Products will be the property of [***] and held in the name of [***] or its designees. [***] shall provide the JDC with regular updates regarding the status of Regulatory Filings and correspondences for Collaboration Products, and such Regulatory Filings and correspondences shall be reviewed by the JDC or a working group established by such committee.
- (b) With respect to the Collaboration Products, if not previously prepared and filed, Moderna will, at Merck's request, prepare, file and maintain with all applicable Regulatory Authorities a DMF for the Collaboration Products and, subject to the remainder of this Section 7.2(b), Moderna shall also provide such other information and assistance as Merck may reasonably request in connection with the completion of and submission of applications for Regulatory Approvals for Collaboration Products and the maintenance thereof. Merck and its Affiliates and Sublicensees may refer to such DMF in any filing made in connection with obtaining or maintaining a Regulatory Approval for a Collaboration Product and [***] hereby grants such a Right of Reference. [***] will be responsible for assuring that during the Term, such [***] will be in the form appropriate for filing with all applicable Regulatory Authorities, including those in [***], and [***] shall be maintained in full force and effect by [***] during the Term and will not be amended without the consent of [***], other than with respect to amendments that [***] will, on written request by [***], provide to the requesting party and to any specified Regulatory Authority [***]. If [***] has not filed [***], then any and all [***] required to be included in any Regulatory Filing [***] shall be provided by [***] to the appropriate individuals [***]. To the extent that [***], then [***] will first notify and discuss with the appropriate representatives at [***]; provided that such [***] employees [***].
- (c) With respect to any Independent Additional Study, upon the IAS Party's completion of an Independent Additional Study for a given Program, the IAS Party will provide the data and related information and documents with respect thereto to the non-IAS Party, and the Parties will meet in person to review and discuss the results and data of such study, the safety and efficacy profile of the proposed Collaboration Product or label expansion with respect to such Collaboration Product that could be requested via a filing for a Regulatory Approval. [***] shall be responsible for filing, and, subject to [***] shall be obligated to file the application for Regulatory Approval for a given Collaboration Product following receipt of clinical data from the conduct of an Independent Additional Study upon the request of the IAS Party for such Independent Additional Study; provided further that if not already assigned [***].
- 7.3 <u>Adverse Event Reporting</u>. During the Merck Participation Term for a given Program, prior to [***] shall be responsible for individual and aggregate safety reporting for any Clinical Studies involving the

applicable Collaboration Product for such Program (as applicable), [***] shall provide [***] an electronic copy of the [***]. Upon receipt of completion of [***] shall assume responsibility for the individual and aggregate safety reporting (as applicable) [***]. Until [***], each Party agrees to notify the other Party of any information of which such Party becomes aware concerning any Adverse Events with respect to such Collaboration Product for such Program. Such notice shall be provided in English in the form of a processed CIOMS I within [***] days of such Party receiving such information where such potential Adverse Events is a SAE and associated with the clinical uses, Clinical Studies, investigations, tests or marketing of such Collaboration Product for such Program. Adverse Event reports of unexpected and fatal or life-threatening events which are possibly, probably, definitely related or of unknown relationship to the use of a given Collaboration Product for such Program must be forwarded to the other Party within [***] after receipt of such information. It is understood and agreed that these Adverse Events reporting requirement provisions are based on the respective policies and procedures of the Parties and applicable regulatory reporting requirements. In the event of changes to applicable regulatory requirements for Adverse Events reporting, the Parties agree to comply with any such required revised notification requirements. At this same time, Moderna and Merck shall enter into discussions regarding one or more pharmacovigilance agreements (or updates to the current pharmacovigilance agreement) for the Collaboration Product for such Program, as applicable (the "Pharmacovigilance Agreement"). In all cases, [***]. For the avoidance of doubt, [***].

7.4 Right of Reference During Merck Participation Term for a given Program. During the Merck Participation Term for a given Program, each Party shall provide to the other, as necessary, a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the Right of Reference such other Party's Other Component(s) that are included in a Development Plan. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to a Moderna Agent, Merck Agent or Keytruda, as applicable. Each Party shall authorize FDA and other applicable Regulatory Authorities to cross-reference the applicable INDs and CTAs for any Collaboration Product, Moderna Agent, Merck Agent or Keytruda, as applicable, used in the conduct of a Clinical Study for such Program under a Development Plan to provide data access to the other Party sufficient to support conduct of any Clinical Study sponsored by such other Party involving such Collaboration Product for such Program, Moderna Agent, Merck Agent or Keytruda, as applicable. If a Party's IND or CTA for such Program is not available in a given country, subject to [***], such Party will file its CMC data for such Program with the applicable Regulatory Authority for such country, referencing the other Party's IND or CTA for such Program as appropriate (however, [***]. The Party conducting a Clinical Study under a Right of Reference shall (a) track and collect financial disclosure information from all "clinical investigators" involved in such Clinical Study for such Program and (b) prepare and submit the certification or disclosure of the same in accordance with all applicable Law, including Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. Prior to the initiation of clinical activities under any Clinical Study for such Program sponsored by (a) Moderna involving a Collaboration Product for such Program, Keytruda or a Merck Agent or (b) Merck involving a Moderna Agent, the Parties shall determine, in writing, whether the Party conducting such Clinical Study for such Program shall track and collect separate certification or disclosure forms for each of Merck and Moderna or one (1) "combined" certification or disclosure form for both Merck and Moderna. For purposes of this Section 7.4, the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

7.5 <u>Regulatory Costs</u>. During the Merck Participation Term for a given Program, the reasonable and documented costs and expenses of the Parties in performing its respective regulatory obligations pursuant to this Section 7 prior to receipt of Regulatory Approval for a given Collaboration Product for such Program shall be considered Development Costs.

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8. <u>COMMERCIALIZATION RESPONSIBILITIES</u>

8.1 Overview. On a Collaboration Product-by-Collaboration Product basis, subject to the oversight of the JSC and JCC and the remainder of this Section 8, Merck will plan Commercialization Activities with respect to such Collaboration Product in the Territory, including discussing such plans with Moderna and the Co-Promotion of such Collaboration Products by Moderna in the U.S. Merck will be solely responsible for all Commercialization Activities relating to such Collaboration Product in the Territory, including the booking of all sales of Collaboration Products, subject to Moderna's right to perform certain Co-Promotion activities (with Merck) in the United States as specified in Sections 8.5 and 8.6 and any Co-Promotion Agreement.

8.2 Commercialization Efforts.

- (a) *United States*. On a Collaboration Product-by-Collaboration Product basis, Merck (itself or through one or more Affiliates) will use Commercially Reasonable Efforts to Commercialize such Collaboration Product in the U.S., and to carry out the tasks specified under the Global Commercialization Plan for such Collaboration Product in the U.S. in a timely and effective manner and in compliance in all material respects with applicable Law.
- (b) Ex-U.S. On a Collaboration Product-by-Collaboration Product basis, Merck (itself or through one or more Affiliates) will use Commercially Reasonable Efforts to Commercialize such Collaboration Product ex-U.S., and to carry out the tasks specified under the Global Commercialization Plan for Merck for such Collaboration Product ex-U.S. in a timely and effective manner and in compliance in all material respects with applicable Law.
- 8.3 Global Commercialization Strategy. Before the Commencement of the first Registrational Study for any Collaboration Product following the exercise of the Merck Participation Election for the applicable Program, Merck shall provide, and within [***] days after such provision the JCC will review and update for approval by the JSC, a written summary of the global Commercialization strategy for all Collaboration Products included in the Joint Development Plan and Budget for the applicable Program in the Territory. Such strategy should include [***]. For clarity, any and all such communications and strategy involving the Commercialization of a Collaboration Product will be limited to those permitted under applicable Law, including antitrust Laws.

8.4 Global Commercialization Plan(s).

(a) *Initial Global Commercialization Plan(s)*. For each Collaboration Product, an initial high-level Global Commercialization Plan shall be prepared by Merck and submitted to the JCC for review and JSC approval no later than [***] prior to the anticipated date of first filing for Regulatory Approval for such Collaboration Product. The JCC will set the required form and contents of such Global Commercialization Plan, which will include activities relating to [***]; provided that, for clarity, the JCC may determine that not all of the foregoing elements are appropriate for inclusion in the initial Global Commercialization Plan or updates thereto prior to Collaboration Product launch.

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(b) Global Commercialization Budget(s). At such times as the JCC will deem appropriate, but in no event later than [***] prior to the anticipated date of first filing for Regulatory Approval for a Collaboration Product, and concurrently with the preparation of the initial Global Commercialization Plan, on a Collaboration Product-by-Collaboration Product basis, Merck will prepare an initial budget for the Global Commercialization Plan for such Collaboration Product, that outlines the financial resources and expenses to be incurred by or on behalf of the Parties (or their Affiliates) in execution of the Global Commercialization Plan, with input from Moderna on costs associated with activities assigned to Moderna in the associated Global Commercialization Plan (each a "Global Commercialization Budget"). The JCC will review and comment on and the JSC will approve such Global Commercialization Budget; provided that the Global Commercialization Budget may not be increased by more than [***] of the anticipated Allowable Commercialization Costs in such Global Commercialization Budget within a Calendar Year without submitting an amended Global Commercialization Budget for review and comment by the JCC and approval by the JSC; provided that, Merck shall have the right to incur Commercialization costs in excess of [***] of the anticipated Allowable Commercialization Costs in such Global Commercialization Budget within a Calendar Year to the extent that such Commercialization costs that are not previously approved by the JSC shall be solely borne by Merck for the purposes of calculating each Party's share of the Cash Profits or Losses for such Calendar Year. Thereafter, Merck, with input from Moderna, will update the Global Commercialization Budget at least [***] per Calendar Year (and in any event at any time the Global Commercialization Plan is updated or amended with respect to any Commercialization Activities), and the JCC will review and comment on and the JSC shall approve any such update or any other amendment to the Global Commercialization Budget. The JCC will set the required form and contents of the Global Commercialization Budget, but at a minimum the contents shall include [***].

(c) Updated Global Commercialization Plan(s) and Global Commercialization Budget(s). Not later than [***] of each Calendar Year, or more often as the Parties mutually deem appropriate, Merck shall submit to the JCC for review and comment updated Global Commercialization Plans and Global Commercialization Budgets for the following Calendar Year, which the JCC shall review and comment on, and the JSC shall approve, no later than [***] of such Calendar Year and attach to the minutes of the meeting of the JSC at which

any Global Commercialization Plan, Global Commercialization Budget or any amendment, modification or update to either or both is approved by the JSC.

8.5 Co-Promotion of Collaboration Products in U.S.

- (a) *Co-Promotion*. Except as otherwise set forth in this Agreement, the Parties intend that the Parties will share in the Co-Promotion of Collaboration Products in the U.S. on the terms and conditions set forth in this Section 8.5 and Section 8.6.
- (b) Co-Promotion Agreements. On a Collaboration Product-by-Collaboration Product basis, prior to the submission of the first Global Commercialization Plan for such Collaboration Product to the JCC, the Parties will enter into a co-promotion agreement (the "Co-Promotion Agreement") setting forth the terms and conditions of the Parties' Co-Promotion of such Collaboration Product in the U.S. Each Co-Promotion Agreement will be consistent with this Section 8.5 and Section 8.6, and will contain additional reasonable and customary terms and

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conditions, including an equitable allocation of responsibilities for the Co-Promotion of such Collaboration Product and the promotional efforts in the U.S. The Parties may commence negotiating the terms and conditions of the Co-Promotion Agreement at any time after the commencement of the Merck Participation Term for a given Program.

- 8.6 <u>Co-Promotion Terms</u>. Each Co-Promotion Agreement entered into pursuant to Section 8.5 will reflect the principles set forth in this Section 8.6, unless otherwise expressly agreed by the Parties.
- (a) *Team Building and Training*. Merck will direct the standards for job descriptions, qualifications, roles, responsibilities and training of Moderna's sales representatives and key account managers and Moderna will prepare and implement, consistent in all material respects with the Global Commercialization Plan, a training program and training materials for such sales representatives, to which Merck may contribute, at its election. In addition, Merck will specify the conduct and content of details (including detail scripts) for a Collaboration Product. Moderna will cause each of its sales representatives and key account managers assigned to a Collaboration Product to attend and complete the training program developed by Merck for such Collaboration Product in the U.S. to assure a consistent, focused promotional strategy and message as and to the extent consistent with applicable Law.
- (b) Responsibilities. Subject to Section 8.6(c) below, each Party will be solely responsible for recruiting, hiring and maintaining its sales force of sales representatives and key account managers for promotion of a Collaboration Product in accordance with its standard procedures and the requirements of this Agreement. Each Party will be responsible for the activities of its sales representatives and key account managers, including compliance by its sales representatives and key account managers with training and detailing requirements. In particular, each Party will provide its sales representatives and key account managers assigned to a Collaboration Product with the level of oversight, management, direction and sales support with respect to the promotion of such Collaboration Product necessary to effectively and efficiently promote such Collaboration Product in accordance with the terms of this Agreement and applicable Law.

(c) Sales Force Matters.

- (i) Number of Representatives. Moderna will have the right, but not the obligation, to provide no less than [***] but no more than [***] of the total sales representatives and of the total key account managers used by both Parties for promotion of a Collaboration Product in the U.S. The Global Commercialization Plan for a Collaboration Product that is intended to be Co-Promoted in the U.S. will set forth the precise number of Moderna sales representatives and key account managers consistent with the foregoing and Moderna shall [***]s. Each Party agrees that any of its sales representatives or key account managers involved in the promotion of a Collaboration Product will not have any legal or regulatory disqualifications, bars or sanctions.
- (ii) Establishment; Launch Readiness. No later than [***] prior to the estimated date of the launch of the first Collaboration Product in the U.S., Moderna will present its sales representative and key account manager capabilities to Merck. If Merck identifies [***], then Merck shall have the right to [***].

- (iii) Hiring. Moderna will be solely responsible for recruiting, hiring and maintaining its sales representatives and key account managers in accordance with [***], if any, and shall have sole control over such sales representatives and key account managers. Notwithstanding the foregoing, however, upon Moderna's reasonable request, Merck will assist Moderna in the establishment of the sales representatives and key account managers by providing assistance with the profiling of personnel during hiring.
 - (iv) Use of Contract Sales Organizations. [***].
- (v) Compensation Programs for Sales Representatives. Each Party shall be solely responsible for any compensation that is payable to its sales representatives and key account managers consistent with the applicable Global Commercialization Plan. Each Party represents and warrants to the other Party that its compensation programs for its sales representatives and key account managers do not, and will not, provide financial incentives that, to its knowledge, facilitate the promotion, sales, and marketing of the Collaboration Product in violation of applicable Laws.
- (d) *Promotional Materials*. In the United States, to the extent Moderna is Co-Promoting, each Party's sales representatives and key account managers assigned to a Collaboration Product will utilize only Promotional Materials that have been approved by the JCC. All detailing activities conducted by each Party's sales representatives will be consistent in all material respects with the Promotional Materials so approved. Each Party will train and instruct their respective sales representatives to make only those statements and claims regarding such Collaboration Product, including as to efficacy and safety, which are consistent with such Collaboration Product labeling and accompanying inserts and the approved Promotional Materials.
- (e) *JCC Reports*. Each of Merck and Moderna will provide the JCC with a report, as soon as practicable but in no event later than [***] days following the end of each Calendar Quarter during the Term following the Regulatory Approval of a Collaboration Product to be Commercialized in the U.S., setting forth the number of details made by its sales representatives of such Collaboration Product in the U.S. during such Calendar Quarter. Costs and expenses for sales representatives and key account managers will be charged to the Profit & Loss Share as in **Exhibit D**.
- (f) *Records*. Each Party will maintain records and otherwise establish procedures to ensure compliance with all applicable Laws and professional requirements that apply to the promotion and marketing of the Collaboration Products.
- 8.7 <u>Branding</u>. To the extent permitted by applicable Law and applicable Regulatory Authorities, all Collaboration Products sold in or distributed for the Territory will have the corporate brands of each Party displayed on an equally prominent basis. At such time as the JCC will deem appropriate, the Parties will enter into appropriate trademark licensing agreements to achieve the foregoing.
- 8.8 <u>Promotional Materials</u>. Merck will be responsible for the creation, preparation, production, reproduction and filing with the applicable Regulatory Authorities, of relevant Promotional Materials relating to each Collaboration Product for use in the Territory. All such Promotional Materials will be compliant with applicable Law and, if applicable, consistent in all material respects with the Global Commercialization Plan for such Collaboration Product and, if applicable, consistent in all material respects with the branding strategy for such Collaboration Product.

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8.9 Sales and Distribution.

- (a) Collaboration Products. Merck will be solely responsible for booking of sales, handling all returns, recalls, order processing, invoicing and collection, inventory and receivables, and, subject to the good faith consideration by Merck of input from Moderna, Distribution Matters relating to each Collaboration Product in the Territory. Moderna will not accept orders for Collaboration Products or make sales for its own account or for Merck's account, and if Moderna receives any order for Collaboration Products in the Territory, it will refer such orders to Merck for acceptance or rejection. Merck will be solely responsible for negotiating and contracting with managed care entities, hospitals, integrated systems, pharmacies, long term care organizations, group purchasing organizations, pharmacy benefit managers, and governments, consistent in all material respects with the Global Commercialization Plan.
- (b) Keytruda and Merck Agents. Merck will be solely responsible for all Commercialization activities for Keytruda and for all Merck Agents in the Territory, in each case including handling all returns, recalls, order processing, invoicing and collection, booking of sales, inventory and receivables, government

pricing programs and medical affairs, including negotiating and contracting with managed care entities, hospitals, integrated systems, pharmacies, long term care organizations, group purchasing organizations, pharmacy benefit managers, and governments. Moderna will not accept orders for Keytruda or for Merck Agents, or make sales for its own account or for Merck's account, and if Moderna receives any order for Keytruda or a Merck Agent (as applicable) in the Territory, it will refer such orders to Merck for acceptance or rejection. For clarity, Moderna shall have no rights to any revenue from any Merck Agent or Keytruda.

(c) Moderna Agents. Moderna will be solely responsible for all Commercialization activities for all Moderna Agents in the Territory, in each case including handling all returns, recalls, order processing, invoicing and collection, booking of sales, inventory and receivables, government pricing programs and medical affairs, including negotiating and contracting with managed care entities, hospitals, integrated systems, pharmacies, long term care organizations, group purchasing organizations, pharmacy benefit managers, and governments. Merck will not accept orders for Moderna Agents or make sales for its own account or for Moderna's account, and if Merck receives any order for Moderna Agents in the Territory, it will refer such orders to Moderna for acceptance or rejection. For clarity, Merck shall have no rights to any revenue from any Moderna Agent.

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(d) *Third Party Agents*. With respect to any Third Party Agent to be used in combination with any Collaboration Product, the Parties will discuss in good faith and agree upon the allocation of responsibilities for Commercialization activities for such Third Party Agent in combination with a Collaboration Product in the Territory, if and to the extent either Party has any rights in or to such Third Party Agent.

8.10 <u>Commercialization Reports</u>. Each Party will keep the JCC fully informed regarding the progress and results of Commercialization activities for Collaboration Products in the U.S., including [***]. Merck will provide the JCC on a [***] basis a rolling annual forecast of projected unit sales, revenue and market share for Collaboration Products ex-U.S. The Parties will work together to provide such forecast for Collaboration Products in the U.S.

9. PAYMENTS

9.1 <u>Program Funding</u>. The Parties agree and acknowledge that pursuant to the terms of the Original Agreement, Merck has previously paid Moderna a one-time payment of Two Hundred Million Dollars (U.S. \$200,000,000) (the "<u>Upfront Payment</u>"), which payment will be non-refundable, non-creditable, not subject to set-off, and not be reduced by any withholding or similar taxes. Subject to Sections 3.5(d) and 3.7(b) and **Exhibit D**, Moderna shall utilize the Upfront Payment for the performance of Collaboration Activities for the PCV Program under this Agreement.

9.2 Non-Exercise of Merck Participation Election. If Merck does not exercise the Merck Participation Election for a given Program, (a) [***], no further payments shall be due under this Agreement from Merck to Moderna with respect to such Program or the Collaboration Products thereunder (other than with respect to any payment obligations that have accrued prior to the Merck Participation Election Period expiry for such Program, Merck's indemnification obligations under Section 13.6(a) or for supply of the applicable Collaboration Products in accordance with Section 3.7) and (b) Moderna shall pay to Merck for a given Calendar Quarter its share of (1) Moderna Net Profits allocated to sales of any Financial PCVs or (2) the Moderna Net Profits allocated to sales of any Financial SAVs up to an aggregate amount equal to the Merck SAV Program Costs (at which point, such SAVs shall cease to be Financial SAVs) in accordance with **Exhibit E**.

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9.3 Exercise of Merck Participation Election.

(a) Participation Election Payment.

(i) If Merck exercises the Merck Participation Election for the PCV Program, then within [***] Business Days after the exercise of the Merck Participation Election for the PCV Program, and receipt of an invoice from Moderna, Merck will pay to Moderna a one-time payment of Two Hundred Fifty Million Dollars (U.S. \$250,000,000) (the "PCV Participation Election Payment"), which payment will be non-refundable, non-creditable, not subject to set-off, and not be reduced by any withholding or similar taxes.

- (ii) If Merck exercises the Merck Participation Election for a given Joint SAV Program, then within [***] Business Days after the Parties agree to the initial Joint Development Plan and Budget for such Joint SAV Program in accordance with Section 4.3(c)(i), Moderna will send an invoice to Merck, and within [***] Business Days after receipt of such invoice, Merck will pay to Moderna a one-time payment of, as applicable, (i) with respect to the exercise of the Merck Participation Election for the KRAS Program, [***], or (ii) for a Joint SAV Program other than the KRAS Program, (A) if prior to the Merck Participation Election for such Joint SAV Program, Merck has not previously exercised the Merck Participation Election for any Joint SAV Program, [***], (B) if prior to the Merck Participation Election for such Joint SAV Program, Merck has exercised the Merck Participation Election for any Joint SAV Program, [***], or (C) thereafter for any other Joint SAV Program, [***] (each, an "SAV Participation Election Payment"), which payment with the PCV Participation Election Payment, each a "Participation Election Payment"), which payment will be non-refundable, non-creditable, not subject to set-off, and not be reduced by any withholding or similar taxes.
- (b) *Profit & Loss Share*. If Merck pays the Participation Election Payment for a given Program, then, subject to [***] and **Exhibit E** with respect to a Joint SAV Program, the Parties will share in Cash Profits or Losses with respect to Collaboration Products from such Program as follows: Moderna will bear (and be entitled to) fifty percent (50%), and Merck will bear (and be entitled to) fifty percent (50%) (the "<u>Profit & Loss Share</u>"). [***] Procedures for Calendar Quarter reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, are set forth on **Exhibit D**, and to the extent not set forth in **Exhibit D**, will be established by the JSC, subject to Section 2.7(b).
- 9.4 <u>Payments for In-Licenses</u>. The Parties will make payments for In-Licenses in accordance with **Exhibit D**, **Exhibit E** and **Exhibit F**.

9.5 Payment Terms.

- (a) *Manner of Payment*. All payments to be made by a Party hereunder will be made in U.S. dollars by wire transfer to such bank account as the other Party may designate.
- (b) Reports and Payments of Cash Profits or Losses. For as long as payments are due under this Section 9, Merck or Moderna will furnish to the other Party, as applicable, a written report, after the end of each Calendar Quarter, showing the amount of Cash Profits or Losses and each Party's allocation of the Cash Profits or Losses in accordance with **Exhibit D** and **Exhibit E**, and any other payments accrued during such Calendar Quarter.

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(c) Records; Audits. Each Party will keep, and will cause each of their other Selling Parties, as applicable, to keep adequate books and records of accounting for the purpose of calculating all amounts payable by either Party to the other Party hereunder and ensuring each Party's compliance hereunder. For the [***] following the end of the Calendar Year to which each will pertain, such books and records of accounting (including those of its Affiliates, as applicable) will be kept at each of their principal place of business. At the request of either Party, the other Party will permit (and procure its Affiliates, to permit) an independent certified public accounting firm of internationally recognized standing selected by the auditing Party and reasonably acceptable to the other Party to have access during normal business hours to such of the records as may be reasonably necessary to verify the accuracy of the payments due hereunder for any Calendar Year ending not more than [***] following the end of any Calendar Year. Such examinations may not be conducted more than [***] in any Calendar Year or be repeated for any Calendar Year. The accounting firm shall disclose to the auditing Party only whether the reports are correct or incorrect and the amount of any discrepancy. No other Confidential Information shall be provided. If such accounting firm correctly identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within [***] days of the date of delivery of such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by the auditing Party, provided that if the underpayment or overcharge exceeds [***], the audited Party shall pay the fees. Upon the expiration of [***] following the end of any Calendar Year, absent willful misconduct or fraud by a Party (its Affiliates, as applicable) the calculation of amounts payable with respect to such Calendar Year shall be binding and conclusive upon the Parties, and the Parties shall be released from any liability or accountability with respect to amounts payable for such Calendar Year. The auditing Party shall treat all financial information subject to review under this Section 9.5(c) in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the

audited Party obligating it to retain all such Confidential Information in confidence pursuant to such confidentiality agreement.

(d) *Taxes*. Subject to Section 9.1 and Section 9.3, a Party may deduct or withhold from any payments due to the other Party amounts for payment of any withholding Tax that is required by Law to be paid to any tax authority with respect to such payments. To the extent that any such amounts are so deducted or withheld, such amounts will be treated for all purposes of this Agreement as having been paid to the other Party. The paying Party will give written notice of its intent to withhold any amounts under this Section 9.5(d) at least [***] days in advance of any payment being made. The paying Party will give proper evidence as to the payment of any such Tax within a reasonable amount of time, but in any event within [***] days of payment. The receiving Party will provide the paying Party all necessary documents and correspondence, and will also use commercially reasonable efforts to provide to the paying Party any other cooperation or assistance on a reasonable basis as may be necessary to enable the paying Party to claim exemption from such deduction or withholding Taxes. The Parties will reasonably cooperate with each other in seeking relief or reduction in the deduction or withholding of any Tax under any double Taxation or other similar treaty or agreement from time to time in force and in seeking to receive a refund of any withholding Tax or to claim a foreign Tax credit.

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- (e) Currency Exchange. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due hereunder will be expressed in U.S. dollars. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States Dollars due a Party shall be made at [***].
- (f) Blocked Payments. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for the paying Party (or any other Selling Party) to transfer, or have transferred on its behalf, payments owed the other Party hereunder, the paying Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [***] days, in a recognized banking institution selected by the paying Party or another Selling Party, as the case may be, and identified in a written notice given to the other Party.
- (g) Interest Due. If any payment due to either Party under this Agreement is overdue (and is not subject to a good faith dispute), then such paying Party will pay interest thereon (before and after any judgment) at an annual rate [***] of the lesser of [***] after payment of such sum became due until payment thereof in full together with such interest.
- 9.6 <u>Equity Investment</u>. Moderna and Merck will enter into the Equity Agreement as of the Amended Effective Date.

10. LICENSES; EXCLUSIVITY

10.1 Grants to Merck.

- (a) Licenses During Internal SAV Program Term and POC Term.
- (i) Subject to the terms of this Agreement, solely to the extent Merck conducts any Research activities under a given Internal SAV Program Plan for a Merck Internal SAV Program, during the Internal SAV Program Term for such Merck Internal SAV Program, Moderna, on behalf of itself and its Affiliates, hereby grants to Merck a sublicensable (subject to Section 10.3(a)), worldwide, co-exclusive license (with Moderna and its Affiliates), under the Moderna Technology to perform Research activities under such Internal SAV Program Plan.
- (ii) Subject to the terms of this Agreement, solely to the extent Merck has any Research, Development or Manufacturing obligations under a given POC Plan, during the POC Term for such Program, Moderna, on behalf of itself and its Affiliates, hereby grants to Merck a sublicensable (subject to Section 10.3(a)), worldwide, co-exclusive license (with Moderna and its Affiliates), under the Moderna Technology to perform Research or Development under such POC Plan, or to perform such Manufacturing activities set forth in such POC Plan, Supply Agreement, or **Exhibit K**, or as mutually agreed by the Parties in writing; provided, for clarity, Merck will exercise its rights to Manufacture solely (A) as set forth in the applicable POC Plan, Supply Agreement, or **Exhibit K**, or as mutually agreed by the Parties in writing or

- (b) *Licenses in the Event of a Merck Non-Participation*. Subject to the terms of this Agreement, in the event a Merck Non-Participation for the PCV Program occurs, then, Moderna, on behalf of itself and its Affiliates, hereby grants to Merck [***].
- (c) Licenses Following the Merck Participation Election Date. Subject to the terms of this Agreement, including Sections 10.8, 10.10 and [***], during the Merck Participation Term for a given Program, Moderna, on behalf of itself and its Affiliates, hereby grants to Merck sublicensable (subject to Section 10.3(a)), worldwide licenses, under the Moderna Technology, to:
- (i) Research mRNA Cancer Vaccines for such Program, only under and in accordance with any applicable Additional Research Plan for such Program; provided, however, that [***];
- (ii) Develop Collaboration Products from such Program, under and in accordance with any applicable Joint Development Plan and Budget for such Program or Independent Additional Study Development Plan for such Program;
 - (iii) Commercialize Collaboration Products from such Program in the Territory; and
- (iv) subject to Section 10.1(e), Manufacture Collaboration Products from such Program; provided, for clarity, Merck will exercise its rights to Manufacture any Collaboration Product solely [***];

Subject to Section 10.1(e), the licenses set forth in clauses (i), (ii) and (iv) will be co-exclusive (with Moderna and its Affiliates), and the license set forth in clause (iii) will be exclusive (even as to Moderna and its Affiliates but subject to Sections 8.5 and 8.6).

- (d) Additional Licenses. Subject to the ter ms of this Agreement (including Section 3.1(d), 10.8, 10.10 and [***] and without limiting Section 10.1(b)), Moderna, on behalf of itself and its Affiliates, hereby grants to Merck, [***]:
 - (i) under [***]
 - (ii) under [***]
 - (iii) under [***].
- (e) Retained Rights; Limitations. Notwithstanding the co-exclusive or exclusive licenses set forth in Section 10.1(a) or Section 10.1(c), Moderna retains rights under the Moderna Technology to perform and to have its Affiliates, Sublicensees and Third Party subcontractors, and Third Party licensees (and Moderna will be responsible for ensuring the performance and compliance by such Third Party licensee with the applicable terms of this Agreement as if such Third Party were "Moderna" hereunder), perform Moderna's assigned obligations and responsibilities and exercise its rights under this Agreement (including any Internal SAV Program Plan, POC Plan, any Additional Research Plan or any Development Plan), any Supply Agreement and any Co-Promotion Agreement, provided Moderna complies with Section 10.4 for any such Third Party subcontractors.

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10.2 Grants to Moderna.

- (a) Licenses During Internal SAV Program Term and POC Term.
- (i) Subject to the terms of this Agreement, solely to the extent Moderna conducts Manufacturing activities in accordance with the supply terms set forth in Exhibit N for a given Merck Internal SAV Program, during the Internal SAV Program Term for such Merck Internal SAV Program, Merck, on behalf of itself and its Affiliates, hereby grants to Moderna a sublicensable (subject to Section 10.3(a)), worldwide, coexclusive license (with Merck and its Affiliates), under the Merck Technology to perform Manufacturing activities on SAVs in accordance with the terms set forth in Exhibit N for such Merck Internal SAV Program.
- (ii) Subject to the terms of this Agreement, solely with respect to Moderna's Research, Development and Manufacturing activities under a given POC Plan or, to the extent permitted pursuant to

Section 3.3(d), during the POC Term for such Program, Merck, on behalf of itself and its Affiliates, hereby grants to Moderna a sublicensable (subject to Section 10.3(b)), worldwide, co-exclusive license (with Merck and its Affiliates), under the Merck Technology, to perform Research, Development and Manufacturing activities under the applicable POC Plan or as otherwise provided by Section 3.3(d).

- (b) Licenses in the Event of a Merck Non-Participation. Subject to the terms of this Agreement, in the event a Merck Non-Participation occurs for a given Program [***] then Merck, on behalf of itself and its Affiliates, hereby grants to Moderna [***].
- (c) Licenses Following the Merck Participation Election Date. Subject to the terms of this Agreement, including Sections 10.7, 10.10 and [***], during the Merck Participation Term for a given Program, Merck, on behalf of itself and its Affiliates, hereby grants to Moderna a sublicensable (subject to Section 10.3(b)), worldwide licenses, under the Merck Technology, to:
- (i) Research mRNA Cancer Vaccines for such Program, solely under and in accordance with any applicable Additional Research Plan for such Program; provided, however, that [***];
- (ii) Develop Collaboration Products from such Program, under and in accordance with any applicable Joint Development Plan and Budget for such Program or Independent Additional Study Development Plan for such Program; and
- (iii) subject to Sections 6.2 and 6.3, Manufacture Collaboration Products from such Program in accordance with the applicable Supply Agreements.

Subject to Section 10.2(e), the licenses set forth in clauses (i), (ii) and (iii) will be co-exclusive (with Merck and its Affiliates).

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- (d) Additional Licenses. Subject to the terms of this Agreement (including Section 10.7), Merck, on behalf of itself and its Affiliates, hereby grants to Moderna [***]:
 - (i) under [***];
 - (ii) under [***].
 - (iii) under [***].
- (e) Retained Rights; Limitations. Notwithstanding the co-exclusive licenses set forth in Section 10.2(a) or Section 10.2(c), Merck retains rights under the Merck Technology to perform and to have its Affiliates, Sublicensees and Third Party subcontractors, and Third Party licensees (and Merck will be responsible for ensuring the performance and compliance by such Third Party licensee with the applicable terms of this Agreement as if such Third Party were "Merck" hereunder), perform Merck's assigned obligations and responsibilities and exercise its rights under this Agreement (including any Internal SAV Program Plan, POC Plan, any Additional Research Plan or any Development Plan) or any Supply Agreement, provided Merck complies with Section 10.4 for any such Third Party subcontractors.

10.3 Sublicensing.

- (a) *Merck Sublicensing*. Merck may grant sublicenses under any of the licenses granted to Merck by Moderna under Section 10.1 or to the Rights of Reference granted under this Agreement, (1) to one or more Affiliates (with the right to sublicense through multiple tiers in accordance with this Agreement) without requiring Moderna's prior written consent, (2) to one or more Third Party subcontractors (in accordance with Section 10.4) of Merck (or its Affiliate) to perform the subcontracted activities, [***]; provided that[***], the grant of any such sublicense to an Affiliate or Third Party shall not relieve Merck of its obligations under this Agreement, and Merck will be responsible for ensuring the performance and compliance by such Affiliate or Third Party with the applicable terms this Agreement as if such Affiliate or Third Party were "Merck" and any [***] as if such Affiliate or Third Party were "Merck", in each case, to the extent applicable to such Sublicensee; provided, further, that, as a condition precedent to and requirement of any such sublicense to a Third Party under the foregoing clauses [***]:
 - (i) such sublicense is set forth in a written agreement;

- (ii) Merck will provide Moderna with a copy of any such sublicense agreement and each material amendment thereto within [***] days of execution thereof, which may be redacted as necessary to protect confidential information and other commercially sensitive information; and
- (iii) such sublicense agreement shall be consistent with and subject to the applicable terms and conditions of this Agreement.
- (b) *Moderna Sublicensing*. Moderna may grant sublicenses under any of the licenses granted to Moderna by Merck under Section 10.2 or Section 10.10 or to the Rights of Reference granted under this Agreement (1) to one or more Affiliates (with the right to sublicense through multiple tiers in accordance with this Agreement) without requiring Merck's

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prior written consent, (2) to one or more Third Party subcontractors (in accordance with Section 10.4) of Moderna (or its Affiliate) to perform the subcontracted activities, [***]; provided that, [***], the grant of any such sublicense to an Affiliate or Third Party shall not relieve Moderna of its obligations under this Agreement, and Moderna will be responsible for ensuring the performance and compliance by such Affiliate or Third Party with the applicable terms this Agreement as if such Affiliate or Third Party were "Moderna" and any Included Merck In-License as if such Affiliate or Third Party were "Moderna", in each case, to the extent applicable to such Sublicensee; provided, further, that, as a condition precedent to and requirement of any such sublicense to a Third Party under the foregoing clauses [***]:

- (i) such sublicense is set forth in a written agreement;
- (ii) Moderna will provide Merck with a copy of any such sublicense agreement and each material amendment thereto within [***] days of execution thereof, which may be redacted as necessary to protect confidential information and other commercially sensitive information; and
- (iii) such sublicense agreement shall be consistent with and subject to the applicable terms and conditions of this Agreement.
- 10.4 Subcontractors. Each Party may subcontract any of its Research, Development or Manufacturing activities to be performed hereunder to an Affiliate or, solely with the prior written consent of the other Party (such consent not to be unreasonably withheld), to a Third Party; provided, however, that in all cases, such Party shall ensure that any such Third Party permitted subcontractor will have entered into a written agreement with such Party that includes terms and conditions protecting and limiting use and disclosure of Confidential Information and Know-How at least to the same extent as under this Agreement, and such Party shall require any such Affiliate or Third Party and its personnel to assign to such Party all right, title and interest in and to any Patents or Know-How created, conceived or discovered in connection with the performance of any subcontracted activities; provided, however, that a Party shall be entitled to [***]. Notwithstanding the foregoing, each Party shall be permitted to (x) utilize Third Party permitted subcontractors that are identified on Exhibit L-1 with respect to such Party, which exhibit lists the identity of the applicable Third Party subcontractor and a description of the activities that such Third Party subcontractor is authorized to perform hereunder and also with respect to Merck any other Manufacturing Subcontractor, and (y) subcontract or otherwise agree to perform any Development activities to be performed under an Independent Additional Study Development Plan to any Third Party, in each case, without requiring the prior written consent of the other Party, subject to Section 10.12 and also allowing for customary and reasonable provisions for the treatment of sharing of resulting data and the performance of the Independent Additional Study (other than to any Third Party that is a direct competitor in the mRNA therapeutic/vaccine field (for example, as of the Amended Effective Date, the Third Parties listed on Exhibit L-2), which subcontract will require such other Party's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed) and (z) Merck may subcontract any of its Commercialization activities to be performed hereunder to (1) an Affiliate or (2) a Third Party. Each Party shall oversee the performance by any of its Affiliate or Third Party permitted subcontractors, and shall remain responsible and primarily liable for the performance of such activities in accordance with this Agreement. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance hereunder, prior to proceeding directly against the Party engaging the subcontractor.

- 10.5 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, are, and will be deemed to be for all purposes of Section 365(n) of Title 11 of the United States Code and of any similar provisions of applicable Laws under any other jurisdiction (the "Bankruptcy Code"), rights and licenses to "intellectual property" (as defined in Section 101(35A) of the Bankruptcy Code). Each Party agrees that the other Party, as a licensee of rights and licenses under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code or analogous provisions of applicable Law outside the U.S., the other Party will be entitled to a complete duplicate of, or complete access to (as appropriate), any intellectual property licensed to such other Party held by such first Party and its successors and assigns (including all embodiments thereof), which, if not already in such other Party's possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless such first Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a), following the rejection of this Agreement by such first Party in the bankruptcy proceeding upon written request therefor by such other Party.
- 10.6 <u>Third Party In-Licenses</u>. The terms and conditions for the inclusion and treatment under the Collaboration of Patents and Know-How in-licensed by a Party pursuant to Third Party In-Licenses are set forth on **Exhibit F**.
 - 10.7 Moderna Exclusivity.
 - (a) [***]
 - (i) [***]
 - (ii) [***]
 - (b) mRNA-PCV Field.
 - (i) During the POC Term for the PCV Program, Moderna will not, [***].
 - (ii) During the Merck Participation Term for the PCV Program, Moderna will not, [***].
 - (c) SAV Research Term Exclusivity. During the SAV Research Term, Moderna will not, [***].
 - (d) [***] Exclusivity.

- (i) On a Joint SAV Program-by-Joint SAV Program basis, during the POC Term for such Joint SAV Program, [***].
 - (ii) [***], during the Merck Participation Term for such Joint SAV Program, [***].
 - (iii) [***], during the POC Term and any Merck Participation Term (as applicable) [***].
 - (iv) [***]
 - (e) Exception for Business Combination.
- (i) Notwithstanding Sections [***], if a Business Combination occurs with respect to Moderna or its parent Affiliate with a Third Party, and the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than Moderna and its Affiliates as of the Business Combination) has as of the Business Combination, or later has, a program (or rights thereto) that would otherwise violate any of [***] "Moderna Business Combination Program"), then [***]; provided that [***]. In addition, upon any such Business Combination of Moderna or its parent Affiliate, the following shall apply:
- (1) At Merck's written election within [***] after the closing date of such Business Combination of Moderna or its parent Affiliate, [***];
- (2) If, within the period from [***] after the closing of such Business Combination until [***] of such closing, [***].
- (ii) In addition to the other provisions of this Section 10.7(e), Merck shall have the right to [***].

(iii) In addition, notwithstanding [***], if (A) Moderna or its Affiliate acquires a Third Party (by merger, consolidation or otherwise) so that such Third Party becomes an Affiliate over which Moderna or its Affiliate has control (as defined in Section 1.13), or (B) Moderna or its Affiliate acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof) (each of (A) and (B), a "Moderna Acquisition"), and, in each case, the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than Moderna and its Affiliates as of the Moderna Acquisition) already has, or the acquired assets contain, as applicable, a program that existed prior to, or was substantially in the process of being implemented prior to such Moderna Acquisition and is in fact implemented shortly after such Moderna Acquisition, the Moderna Acquisition that would otherwise violate any of [***] (a "Moderna Acquisition Program"), then Moderna or such Affiliate will, within thirty (30) days after the closing of such Moderna Acquisition, provide written notice to Merck that Moderna or such Affiliates has rights to a Moderna Acquisition Program as a result of a Moderna Acquisition, which written notice will [***]. Alternatively, [***].

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(f) Non-Restricted Activities.

- (i) The Parties hereby acknowledge and agree that Moderna's obligations under [***] will not apply to any Research, Development, Manufacture or Commercialization of [***]; provided that Moderna will ensure that during the Collaboration Term for the PCV Program, [***].
- (ii) The Parties hereby acknowledge and agree that Moderna's obligations under [***] will not apply to any of Moderna's or its Affiliates' (1) internal Research activities, (2) Research activities with academic collaborators or non-profit institutions, or (3) Non-Commercial Combination Activities, in each case ((1)-(3)) that [***]; provided that, in each case ((1)-(3)), Moderna will ensure that during the Collaboration Term for a given SAV Program, (A) [***], (B) Merck Confidential Information is [***], (C) Merck Background Technology is [***], and (D) the licenses granted under Section 10.2(d)(i) or 10.2(d)(ii) shall not be used in the conduct of the above-referenced activities relating to [***].

10.8 Merck Exclusivity.

- (a) mRNA-PCV Field.
 - (i) During the POC Term for the PCV Program, Merck will not, [***]).
 - (ii) During the Merck Participation Term for the PCV Program, Merck will not, [***].
- (b) SAV Research Term Exclusivity. During the SAV Research Term, [***].
- (c) [***] *Exclusivity*.
 - (i) [***], during the POC Term for such Joint SAV Program, [***].
 - (ii) [***], during the Merck Participation Term for such Joint SAV Program, [***].
 - (iii) [***], during the POC Term and any Merck Participation Term (as applicable[***].
 - (iv) [***]
- (d) Exception for Business Combination.
- (i) Notwithstanding Section [***], if (i) a Business Combination occurs with respect to Merck or its Affiliate with a Third Party, and the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than Merck and its Affiliates as of the Business Combination) has as of the Business Combination, or later has, a program (or rights thereto) that would otherwise violate any of [***] (each, a "Merck Business Combination Program"), then [***]; provided that [***].

Acquisition"), and, in each case, the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than Merck and its Affiliates as of the Merck Acquisition) already has, or the acquired assets contain, as applicable, a program that existed prior to, or was substantially in the process of being implemented prior to such Merck Acquisition and is in fact implemented shortly after such Merck Acquisition, the Merck Acquisition that would otherwise violate any of [***] (a "Merck Acquisition Program"), then Merck or such Affiliate will, within thirty (30) days after the closing of such Merck Acquisition, provide written notice to Moderna that Merck or such Affiliates has rights to a Merck Acquisition Program as a result of a Merck Acquisition, which written notice will [***]. Alternatively, [***].

(e) Non-Restricted Activities.

- (i) The Parties hereby acknowledge and agree that Merck's obligations under [***] will not apply to any Research, Development, Manufacture or Commercialization of [***]; provided that Merck will ensure that during the Collaboration Term for the PCV Program, [***].
- (ii) The Parties hereby acknowledge and agree that Merck's obligations under [***] will not apply to any of Merck's or its Affiliates' (1) internal Research activities, (2) Research activities with academic collaborators or non-profit institutions, or (3) Non-Commercial Combination Activities, in each case ((1)-(3)) that [***]; provided that, in each case ((1)-(3)), Merck will ensure that during the Collaboration Term for a given SAV Program, (A) [***], (B) Moderna Confidential Information is [***], (C) Moderna Background Technology is [***], and (D) the licenses granted under Section 10.1(d) shall not be used in the conduct of the above-referenced activities relating [***].
- 10.9 No Grant of Inconsistent Rights. Neither Party nor its Affiliates shall assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise, but excluding liens in connection with financings) any rights to any Moderna Technology or Merck Technology (or any rights to any intellectual property that would otherwise be included in the Moderna Technology or Merck Technology), as applicable, in any manner that is inconsistent with or would interfere with the grant of the rights or licenses to Merck or Moderna hereunder. For the avoidance of doubt, the Parties understand and agree that the Merck Participation Election right for a given Program, as described herein, shall be [***].
- 10.10 Merck Cessation of Collaboration Activities. Notwithstanding anything to the contrary set forth herein, on a Program-by-Program basis, at any time during the Merck Participation Term for a given Program, Merck shall have the right, but not the obligation, to elect to cease performance of activities under the Collaboration with respect to such Program upon delivery of [***] prior written notice to Moderna (each, a "Merck Cessation Election"). Each Merck Cessation Election for a given Program shall clearly identify [***]. Subject to the terms of this Agreement, upon the exercise of a Merck Cessation Election for a given Program, the following shall apply:

- (a) The Merck Participation Term, the Collaboration Term and the Collaboration for such Program shall terminate, and all Collaboration Products from such Program then in existence will be treated thereafter as "PCVs" or "SAVs", as applicable, under this Agreement (other than [***]). Merck shall no longer have any licenses or other rights under this Agreement (without limiting the license grants in Section 10.1(d)) to Research, Develop, Manufacture and Commercialize Collaboration Products from such Program under this Agreement. [***]
- (b) Merck will prepare and provide to Moderna a draft plan for the transition of Collaboration Activities with respect to such Program from Merck to Moderna (a "Cessation Transition Plan"), which Cessation Transition Plan will be reviewed and approved by the Parties. Each Party will use Commercially Reasonable Efforts to perform the obligations assigned to it under the Cessation Transition Plan in accordance with the timelines set forth therein.
- (c) The license grants to Merck under Section 10.1(b) with respect to such Program shall terminate. Each sublicense granted by Merck to any rights licensed to it under Section 10.1(c) with respect to such Program shall terminate. The license grants set forth in Section 10.1(d) shall continue in full force and effect.
- (d) The license grants to Moderna under Section 10.2(c) with respect to such Program shall terminate, and each sublicense granted by Moderna to any rights licensed under Section 10.2(c) shall terminate. Effective as of the date of the Merck Cessation Election for such Program, Merck shall grant, and hereby does grant (without any further action on the part of either Party), on behalf of itself and its Affiliates, to Moderna a

sublicensable (subject to Section 10.3(b)), worldwide, perpetual, irrevocable exclusive license under the Merck Technology, to Research, Develop, Manufacture and Commercialize the Collaboration Products from such Program in the Territory, and the license grants set forth in Section 10.2(d) shall continue in full force and effect.

- (e) In the event of a Merck Cessation Election for the PCV Program, the exclusivity provisions in Sections [***] shall terminate for the PCV Program.
- (f) In the event of a Merck Cessation Election for a given Joint SAV Program, then the exclusivity provisions in Sections [***] shall terminate with respect to such Joint SAV Program.
- (g) At Moderna's election, Merck will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, any on-going Clinical Studies with respect to Collaboration Products from such Program then in existence in [***] or, if requested by Moderna, Merck will transfer responsibility for any such Clinical Study to Moderna, in each case in accordance with the Cessation Transition Plan. Merck will be responsible for payment of any costs associated with such wind-down or transfer. [***].

- (h) As promptly as practicable after the date of the Merck Cessation Election for a given Program, Merck and its Affiliates shall, to the extent Merck and its Affiliates have the right to do so under applicable Law, assign and transfer to Moderna or Moderna's designee possession and ownership of all material Regulatory Filings, Regulatory Approvals, all final pre-clinical and Clinical Study reports and clinical study protocols, and all data, including non-clinical and Clinical Data, in each case, in Merck's possession and Control and to the extent solely related to Collaboration Products from such Program then in existence. All data and other information shall be transferred in the form and format in which it is maintained by Merck or its Affiliate. Original paper copies shall only be transferred, if required by applicable Law. Merck and its Affiliates shall not be required to [***]. At Merck's election, for such Program, Merck shall either [***]. In the event of failure to obtain assignment of any of the items required to be assigned under this Section 10.10(h), Merck hereby consents and grants to Moderna or its designee the right to access and reference (without any further action required on the part of Merck, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item to the extent solely related to Collaboration Products from such Program.
- (i) Subject to the terms of the applicable Cessation Transition Plan, Merck and its Affiliates shall [***].
- (j) Merck will promptly transfer and assign to Moderna all of Merck's and its Affiliates' rights, title and interests in and to the trademark(s) solely used to identify the Collaboration Products from such Program then in existence (but not any house marks, or logos or any trademark of Merck or its Affiliates, containing the word "Merck" or any such Affiliate) owned by Merck and used for the Collaboration Products from such Program then in existence.
- (k) Subject to the applicable Cessation Transition Plan, Merck will transfer to Moderna any finished goods inventory of Collaboration Products from such Program then in existence Controlled by Merck or its Selling Parties as of the date of the Merck Cessation Election for such Program (if any) at cost for such supply. [***]
- (l) For any Collaboration Product from such Program then being Developed in a Clinical Study pursuant to this Agreement in combination with [***] or any Merck Agent that is commercially available:
- (i) Merck will grant to Moderna a Right of Reference [***] to continue the Development of such Collaboration Products from such Program in combination with [***] or such Merck Agent (as applicable) under appropriate Regulatory Filings or Regulatory Approvals.
- (ii) Merck shall supply [***] or such Merck Agent (as applicable) to Moderna in accordance with **Exhibit K** for further Clinical Studies of such Collaboration Products from such Program in combination with [***] or such Merck Agent until Regulatory Approval for such Collaboration Product, but in any event [***]. Moderna shall provide Merck with a copy of any data generated from any such Clinical Study for Merck's use in connection with [***] or such Merck Agent, and in all cases, if Moderna is conducting a Clinical Study involving [***], the provisions of Section 3.4(m) shall apply *mutatis mutandis*.

(m) The Parties' rights and obligations under [***] shall terminate in full with respect to such Program and the Collaboration Products thereunder (provided that for clarity, this Agreement shall remain in full force and effect for all other Programs and Collaboration Products). [***]. In addition, on a Program-by-Program basis, if, as of the date of the Merck Cessation Election for such Program, a Party is granting a sublicense to the other Party under an Included In-License for such Program, and such sublicense under such Included In-License survives the Merck Cessation Election for such Program pursuant to this Section 10.10, then, (i) the Party receiving such sublicense under such Included In-License shall [***] and (ii) such Party's rights under such Included In-License will be subject to the terms of such Included In-License; provided that in each case of (i) and (ii), the licensor Party promptly informs the other Party of any [***].

(n) [***] 10.11 [***]. (a) [***] (b) [***]

- 10.12 Exclusion of Agent Intellectual Property.
- (a) Notwithstanding any other provision of this Agreement, "Moderna Background Know-How", "Moderna Background Patents", "Merck Background Know-How" and "Merck Background Patents" shall not include any Know-How, Patents or other rights, and no licenses shall or are granted hereunder, with respect to [***] or any Moderna Agent, Merck Agent or Third Party Agent, including any Agent Technology, other than [***].
 - (b) Further, notwithstanding Sections 11.2 through 11.4, [***].
- 10.13 Supply and Use of Materials; Cooperation. At the reasonable request of the other Party, a Party will supply the other Party Materials Controlled by such Party for Research consistent with and in furtherance of the POC Plan, Joint Development Plan and Budget or Additional Research Plan for a given Program, as applicable. Each Party will use any Materials provided by the other Party hereunder only in accordance with the POC Plan, Joint Development Plan and Budget or Additional Research Plan for the applicable Program, and otherwise in accordance with the terms and conditions of this Agreement (including for clarity in connection with activities conducted by the Parties during the Merck Participation Election Period for a given Program in connection with the Research, Development, Manufacture or Commercialization of the Collaboration Products from such Program), the use limitations agreed to by the Parties and any reasonable instructions provided by the Party furnishing the Materials. Except with the prior written consent of the supplying Party (such consent not to be unreasonably withheld, delayed or conditioned), the Party receiving any Materials will not distribute or otherwise allow the release of such Materials to any Third Party, except for subcontracting as permitted hereunder or otherwise in connection with the Research, Manufacture, Development and Commercialization of Collaboration Products by the Parties hereunder, to the extent consistent with the use limitations agreed to by the Parties. All Materials delivered to the receiving Party will be used in compliance with all applicable Law. The

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Materials supplied under this Agreement will be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. The receiving Party shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the provider's Materials, and in particular shall not analyze the provider's Materials by physical, chemical or biochemical means except as necessary to perform its obligations under this Agreement.

11. OWNERSHIP OF TECHNOLOGY

- 11.1 <u>Disclosure</u>. Subject to Section 6.1(e), each Party will promptly disclose to the other Party in writing, and will cause its Affiliates and subcontractors to so disclose, the conception, creation or discovery of any Collaboration Know-How.
- 11.2 Ownership of Moderna Agent Technology[***]. Subject to the license grants to Merck under this Agreement, as between the Parties, Moderna will own and retain all right, title and interest in and to all (a) improvements, modifications, developments, enhancements and inventions arising in the performance of

activities hereunder from the use of, and specifically relating to, any Moderna Agent or their use (collectively "Moderna Agent Technology"), [***] conceived, created or discovered during the performance of Collaboration Activities. Accordingly, Merck will promptly disclose to Moderna in writing, the conception, creation, or the discovery, of any Moderna Agent Technology, [***] by or on behalf of Merck or its Affiliates. Merck, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Moderna all its right, title and interest in and to any Moderna Agent Technology, [***]. Merck will cooperate, and will cause the foregoing persons and entities to cooperate, with Moderna to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership.

- 11.3 Ownership of Merck Agent Technology [***]. Subject to the license grants to Moderna under this Agreement, as between the Parties, Merck will own and retain all right, title and interest in and to all (a) improvements, modifications, developments, enhancements and inventions arising in the performance of activities hereunder from the use of, and specifically relating to, Keytruda or any Merck Agent or their use (collectively, "Merck Agent Technology") [***] conceived, created or discovered during the performance of Collaboration Activities. Accordingly, Moderna will promptly disclose to Merck in writing, the conception, creation or discovery of any Merck Agent Technology [***] by or on behalf of Moderna or its Affiliates. Moderna, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to Merck all its right, title and interest in and to any Merck Agent Technology [***]. Moderna will cooperate, and will cause the foregoing persons and entities to cooperate, with Merck to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership.
- 11.4 Ownership of [***]; Joint Technology. Subject to the license grants by one Party to the other under this Agreement, as between the Parties, all [***] conceived, created or discovered, by or on behalf of either Party or its Affiliates either alone or jointly with Third Party(ies), or by the Parties or their Affiliates jointly under or in connection with this Agreement,

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whether or not conceived, created or discovered at a facility owned or controlled by such Party and whether or not patented or patentable (including any and all Patents and other intellectual property rights with respect thereto), will be owned in accordance with inventorship and in accordance with applicable Law in the United States. For the avoidance of doubt, subject to Section 11.6, and to the license grants in this Agreement, the Parties will each own an equal, undivided interest in any and all Joint Technology. Each Party will, and does hereby, assign, and will cause its Affiliates and subcontractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Joint Technology as well as any intellectual property rights with respect thereto, as is necessary to fully effect the joint ownership provided for in the foregoing sentence of this Section 11.4.

- 11.5 <u>United States Law</u>. The determination of whether Know-How and Patents are conceived, created or discovered by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, in accordance with Section 11.4, will, for purposes of this Agreement, be made in accordance with applicable Law in the United States. In the event that United States Law does not apply to the conception, creation or discovery of any Know-How or Patents hereunder, each Party will, and does hereby, assign, and will cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How and Patents as well as any intellectual property rights with respect thereto, as is necessary to fully effect ownership as would have been determined under U.S. Law.
- 11.6 Exploitation of Joint Technology. Each Party will exercise its ownership rights in and to the Joint Technology, including the right to license and sublicense or otherwise to exploit, transfer or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to Section 12 and the license grants under this Agreement. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Technology.
- 11.7 No Implied Rights. No license, sublicense or other right is or will be created or granted hereunder by implication, estoppel or otherwise. Any licenses, sublicenses or rights will be granted only as expressly provided in this Agreement. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

11.8 <u>Patent Prosecution, Maintenance and Enforcement</u>. Provisions regarding the Prosecution and Maintenance of Patents, and enforcement of Patents, are set forth in **Exhibit J.**

12. CONFIDENTIALITY

12.1 Confidential Information.

(a) Confidential Information. Each Party ("<u>Disclosing Party</u>") may have disclosed or will disclose to the other Party ("<u>Receiving Party</u>"), and Receiving Party may acquire during the course and conduct of activities under this Agreement, certain proprietary or confidential information of Disclosing Party. The term "<u>Confidential Information</u>" means (i) all

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proprietary tangible samples of, and confidential information about, Materials and (ii) all confidential ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available to Receiving Party by Disclosing Party or at the request of Receiving Party. Without limiting the foregoing, all confidential information about (1) the Moderna Technology will be considered Confidential Information of Moderna, (2) the Merck Technology will be considered Confidential Information of Merck, (3) Joint Technology will be treated as Confidential Information of both Parties, and (4) the Collaboration Products from a given Program will be treated as Confidential Information of both Parties during the Collaboration Term for such Program. For the avoidance of doubt, the restrictions and limitations set forth in this Section 12 shall not limit any other restrictions or limitations set forth herein with respect to the use and disclosure of information.

- (b) Restrictions. During the Term and for [***] thereafter, Receiving Party will, and will cause its Affiliates and their respective officers, directors, employees and agents to, keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (though no less than reasonable care). Receiving Party will not use, and will cause its Affiliates and their respective officers, directors, employees and agents not to use, Disclosing Party's Confidential Information except for in connection with the performance of its obligations and exercise of its rights under this Agreement. Subject to the terms of this Agreement, Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent, to the extent and only to the extent reasonably necessary or useful, to Receiving Party's Affiliates and their employees, subcontractors, Sublicensees, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are required to comply with restrictions on use and disclosure similarly restrictive as those in this Section 12.1(b). Receiving Party will use [***] to cause those entities and persons to comply with such restrictions on use and disclosure. Notwithstanding the foregoing sentence, Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.
- (c) Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information set forth in Section 12.1(b) will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (i) was known to Receiving Party or any of its Affiliates prior to the time of disclosure; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (iii) is obtained by Receiving Party or any of its Affiliates from a Third Party under no obligation of confidentiality to Disclosing Party; or (iv) has been independently developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the aid, application or use of Disclosing Party's Confidential Information, as evidenced by contemporaneous written records. Notwithstanding the foregoing, (A) any Confidential Information will not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information in the public domain or in the possession of the Receiving Party or any of its Affiliates, and (B) any combination of features will not be deemed to be within the foregoing exceptions merely because individual features are in the public domain or in the possession of the Receiving Party or any of its Affiliates, but only if the combination itself and its principle of operation are in the public domain or in the possession of the Receiving Party or any of its Affiliates.

- (d) *Permitted Disclosures*. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
 - (i) in order to comply with applicable Law or with a legal or administrative proceeding;
- (ii) in connection with (a) prosecuting or defending litigation or (b) the Prosecution and Maintenance of Patents in accordance with this Agreement;
- (iii) in connection with exercising any rights or other licenses under this Agreement, including [***];
 - (iv) in the case of Merck, [***]; and
 - (v) in the case of Moderna, [***].

In the case of a disclosure pursuant to (A) Sections [***], where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure [***], and (B) with respect to [***], each of those named people and entities are required to comply [***], the Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

12.2 <u>Publications</u>. The Parties may desire to publish in scientific journals and present at scientific conferences the results of the Collaboration Activities, subject to the following process. Notwithstanding anything to the contrary herein, either Party may propose publication of the results of the Collaboration Activities following scientific review by the JSC (if in force); *provided*, that no such publication will be made without written approval by Moderna and Merck. After receipt of the proposed publication by both Merck and Moderna, such written approval or disapproval will be provided within [***] days. Both Parties understand that a reasonable commercial strategy may require delay of publication of information or filing of Patent applications, therefore the Parties agree to review and consider delay of publication and filing of patent applications under certain circumstances for a reasonably limited period of time. Once publications have been reviewed by each Party and have been approved for publication, the same publications do not have to be provided again to the other Party for review for a later submission for publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Parties. Each Party will acknowledge the other Party's technical, non-financial contributions in any such publication.

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12.3 Terms of this Agreement; Publicity.

- (a) *Restrictions*. The Parties agree that the terms of this Agreement and the Equity Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 12.1(d). Each Party will also be permitted to disclose the terms of this Agreement and any Supply Agreement (including the exhibits hereto and thereto), in each case under appropriate confidentiality provisions, on a need to know basis, to a Party's (and its Affiliates') existing investors and equity holders and to [***], provided that (1) the disclosing Party agrees to redact information that it reasonably believes is not relevant to the proposed transaction, and (2) [***]. Except as required by applicable Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement, the transactions contemplated hereby or any of the terms hereof without the prior written consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), or as such consent may be obtained in accordance with Section 12.1(c), or as permitted by Section 12.1(d).
- (b) Securities Filings; Law. Each Party acknowledges and agrees that the other Party may submit this Agreement (including for clarity, the Exhibits and Schedules hereto) to the United States Securities and Exchange Commission (the "SEC") or any other securities exchange and if a Party does submit this Agreement to the SEC or any other securities exchange, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. If a Party is required by applicable Law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC or any other securities exchange or otherwise to comply with Law, and (i) such Party has provided copies of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably

practicable under the circumstances, (ii) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (iii) such Party has given the other Party a reasonable amount of time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by Law. [***]

(c) Press Releases. Neither Party may issue any press release or make any other public announcement or statement concerning this Agreement, the transactions contemplated hereby or the terms hereof, without the prior written approval of the other Party, except as may be required by applicable Law. In the event either Party (the "Issuing Party") desires to issue a press release or other public statement disclosing information relating to this Agreement, the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the "Reviewing Party") with a copy of the proposed press release or public statement (the "Release") and seek the Reviewing Party's prior written consent; provided that no such consent shall be required for press releases or other public statements required by Law (but the Issuing Party shall still provide the Reviewing Party with a copy of the Release for comment in accordance with this Section 12.3(c)). The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such Release and if the Receiving Party fails to provide any comments during the response period called for by the Issuing Party, the Reviewing Party will be deemed to have not consented to the issuance of such Release. If the Receiving Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release so consented to.

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(d) Joint Press Release. The Parties agree to issue the joint press release in **Exhibit I** promptly following Antitrust Clearance Date; provided that (i) if either Party reasonably believes that there should be revisions to the form of press release in **Exhibit I** as a result of events or circumstances occurring after the Amended Effective Date but prior to the issuance of such press release, then prior to the issuance of the joint press release, the Parties will work in good faith and mutually agree on revisions to the joint press release in **Exhibit I** to reflect such events or circumstances and (ii) prior to the issuance of the joint press release in **Exhibit I**, either Party shall have the right, upon notice to the other Party, to propose revisions to any quotes from such Party's personnel in the press release set forth in **Exhibit I**, and the other Party shall not unreasonably withhold consent to such revisions.

13. REPRESENTATIONS AND WARRANTIES; LIMITATIONS OF LIABILITY; INDEMNIFICATION; COVENANTS

- 13.1 <u>Representations and Warranties of Each Party</u>. Each Party represents and warrants to the other as of the Effective Date and as of the Amended Effective Date that:
- (a) Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.
- (b) Such Party (i) has the legal right and power to enter into this Agreement, to extend the rights granted or to be granted to the other in this Agreement, and to fully perform its obligations hereunder, including to grant the licenses set forth herein, and (ii) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation, enforceable against such Party in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization or other laws affecting creditors' rights generally and by general equitable principles.
- (c) Neither such Party nor its Affiliates has been debarred or is subject to debarment. Neither it nor its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any person who has been debarred pursuant to Section 306 of the Act, or who is the subject of a conviction described in such section. In addition, neither it nor its Affiliates has used in any capacity, in connection with any Research or Development activities with respect to the mRNA Technology or any Collaboration Product included hereunder carried out prior to the Amended Effective Date, any person who has been debarred or was the subject of a conviction described in Section 306 of the Act. Such Party agrees to inform the other Party in writing immediately if it or any person who is performing services under this Agreement is debarred or is the subject of a conviction described in Section 306 of the Act, or if any action, suit, claim, investigation or legal or

administrative proceeding is pending or, to the best of such Party's or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of such Party or any person performing services under this Agreement.

(d) All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party to enter into, or perform its obligations under, this Agreement have been obtained.

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- (e) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) will not conflict with or violate any requirement of applicable Law or orders of governmental bodies, (ii) do not conflict with, or constitute a default under, any contractual obligation of such Party and (iii) do not conflict with or violate any provision of the corporate charter, by-laws or other organizational documents of such Party.
- 13.2 <u>Additional Representations of Moderna</u>. Moderna represents and warrants to Merck that as of the Effective Date and the Amended Effective Date; provided, for clarity, that Moderna has made representations and warranties with respect to SAVs solely as of the Amended Effective Date:
- (a) there are no actions, judgments or settlements against or owed by Moderna (or any of its Affiliates) and to Moderna's Knowledge, no threatened claims or litigation relating to the Moderna Background Patents and/or Moderna Background Know-How;
- (b) <u>Schedule 1.235</u> sets forth a true, correct and complete list of Moderna Background Patents and such schedule contains all application numbers and filing dates, registration numbers and dates, jurisdictions and owners. [***]
- (c) to Moderna's Knowledge (i) all Patents within the Moderna Background Patents have been procured or are being procured from the respective patent offices in accordance with applicable Law, and (ii) the issued Patents within the Moderna Background Patents are not invalid or unenforceable, in whole or in part;
- (d) it (and its Affiliates) has not prior to the Amended Effective Date (i) assigned, transferred or conveyed its right, title and/or interest in Moderna Background Patents or Moderna Background Know-How, or (ii) otherwise granted any rights to any Third Parties that would, in the case of clauses (i) and/or (ii), conflict with the rights granted to Merck hereunder, and, to Moderna's Knowledge, there is no unauthorized use, infringement or misappropriation of any Moderna Background Patent or Moderna Background Know-How;
- (e) it or its Affiliate is the sole and exclusive owner of the Moderna Background Patents and Moderna Background Know-How, all of which are as of the Amended Effective Date free and clear of any liens, charges and encumbrances (excluding those entered into the ordinary course of financing its business), and no other Person has as of the Amended Effective Date any claim of ownership whatsoever with respect to the Moderna Background Patents and Moderna Background Know-How;
 - (f) [***]
 - (g) [***]
- (h) there are no agreements to which Moderna or its Affiliates are a party (including any licenses), granting any licenses or other rights to (or from) Moderna (or any of its Affiliates) relating to the Research, Development, Manufacture and Commercialization of mRNA Cancer Vaccines (including Collaboration Products) as contemplated hereunder; and
 - (i) [***]
 - (j) [***]

- 13.3 <u>Additional Representations of Merck</u>. Merck represents and warrants to Moderna that as of the Effective Date and the Amended Effective Date; provided, for clarity, that Merck has made representations and warranties with respect to SAVs solely as of the Amended Effective Date:
- (a) there are no actions, judgments or settlements against or owed by Merck (or any of its Affiliates) and to Merck's Knowledge, no threatened claims or litigation relating to the Merck Background Patents and/or Merck Background Know-How;

- (b) [***]
- (c) [***]
- (d) there are no agreements to which Merck or its Affiliates are a party (including any licenses), granting any licenses or other rights to (or from) Merck (or any of its Affiliates) relating to the Research, Development, Manufacture or Commercialization of mRNA Cancer Vaccines (including Collaboration Products) as contemplated hereunder.
- 13.4 <u>Disclaimers</u>. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT THE COLLABORATION ACTIVITIES OR ANY MRNA CANCER VACCINE OR COLLABORATION PRODUCT WILL BE SUCCESSFUL, IN WHOLE OR IN PART. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR ANY SUPPLY AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY MRNA TECHNOLOGY, MRNA CANCER VACCINE TECHNOLOGY, PATENTS OR KNOW-HOW, MRNA CANCER VACCINES OR COLLABORATION PRODUCTS, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS, TITLE, QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS.
- 13.5 No Consequential Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT, EXCEPT FOR DAMAGES DUE TO THE FRAUD OR WILLFUL MISCONDUCT OR GROSS NEGLIGENCE OF THE LIABLE PARTY, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED, THAT THIS SECTION 13.5 WILL NOT APPLY TO THE PARTIES' INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 13.6.

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13.6 Indemnification and Liability.

- (a) *Indemnification by Merck*. Merck will indemnify Moderna, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, "Moderna Indemnitees"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "Third Party Claims") arising from or occurring as a result of: [***], except in each case [***] for those Losses and Third Party Claims for which Moderna has an obligation to indemnify Merck pursuant to Section 13.6(b) (or would have had such Third Party Claim been made against Merck under this Agreement), as to which Losses each Party will indemnify the other to the extent of their respective liability; provided, that Merck will not be obligated to indemnify Moderna Indemnitees for any Losses or Third Party Claims to the extent that such Losses or Third Party Claims arise as a result of gross negligence or willful misconduct on the part of a Moderna Indemnitee or breach of this Agreement by Moderna.
- (b) *Indemnification by Moderna*. Moderna will indemnify Merck, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, "Merck Indemnitees"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: [***] except in each case ((i)-(vii)) for those Losses and Third Party Claims for which Merck has an obligation to indemnify Moderna pursuant to Section 13.6(a) (or would have had such Third Party Claim been made against Moderna under this Agreement), as to which Losses each Party will indemnify the other to the extent of their respective liability for the Losses; provided, that Moderna will not be obligated to indemnify Merck Indemnitees for any Losses or Third Party Claims to the extent that such Losses or Third Party Claims arise as a result of gross negligence or willful misconduct on the part of an Merck Indemnitee or breach of this Agreement by Merck.

(c) *Notice of Claim*. All indemnification claims provided for in Section 13.6(a) and Section 13.6(b) will be made solely by such Party to this Agreement (the "<u>Indemnified Party</u>"). The Indemnified Party will promptly notify the indemnifying Party (an "<u>Indemnification Claim Notice</u>") of any Losses or the discovery of any fact upon which the Indemnified Party intends to base a request for indemnification under Section 13.6(a) or Section 13.6(b), but in no event will the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and estimated amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims. Notwithstanding the foregoing, any delay or failure to provide any notices or copies pursuant to this Section 13.6(c) shall not constitute a waiver or release of, or otherwise limit, the Indemnified Party's rights to indemnification under this Section 13.6 except to the extent that such delay or failure materially prejudices the indemnifying Party's ability to defend against the relevant claims.

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(d) Defense, Settlement, Cooperation and Expenses.

- (i) At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party will not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party (the indemnifying Party will consult with the Indemnified Party with respect to a possible conflict of interest of such counsel retained by the indemnifying Party). In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party will not be liable to the Indemnified Party for any legal costs or expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. [***]
- (ii) Without limiting Section 13.6(d)(i), any Indemnified Party will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, that such employment will be at the Indemnified Party's own cost and expense unless [***].
- (iii) With respect to any Third Party Claims that relate solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party will have the sole right to agree to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.6(d)(i), the indemnifying Party will have authority to agree to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, delayed or conditioned). The indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party will admit any liability with respect to or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, delayed or conditioned.

conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket costs and expenses in connection therewith.

- (v) Except as provided above in this Section 13.6(d), the reasonable and verifiable costs and expenses, including attorneys' fees and expenses, incurred by the Indemnified Party in connection with any claim will be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.
- 13.7 <u>Insurance</u>. Each Party will maintain at its sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of activities to be performed under this Agreement, and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the U.S. pharmaceutical industry, or, if such activities are conducted outside the U.S., as are customary in such country, for the activities to be conducted by such Party under this Agreement. The coverage limits set forth herein will not create any limitation on a Party's liability to the other under this Agreement. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.
 - 13.8 Covenants of Moderna. Moderna hereby covenants that Moderna shall throughout the Term:
 - (a) [***]
 - (b) [***]

14. TERM AND TERMINATION

14.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated by mutual written consent, will continue on a Program-by-Program basis (a) if Merck exercises the Merck Participation Election for such Program, until the date on which both Parties cease Researching, Developing, Manufacturing or Commercializing mRNA Cancer Vaccines (including the Collaboration Products) from such Program without the intention to resume, and (b) if Merck does not exercise the Merck Participation Election for such Program or if Merck exercises the Merck Cessation Election for such Program, until the date on which Moderna and its Affiliates cease Researching, Developing, Manufacturing or Commercializing Financial PCVs or Financial SAVs, as applicable, with respect to such Program without the intention to resume (each, a "Program Term"). This Agreement shall expire in full upon the later of (i) the end of the SAV Research Term and (ii) the expiration of all Program Terms (the "Term"). Notwithstanding the foregoing, the Parties shall make an HSR Filing under the Equity Agreement, and this Agreement shall terminate and the Original Agreement shall be reinstated in full without any amendments or modifications (A) at the election of either Party, immediately upon notice to the other Party, in the event that the FTC or the DOJ obtains a preliminary injunction under the HSR Act against the Parties to enjoin the transactions contemplated by the Equity Agreement or (B) at the election of either Party, immediately upon notice to the other Party, in the event that the Antitrust Clearance Date has not occurred on or prior to ninety (90) days after the submission of the HSR Filing. As used herein: (1) "FTC" means the United States Federal Trade Commission, (2) "DOJ" means the Antitrust Division of the United States of America Department of Justice, and (3) "Antitrust Clearance Date" means the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated by this Agreement have expired or have been terminated.

14.2 No Termination; Right to Seek Damages.

(a) In further consideration of the payments by Merck and the significant contributions by each Party, neither Party shall have any right to terminate this Agreement except as expressly set forth herein and the Parties hereby agree and acknowledge that the foregoing is reasonable and necessary to protect the legitimate interests of each Party.

(b) Notwithstanding anything to the contrary in this Agreement (including Sections 14.2(a) and [***]), in addition to all rights and remedies of the Parties under this Agreement, each Party shall be entitled to seek damages (including reasonable attorneys' fees and expenses) or other equitable remedies (including pursuant to Section 15.2), at Law or otherwise, with respect to any material breach of this Agreement by the other Party.

14.3 [***]

14.4 [***]

14.5 <u>Certain Additional Consequences</u>. For the avoidance of doubt, notwithstanding anything to the contrary contained herein (other than to the extent of the exclusive licenses granted by Merck to Moderna with respect to Collaboration Products, and without any licenses or other rights in or to any Moderna Technology or Confidential Information of Moderna (except as set forth in Sections 10.1(b) and 10.1(d))), (i) in the event of a Merck Non-Participation or Merck Cessation Election, in each case, with respect to a given Program, Merck and Affiliates [***].

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14.6 Return of Confidential Information. Except as otherwise necessary to continue exercising any ongoing licenses under this Agreement, with respect to a given Program, upon the Merck Non-Participation, the [***], the Merck Cessation Election, or the end of the Program Term, in each case, with respect to such Program, the Parties will return (or destroy or erase, as directed by the other Party) all data, files, records and other materials containing or comprising the other Party's Confidential Information with respect to such Program [***]. In addition, except as otherwise necessary to continue exercising any ongoing licenses under this Agreement, upon expiration of this Agreement, the Parties will return (or destroy or erase, as directed by the other Party) all data, files, records and other materials containing or comprising the other Party's Confidential Information. Notwithstanding the foregoing, (i) in respect of physical embodiments of information, the Parties will be permitted to retain one copy of such data, files, records, and other materials for non-commercial archival purposes, and (ii) in respect of any information stored electronically or in other non-physical media, it will be sufficient for such Party to procure that access to such information is restricted to non-commercial archiving purposes only.

14.7 <u>Survival</u>. In addition to [***], as applicable, the following provisions will survive expiration of this Agreement: [***]. Expiration of this Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. All other rights and obligations will terminate upon expiration of this Agreement.

15. GENERAL PROVISIONS

15.1 Dispute Resolution.

- (a) *Disputes*. Disputes of any nature arising under, relating to, or in connection with this Agreement ("Disputes") will be resolved pursuant to this Section 15.1.
- (b) Dispute Escalation. In the event of a Dispute between the Parties, the Parties will first attempt to resolve such dispute by negotiation and consultation between themselves or the JSC. In the event that such dispute is not resolved on an informal basis within [***] days from receipt of the written notice of a Dispute, any Party may, by written notice to the other (or with respect to a Dispute arising at the JSC, by the JSC within [***] days after the JSC first considers such Dispute in accordance with Section 2.4(c)), have such dispute referred to the Executive Officers (or their designee, which designee is required to have decision-making authority on behalf of such Party), who will attempt to resolve such Dispute by negotiation and consultation for a [***] day period following receipt of such written notice.

(c) Full Arbitration.

(i) In the event the Parties have not resolved such Dispute within [***] of receipt of the written notice referring such Dispute to the Executive Officers, either Party may at any time after such [***] period submit such Dispute to be finally settled by arbitration administered in accordance with the procedural rules of the American Arbitration Association ("AAA") in effect at the time of submission, as modified by this Section 15.1(c). The arbitration will be governed by the Laws of the state of New York. The arbitration will be

heard and determined by three (3) arbitrators who are retired judges or attorneys with at least [***] of relevant experience in the pharmaceutical and biotechnology industry, each of whom will be impartial and independent. Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within [***] following appointment of the second arbitrator, by AAA. Such arbitration will take place in [***]. The arbitration award so given will be a final and binding determination of the dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 13.5. Fees, costs and expenses of arbitration are to be divided by the Parties in the following manner: Merck will pay for the arbitrator it chooses, Moderna will pay for the arbitrator it chooses, and the Parties will share payment for the third arbitrator. Except in a proceeding to enforce the results of the arbitration or as otherwise required by applicable Law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties (each such consent not to be unreasonably withheld, delayed or conditioned).

- (ii) In addition to the foregoing provisions of this Section 15.1(c), in the event that a provision of this Agreement requires "Special Arbitration", then the following rules will apply with respect to the Dispute that is subject to Special Arbitration: Within [***] of the appointment of the third (3rd) arbitrator, each Party will submit to the arbitrators in writing its final proposal for resolving the matter that is the subject of such Dispute ("Dispute Proposal") and any relevant background information and materials it deems appropriate. In connection with reaching its decision, the arbitrators may (A) order the Parties to produce any documents or other information that are relevant to the arbitrators' decision, and (B) if the arbitrators deem it necessary, set a date for a hearing no later than [***] Business Days (or such other period of time as agreed to by the Parties) after submission of the last Dispute Proposal, to be attended by both Parties with each Party having the right to be represented by counsel of its choice. The arbitrators will determine which of the two Dispute Proposals submitted by the Parties will prevail in the Special Arbitration in the best interest of the applicable Collaboration Product(s), and will not have authority to render any other substantive decision. The Dispute Proposal selected by the arbitrators shall be binding on the Parties (and, to the extent such Dispute Proposal amends a Plan or budget for a given Program, such Plan or budget shall be deemed amended to the effect of such selected Dispute Proposal, as applicable). Such decision will be rendered by the arbitrators no later than [***] Business Days after the later of (x) receipt by the arbitrators of the Parties' Dispute Proposals as set forth in this Section 15.1(c), or (y) the conclusion of any hearing conducted pursuant to clause (B) above. The Parties will use diligent efforts to cause the completion of any such arbitration within [***] following the initiating Party's written notice to submit the Dispute to Special Arbitration (or such longer period of time as the Parties may mutually agree).
- (d) *Injunctive Relief*. Notwithstanding the dispute resolution procedures set forth in this Section 15.1, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures hereunder.
- (e) *Tolling*. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the dispute resolution procedures set forth in this Section 15.1 are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result.
- 15.2 <u>Cumulative Remedies and Irreparable Harm.</u> All rights and remedies of the Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at law or otherwise. Each Party acknowledges and agrees that breach of any of the terms or conditions of this Agreement may cause irreparable harm and damage to the other and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party would be entitled to seek on an interim basis from a court and on a permanent basis from an arbitral tribunal equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages.
- 15.3 <u>Business Combination</u>. Notwithstanding anything to the contrary herein, in the event of an acquisition of a Party by a Significant Third Party as part of a Business Combination, then for purposes of this Agreement, [***]. "<u>Significant Third Party</u>" means a Third Party [***].
- 15.4 <u>Relationship of Parties</u>. Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein. There are no express or implied Third Party beneficiaries hereunder.

- 15.5 <u>Compliance with Law</u>. Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in good scientific manner and in compliance with all applicable Law.
- 15.6 <u>Force Majeure</u>. Neither Party will be liable to the other for failure of or delay in performing obligations set forth in this Agreement, and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of such Party; provided, that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.
- 15.7 Governing Law. This Agreement will be governed by and construed in accordance with the Laws of the state of New York, without respect to its conflict of laws rules or principles that might otherwise refer construction or interpretation of this Agreement to the substantive Law of another jurisdiction; provided, that any dispute relating to the scope, validity, enforceability or infringement of any Patents will be governed by, and construed and enforced in accordance with, the substantive Laws of the jurisdiction in which such Patents apply. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.
- 15.8 <u>Counterparts; Facsimiles</u>. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Facsimile or PDF execution and delivery of this Agreement by either Party will constitute a legal, valid and binding execution and delivery of this Agreement by such Party.
- 15.9 <u>Headings</u>. All headings in this Agreement are for convenience only and will not affect the meaning of any provision hereof.
- 15.10 <u>Waiver of Rule of Construction</u>. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting party will not apply.
- 15.11 <u>Interpretation</u>. Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" (or "includes without limitations"). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. Except where the context otherwise requires, whenever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Unless otherwise provided, all references to Sections, Schedules and Exhibits in this Agreement are to Sections, Schedules and Exhibits of this Agreement. References to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered "Section 2.1" would be part of "Section 2", and references to "Section 2.1" would also refer to material contained in the subsection described as "Section 2.1(a)"). Citations to a statute or regulation will be deemed to mean such statute or regulation and any amendment or supplement thereto or any replacement thereof. As used herein "\$" or "dollars" means United States Dollars.
- 15.12 <u>Binding Effect</u>. This Agreement will inure to the benefit of and be binding upon the Parties, their Affiliates, and their respective lawful successors and assigns.

15.13 Assignment.

(a) Generally. This Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer any licenses granted herein or other rights created by this Agreement, except as expressly permitted hereunder, without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed or conditioned; provided, that either Party may assign this Agreement (i) in whole or in part, to an Affiliate (provided that the Party assigning to an Affiliate will remain fully liable for any acts or omissions, including financial liabilities, of such Affiliate) or (ii) in whole to such Party's successor in connection with the merger, consolidation, sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, or any Business Combination of such Party, in each case, without the consent of the other Party. The rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 15.13. Any attempted assignment not in accordance with this Section 15.13(a) will be void.

- (b) Additional Confidentiality Procedures. In the event Moderna or any Affiliate of Moderna that does work hereunder or is in possession of Confidential Information of Merck undergoes a Business Combination, neither Merck nor any Affiliate of Merck shall be required to assign to Moderna any right, title or interest in or to any [***] conceived, created or discovered following such Business Combination.
- 15.14 Extension to Affiliates. Each Party shall have the right to extend the rights, licenses, immunities and obligations granted or imposed in this Agreement to one or more of its Affiliates to perform certain activities hereunder. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to such Party. Each Party shall remain fully liable for any acts or omissions, including financial liabilities, of such Affiliates. To the extent that this Agreement imposes obligations on any Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.
- 15.15 <u>Notices</u>. All notices, requests, demands and other communications required or permitted to be given pursuant to this Agreement will be in writing and will be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, confirmed facsimile transmission, or registered or certified mail, return receipt requested, postage prepaid to the following addresses or facsimile numbers:

If to Moderna: ModernaTX, Inc.

200 Technology Square Cambridge, MA 02139

Attention: Chief Executive Officer

With a copy to: ModernaTX, Inc.

200 Technology Square Cambridge, MA 02139 Attention: General Counsel

If to Merck: Merck Sharp & Dohme Corp.

One Merck Drive

Whitehouse Station, NJ 08889-0100 Attention: Office of Secretary Facsimile No.: (908) 735-1246

With a copy to: Merck Sharp & Dohme Corp.

2000 Galloping Hill Road

PO Box 539 Mailstop K-1-4161

Kenilworth, NJ 07033-1310

Attention: Senior Vice President, Business Development

Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 15.15.

- 15.16 Amendment and Waiver. This Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties; *provided*, that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. Any waiver of any rights or failure to act in a specific instance will relate only to such instance and will not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.
- 15.17 Severability. In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provisions will be given no effect by the Parties and will not form part of this Agreement, (b) all other provisions of this Agreement will remain in full force and effect, and (c) the Parties will negotiate in good faith to modify this Agreement to preserve (to the extent possible) their original intent.
- 15.18 Entire Agreement. This Agreement, together with any other agreement executed or to be executed in connection herewith, including the Equity Agreement, Supply Agreements, Quality Agreements, Co-

Promotion Agreements (if any), POC Pharmacovigilance Agreement and the Pharmacovigilance Agreement, sets forth the complete, final and exclusive agreement with respect to the subject matter hereof and supersedes all other agreements and understandings between the Parties with respect to the subject matter hereof (including the Mutual Confidential Disclosure Agreement (dated February 27, 2013, as amended on December 10, 2015)) as it relates to cancer vaccines using mRNA. For the avoidance of doubt, this Agreement and the transactions contemplated hereby do not amend, restate, supplement or otherwise modify any of the terms or conditions of any other agreement between the Parties, including the 2015 Collaboration Agreement, the 2016 CSA and any other agreements entered into pursuant to the 2015 Collaboration Agreement or 2016 CSA. The 2015 Collaboration Agreement and the 2016 CSA shall remain in full force and effect in accordance with their respective terms and conditions.

15.19 HSR Act. Each of Merck and Moderna shall prior to the election of any rights set forth in Section 3.5(c) if legally required submit to the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any HSR Filing required of it under the HSR Act, which forms shall specifically request early termination of the initial HSR Act waiting period; provided further that each of Merck and Moderna shall, prior to the election of any rights set forth in Section 3.5(c) if legally required, make any other applicable competition or antitrust law filing with any other governmental authority ("ex-U.S. Antitrust Filing"). The Parties will cooperate with one another to the extent necessary in the preparation of any such HSR Filing and ex-U.S. Antitrust Filing. The Parties hereto commit to instruct their respective counsel to cooperate with each other and use good faith, diligent efforts to facilitate and expedite the identification and resolution of any such issues and, consequently, the expiration of the applicable HSR Act waiting period or applicable clearances or approvals under any other applicable non-U.S. antitrust or competition law, such good faith diligent efforts to include counsel's undertaking: (i) to keep each other appropriately informed of communications received from and submitted to personnel of the reviewing antitrust authority; and (ii) to confer with each other regarding appropriate contacts with and response to personnel of the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice or other applicable competition or antitrust governmental authority. Each Party will be responsible for its own costs, expenses and filing fees associated with any HSR Filing or other ex-U.S. Antitrust Filing. In respect of any HSR Filing or ex-U.S. Antitrust Filing, each of Merck and Moderna will use its good faith, diligent efforts to eliminate any concern on the part of any court or governmental authority regarding the legality of the proposed transaction, including cooperating in good faith with any government investigation and the prompt production of documents, information and witnesses requested in the course of any such investigation, including those contained in a Request for Additional Information and Documentary Materials (as that term is defined in the HSR Act) or equivalent legal requirements under any other non-U.S. competition or antitrust law. Nothing in this Section shall require either Party to consent to the divestiture or other disposition of any of its or its Affiliates' assets or to consent to any other structural or conduct remedy, and each Party and its Affiliates shall have no obligation to contest, administratively or in court, any ruling, order or other action of the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any non-US antitrust or competition law authority or any Third Party respecting the transactions contemplated by this Agreement. The Parties shall not make any election described in Section 3.5(c) of this Agreement until all applicable competition or antitrust approvals, clearances or decision (including under the HSR Act and any other applicable competition or antitrust laws) are obtained or any applicable waiting periods have expired or terminated.

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IN WITNESS WHEREOF, the Parties have caused this Amended and Restated mRNA Cancer Vaccine Collaboration and License Agreement to be executed by their respective duly authorized officers as of the Amended Effective Date.

MODERNATX, INC.

/s/ Stéphane Bancel

(Signature) Name: Stéphane Bancel

Title: CEO

MERCK SHARP & DOHME CORP.

By: /s/ Benjamin Thorner
(Signature)
Name: Benjamin Thorner
Title: SVP & Head of BD&L

EXHIBIT A-1

POC Plan for PCV Program

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EXHIBIT B

Financial Definitions

"Additional Regulatory Costs" means costs incurred: [***].

a) "Allowable Commercialization Costs" means the internal costs (*i.e.* FTE Costs) and Out-of-Pocket Costs actually incurred by or on behalf of a Party or its Affiliates or Sublicensees, that are [***] including [***]: [***]

in each case (except in the case of [***] to the extent such costs are consistent with, during the Merck Participation Term for a given Joint SAV Program or the PCV Program, the Global Commercialization Plan and the Global Commercialization Budget for such Joint SAV Program or the PCV Program or otherwise approved by the JSC, plus Permitted Overages. [***]The Parties agree that Allowable Commercialization Costs will not include costs or expenses of a Party or its Affiliates or Sublicensees to the extent: [***].

No expense included in an Allowable Commercialization Cost shall also be included in other costs in the calculations of Moderna Net Profits or Cash Profits or Losses.

"Allowable Development Costs" means, with respect to a Joint Development Plan and Budget, or Additional Research Plan, in each case for a given Joint SAV Program or the PCV Program, the Development Costs actually incurred by or on behalf of a Party or its Affiliates or Sublicensees with respect to such Joint Development Plan and Budget or Additional Research Plan that are consistent with the applicable budget [***] or otherwise approved by the JSC, plus Permitted Overages. Allowable Development Costs shall not include costs or expenses of a Party or its Affiliates or Sublicensees to the extent: [***].

"<u>Cash Profits or Losses</u>" has the meaning set forth in **Exhibit D**. In the case where Cash Profits or Losses is positive, it shall be referred to as "<u>Cash Profits</u>", and in the case where Cash Profits or Losses is negative, it shall be referred to as "Cash Losses".

"Commercial Liabilities" means, on a country-by-country basis, any Losses incurred by or on behalf of a Party or its Affiliates or Sublicensees in connection with a Third Party Claim in connection with the Research, Development, Commercialization or Manufacture of a Collaboration Product, including [***]. For purposes of **Exhibit E**, Commercial Liabilities shall also apply to Losses incurred by or on behalf of Moderna or its Affiliates or Sublicensees *mutatis mutandis* with respect to each Financial PCV or Financial SAV, as applicable.

"Cost of Goods Sold" with respect to each mRNA Cancer Vaccine (including a Collaboration Product), means [***]. Notwithstanding the foregoing, with respect to each mRNA Cancer Vaccine (including a Collaboration Product), to the extent there [***].

"Credit Against Profits Mechanism" means each mechanism detailed in (a) Paragraph 4 of Section B of Exhibit **D**, with respect to the Profit & Loss Share and (b) Paragraph 11 of Exhibit E, with respect to the Non-Participation PCV Net Profit Share, Non-Participation SAV Net Profit Share, PCV Cessation Net Profit Share or SAV Cessation Net Profit Share, as applicable.

"<u>Development Costs</u>" means all internal costs (*i.e.* FTE Costs) and Out-of-Pocket Costs actually incurred by or on behalf of a Party (or its Affiliates or Sublicensees) and that [***], to the extent set forth in the budget within the Additional Research Plan, the Joint Development Plan and Budget or an Independent Additional Study Development Plan, in each case for a given Joint SAV Program or the PCV Program, including:

(f) [***]

(g) those Patent and Trademark Expenses incurred for the Prosecution and Maintenance of Patents (which shall not be subject to the budget requirements above);

(h) [***]

[***] With respect to the foregoing, any internal costs shall be calculated based on the number of FTEs used to perform the applicable activity multiplied by the FTE Rate. For purposes of **Exhibit E**, Development Costs shall also apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees *mutatis mutandis* with respect to each Financial PCV or Financial SAV, as applicable.

"<u>Direct Marketing Expenses</u>" means all internal costs (*i.e.* FTE Costs) and Out-of-Pocket Costs actually incurred by or on behalf of a Party [***]:

(r) [***]

Direct Marketing Expenses shall not include any Selling Expenses and the costs of activities that promote a Party's business as a whole without being product specific (*e.g.*, corporate image advertising). For purposes of **Exhibit E**, Direct Marketing Expenses shall also apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees *mutatis mutandis* with respect to each Financial PCV or Financial SAV, as applicable.

"<u>Distribution Expenses</u>" with respect to each Collaboration Product, means [***]. For purposes of **Exhibit E**, Distribution Expenses shall also apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees *mutatis mutandis* with respect to each Financial PCV or Financial SAV, as applicable.

"Financial PCV" means [***].

"Financial SAV" means, [***].

"Gross Profit" means, with respect to a Collaboration Product, Net Sales of a Collaboration Product less Cost of Goods Sold for such Collaboration Product. For purposes of **Exhibit E**, Gross Profit shall apply *mutatis mutandis* with respect to each Financial PCV or Financial SAV, as applicable.

"IAS Costs" means Development Costs incurred with respect to any Independent Additional Study for a Collaboration Product subject to the applicable Independent Additional Study Plan.

[***]

[***

[***]

"Indirect Marketing Expenses" with respect to each Collaboration Product, means [***]. For purposes of **Exhibit E**, Indirect Marketing Expenses shall also apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees with respect to each Financial PCV or Financial SAV, as applicable, *mutatis mutandis*.

[***]

"Manufacturing Costs" shall consist of "U.S. GAAP Standard Cost" and "Product Specific Manufacturing Variances" as defined below. Notwithstanding the foregoing, for purposes of **Exhibit D** and **Exhibit E** as used in Cost of Goods Sold, Manufacturing Costs will not include [***]. For purposes of **Exhibit E**, Manufacturing Costs shall also apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees with respect to each Financial PCV or Financial SAV, as applicable, *mutatis mutandis*.

"Medical Affairs Costs" means all internal costs (*i.e.* FTE Costs) and Out-of-Pocket Costs actually incurred by or on behalf of a Party [***]. For purposes of **Exhibit E**, Medical Affairs Costs shall also apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees with respect to each Financial PCV or Financial SAV, as applicable, *mutatis mutandis*.

[***

"Merck Reimbursement Cap" has the meaning set forth in Exhibit E.

"Moderna Commercialization Costs" means, on a Program-by-Program basis for a given Joint SAV Program or the PCV Program, all Shared Commercialization and Related Manufacturing Costs [***], including [***]. All provisions and principles set forth in the definition of Allowable Commercialization Costs and [***] shall apply to Moderna Commercialization Costs, *mutatis mutandis*.

"Moderna Costs Report" has the meaning set forth in Exhibit E.

"Moderna Development Costs" means, on a Program-by-Program basis for a given Joint SAV Program or the PCV Program, all Shared Development and Related Manufacturing Costs [***], including [***]. All provisions and principles set forth in the definition of Allowable Development Costs and [***] shall apply to Moderna Development Costs, *mutatis mutandis*.

"Moderna Net Profits" means, with respect to Financial PCVs or Financial SAV, as applicable, Gross Profits from such Financial PCVs or Financial SAV, as applicable, less the Moderna Commercialization Costs and Moderna Development Costs for such Financial PCVs or Financial SAV, as applicable. For clarity, costs that are included in one category of costs shall not be deducted a second time in calculating any other costs that are deducted in calculating Moderna Net Profits.

[***]

"Non-Participation PCV Net Profit Share" shall have the meaning set forth in Exhibit E.

"Non-Participation SAV Net Profit Share" shall have the meaning set forth in Exhibit E.

"Other Operating Income/Expense" means the following items, [***]:

"Out-of-Pocket Costs" means costs and expenses paid to Third Parties by or on behalf of Moderna or its Affiliates or Sublicensees or Merck or its Affiliates or Sublicensees [***] in accordance with the budget set forth in, the POC Plans (including POC Capacity PCV Buildup Plan), Development Plan(s), Additional Research Plans, Global Commercialization Plan(s), Incremental Capacity Buildup Plans or Commercial Capacity Buildup Plans, as applicable.

"Patent and Trademark Expenses" means the reasonable, documented, out of pocket fees and expenses of outside counsel [***], and filing and maintenance expenses, [***] incurred in connection with (i) the Prosecution and Maintenance of [***]; and (ii) any trademark applications or registered trademarks used in connection with the Commercialization of any Collaboration Product, including [***]. For purposes of **Exhibit E**, Patent and Trademark Expenses shall also apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees *mutatis mutandis* with respect to each Financial PCV or Financial SAV, as applicable.

"PCV Cessation Net Profit Share" has the meaning set forth in Exhibit E.

[***]

"Product Specific Manufacturing Variances" means [***].

"Profitability Date" means, with respect to a given Joint SAV Program or the PCV Program, the last day of the Calendar Quarter during which the quarterly Cash Profits or Losses (as defined in **Exhibit D**) from such Program are positive (*i.e.*, greater than zero, [***] or the Moderna Net Profits for such Program are positive (*i.e.*, greater than zero), as applicable.

[***]

"Reconciliation Report" has the meaning set forth in Exhibit D.

"SAV Cessation Net Profit Share" has the meaning set forth in Exhibit E.

"Selling Expenses" means, with respect to a Collaboration Product, all costs and expenses associated with [***].

"Shared Commercialization and Related Manufacturing Costs" means Allowable Commercialization Costs and [***].

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"Shared Collaboration Costs" means the Shared Development and Related Manufacturing Costs and the Shared Commercialization and Related Manufacturing Costs.

"Shared Costs Report" has the meaning set forth in Exhibit D.

"Shared Development and Related Manufacturing Costs" means Allowable Development Costs and [***].

"Shared Profits or Losses" has the meaning set forth in **Exhibit D**. In the case where Shared Profits or Losses is positive, it shall be referred to as "Shared Profits", and in the case where Shared Profits or Losses is negative, it shall be referred to as "Shared Losses".

"Sublicensee" as used in this Exhibit B, and Exhibit D and Exhibit E, means [***].

"Testing Costs" means the costs that are [***]. For purposes of **Exhibit E**, Testing Costs shall apply to costs incurred by or on behalf of Moderna or its Affiliates or Sublicensees with respect to each Financial PCV or Financial SAV, as applicable, *mutatis mutandis*.

"U.S. GAAP Standard Cost" means, if applicable, the following with respect to such product:

The U.S. GAAP Standard Cost will be established each Calendar Year for the upcoming year according to the forecast for requirements for such product.

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EXHIBIT D

Exercise of Merck Participation Election - Profit & Loss Share

This **Exhibit D** to the Agreement covers financial planning, accounting policies and procedures to be followed in determining the Profit & Loss Share and the cost sharing between the Parties. The Profit & Loss Share shall be calculated on a Program-by-Program basis for a given Joint SAV Program or the PCV Program. The Profit & Loss Share is not a legal entity and has been defined for identification purposes only.

A. Profit & Loss Share

1. Principles of Reporting.

1.1 The presentation of results of operations of the Parties will include each of the following line items (as each is defined in **Exhibit B** or elsewhere in the Agreement) be based on each Party's respective financial information presented separately and on a consolidated basis in the reporting format depicted as follows (the "P&L"):

[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

1.2 Effect of Commercial Grants.

- 1.2.1 In connection with a Commercial Grant: (a) such Third Party receiving the Commercial Grant [***], and (b) Sublicense Income received by such Party and its Affiliates from such Third Party will [***], unless [***].
- 1.2.2 The treatment of a Commercial Grant under [***] pursuant to the foregoing Paragraph 1.2.1 of this Section A of **Exhibit D** with respect to Commercial Grants by a Party or any of its Affiliates in [***] will require the prior written consent of the other Party, [***].
- 1.2.3 Any Commercial Grant may include rights to Manufacture and Develop to support Commercialization in the country(ies) of such Commercial Grant, but the Parties do not intend for Commercial Grants to be used to Develop or Manufacture the applicable Collaboration Product(s) more generally.

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- 1.3 It is the intention of the Parties to interpret definitions to be consistent with this Exhibit D and GAAP (except for Cost of Goods Sold given the exclusion of depreciation of certain assets in the calculation of Manufacturing Costs). Where costs included in the foregoing calculation are determined based on either Party's system of cost or project accounting, each Party agrees to provide reasonable supporting documentation, as may be requested by the other Party, to ensure that each Party's methodologies are reasonable and consistently applied. To the extent that such costs are not readily determinable based on the respective Party's system of cost or project accounting, the JSC will develop a reasonable methodology for determining such costs. Reasonable methodologies may include a standard rate or some other appropriate basis for allocating costs. For reconciliation, billing and reporting hereunder, any costs included in the P&L incurred in a currency other than U.S. dollars will be translated into U.S. dollars in accordance with Section 9.5(e) of the Agreement.
- 1.4 If necessary, a Party will make the appropriate adjustments to the financial information it supplies under this **Exhibit D** to conform to the above format of reporting results of operation.

1.5 Principles:

- 1.5.1 In calculating the revenues and costs in this $\mathbf{Exhibit} \, \mathbf{D}$, the following principles shall apply:
- (a) There shall be no double counting of any costs or expenses or of any revenues, and to the extent a cost or expense has been included in one category or sub-category, it shall not be included in another; similarly, to the extent any revenue has been taken into account in one category or sub-category it shall not be taken into account in another.
- (b) To the extent an item of income or revenue is received by a Party or a cost or expense is incurred in a given Calendar Quarter by a Party, and can be demonstrated [***].
- (c) To the extent any cost by a Party has applicability to both the Collaboration Product and to any other product, a portion of such costs will be [***] allocated by such Party to the Collaboration Product in good faith; provided the other Party shall have the right to dispute such allocation in good faith and request additional information prior to including such cost as a Shared Collaboration Cost under

this **Exhibit D**. In addition, to the extent any cost by a Party has applicability to more than one Program, a portion of such costs will be [***] allocated by such Party to each applicable Program in good faith; provided the other Party shall have the right to dispute such allocation in good faith and request additional information prior to including such cost as a Shared Collaboration Cost for the applicable Program under this **Exhibit D**.

(d) All costs and expenses shall be determined, and all calculations shall be made, in accordance with GAAP, as applicable, and consistent with the Parties internal cost allocation practices used in connection with pharmaceutical products owned or controlled solely by each Party without requirement to share profits or significant royalties with any Third Party, and further consistent with the same policies and principles as it utilizes consistently within its group and business units when making internal cost allocations.

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Without limiting the foregoing, if either Party in good faith believes that the methodology set forth herein does not accurately reflect the revenues and costs for a Collaboration Product, Program or otherwise for the Collaboration, upon request of such Party, the Parties shall in good faith discuss such concerns and, if the Parties mutually agree upon acceptable revisions to the methodologies set forth herein, they shall amend **Exhibit B**, **Exhibit D** or **Exhibit E**, as appropriate. For clarity, the foregoing principles shall also apply to the costs and expenses calculated in **Exhibit E** mutatis mutandis.

2. Cash Profits or Losses and Shared Collaboration Costs.

- 2.1 If Merck elects the Merck Participation Election for a given Program, each Party is entitled to fifty percent (50%) of the Cash Profits or Losses from such Program for a given [***] subject to this **Exhibit D**.
- 2.2 Certain Exclusions from Shared Collaboration Costs. To the extent any Manufacturing Costs are incurred by a Party due to [***] by such Party, then such Manufacturing Costs shall be borne solely by such Party and shall not be included in Cost of Goods Sold to be included in the Shared Costs Report hereunder.
- 3. <u>Audits</u>. The record keeping and audit provisions set forth in Section 9.5(c) of the Agreement will apply with respect to all amounts payable by either Party to the other Party under the Profit & Loss Share.
- 4. <u>Reporting of Shared Costs</u>. Within [***] days after the end of [***], each Party shall provide the other Party with a detailed activity-based summary statement (with supporting documentation [***] of the Shared Collaboration Costs and Costs of Goods Sold incurred by or on behalf of such Party (or its Affiliate or Sublicensee) in such [***], as applicable (each, a "<u>Shared Costs Report</u>"). [***]
- 5. Reporting of Net Sales. On a [***] basis, Merck will provide to Moderna an estimate of gross sales and Net Sales of such Collaboration Product in U.S. dollars during the prior [***] and units of such Collaboration Product sold during such period according to Merck's sales reporting system, which will be consistent with the financial planning, accounting and reporting procedures set forth in this **Exhibit D**. Each such report will be provided as early as possible, but no later than [***] days after the last day of the [***] in question, and will separately provide [***] figures. The Parties understand that all Net Sales of Collaboration Products will be booked in accordance with GAAP and otherwise in accordance with the definition of Net Sales.
- 6. Reconciliation. Subject to the remainder of this **Exhibit D**, within [***] days after the end of [***], each Party will provide to the other a written report setting forth the calculations of aggregate Net Sales and aggregate costs under the Shared Costs Report for such [***] received or funded by such Party. Within [***] days after receipt of such reports, the Parties will agree on a consolidated written report (the "Reconciliation Report") setting forth the calculations of each Party's share of such aggregate Net Sales and aggregate costs under the Shared Costs Report and the net amount that would be owed from one Party to the other Party to effectuate, subject to Paragraph 6.1 of this Section A of **Exhibit D**, an equal share of the resulting Cash Profits or Losses between the Parties. Such net amount would then be adjusted in accordance with Paragraph 17 of Section B of this **Exhibit D**.

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6.1 [***

7. <u>Payment</u>. Any undisputed net payment owed from one Party to the other Party in order for the Parties to share equally all such costs in the Shared Costs Report, other than [***], shall be paid within [***] days following completion of such Reconciliation Report and an invoice therefor [***]; provided, that [***].

8. <u>Budgets and Overages</u>. Each Party shall use Commercially Reasonable Efforts to ensure that the actual costs associated with the performance of activities allocated to it in the Additional Research Plan, Joint Development Plan and Budget, Global Commercialization Plan, Incremental Capacity Buildup Plan and Commercial Capacity Buildup Plan (if applicable), in each case for the applicable Program, in a Calendar Year do not exceed [***] of the budgeted costs allocated to such Party for such Calendar Year as set forth in the budget for each applicable plan. Costs for the performance of all activities described in the applicable plan and budget and allocated to a given Party that exceed the estimated allocated costs therefor as set forth in the budget by up to [***] shall be referred to herein as the "<u>Permitted Overage</u>", and such costs shall be included as Shared Development and Related Manufacturing Costs or Shared Commercialization and Related Manufacturing Costs, as applicable. If either Party believes that the actual costs in relation to its activities allocated to a given Party in a Calendar Year will exceed the allocated budget as set forth in the applicable plan and budget (plus the Permitted Overage) for all such activities allocated to such Party during such Calendar Year, such Party may request the JSC to review and approve such activities and the costs thereof before undertaking such excess cost. In the event that the JSC does not approve an increase in the

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budget for such activity, then [***]. For clarity, any costs incurred by or on behalf of a Party (or its Affiliates) that are in excess of the budget (plus the Permitted Overage) for such costs as set forth in the applicable Joint Development Plan and Budget, Global Commercialization Plan, Incremental Capacity Buildup Plan, Additional Research Plan or Commercial Capacity Buildup Plan, in each case, for the applicable Program, shall be [***].

- 9. Recording of Costs; Reports. Each Party shall keep records associated with Development Costs incurred through performance of the Joint Development Plan and Budget for the applicable Program strictly separate from records associated with Development Costs incurred through performance of an Independent Additional Study Development Plan. Unless otherwise agreed by the JSC, the financial data in the Shared Costs Report will include calculations in local currency and United States Dollars (converted into United States Dollars in accordance with Section 9.5(e) of the Agreement). The JSC shall approve the form of any necessary documentation relating to any payments hereunder in connection with the Joint Development Program, Additional Study Development Plan, Global Commercialization Plan, Incremental Capacity Buildup Plan, or Commercial Capacity Buildup Plan, as applicable, so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.
- 10. Expense Reduction. The Parties agree to cooperate in identifying and implementing opportunities to reduce the costs incurred in the conduct of each Joint Development Plan and Budget, Additional Study Development Plan, Global Commercialization Plan or Incremental Capacity Buildup Plan or Commercial Capacity Buildup Plan, as applicable, including costs of equipment, consumables such as laboratory supplies and Third Party services such as toxicology, clinical studies or manufacturing services, provided such cooperation does not unduly delay or hamper a Party in the performance of its activities thereunder.
- 11. <u>Effective Accounting Date Termination</u>. The Profit & Loss Share for a given Program shall continue until the earlier of the last day of the month following the effective date of (a) the expiration of the Agreement with respect to such Program, or (b) the exercise of the Merck Cessation Election for such Program pursuant to Section 10.10 of the Agreement. For clarity, following the discontinuation of the Profit & Loss Share for a given Program pursuant to subsection (b) above, the terms of **Exhibit E** shall apply. Termination of the Profit & Loss Share shall not relieve either Party from its obligation to share Shared Collaboration Costs (including any Commercial Liabilities) relating to the period up to the date of termination or expiration.

EXHIBIT E

This **Exhibit E** to the Agreement covers financial planning, accounting policies and procedures to be followed in determining the economic effects and the cost sharing between the Parties in the following situations: (i) a Merck Non-Participation for a given Joint SAV Program or the PCV Program or (ii) a Merck Cessation Election for a given Joint SAV Program or the PCV Program. For the avoidance of doubt, this Exhibit E shall apply and be calculated on a Program-by-Program basis.

A. Merck Non-Participation for the PCV Program

The provisions of this Section A of Exhibit E (*i.e.*, Paragraphs 1-13 of this Exhibit E) shall apply only to Financial PCVs.

1. Allocation of Moderna Net Profits and Costs.

1.1 In the event of a Merck Non-Participation for the PCV Program pursuant to Section 3.7(a) of the Agreement, subject to [***]this **Exhibit E**, Merck shall be entitled to [***] (the "Non-Participation PCV Net Profit Share").

1.2 [***]

2. Principles of Reporting.

2.1 The presentation of results of operations of Moderna with respect to Financial PCVs will include each of the following line items (as each is defined in **Exhibit B** or elsewhere in the Agreement) be based on Moderna's financial information presented separately and on a consolidated basis in the reporting format depicted as follows:

[***]

[***]

[***]

[***]

[***]

[***]

[***]

- 2.2 Effect of Commercial Grants. With respect to Financial PCVs, the following shall apply:
- 2.2.1 In connection with a Commercial Grant: (a) such Third Party receiving the Commercial Grant [***], and (b) [***] shall apply, unless [***].

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- 2.2.2 The treatment of a Commercial Grant under [***] pursuant to the foregoing Paragraph 2.2.1 of this **Exhibit E** with respect to Commercial Grants by a Party or any of its Affiliates in [***] will require the prior written consent of the other Party, [***]t.
- 2.2.3 Any Commercial Grant may include rights to Manufacture and Develop to support Commercialization in the country(ies) of such Commercial Grant, but the Parties do not intend for Commercial Grants to be used to Develop or Manufacture the applicable Collaboration PCV Product(s) more generally.
- 2.3 It is the intention of the Parties to interpret definitions to be consistent with this **Exhibit E** and GAAP (except for Cost of Goods Sold given the exclusion of depreciation of certain assets in the calculation of Manufacturing Costs). Where costs included in the foregoing calculation are determined based on Moderna's system of cost or project accounting, Moderna agrees to provide reasonable supporting documentation, as may be requested by Merck, to ensure that Moderna's methodologies are reasonable and consistently applied. To the extent that such costs are not readily determinable based on Moderna's system of cost or project accounting, the Parties will mutually develop a reasonable methodology for determining such costs. Reasonable methodologies may include a standard rate or some other appropriate basis for allocating costs. For reconciliation, billing and reporting hereunder, any costs included in the above table incurred in a currency other than U.S. dollars will be translated into U.S. dollars in accordance with Section 9.5(e) of the Agreement.
- 2.4 If necessary, Moderna will make the appropriate adjustments to the financial information it supplies under this **Exhibit E** to conform to the above format of reporting results of operation.
- 3. <u>Audits</u>. The record keeping and audit provisions set forth in Section 9.5(c) of the Agreement will apply with respect to all amounts payable by Moderna to Merck under this **Exhibit E**.

- 4. <u>Reporting of Moderna Costs</u>. Within [***] days after the end of [***], Moderna shall provide Merck with a [***] summary statement (with supporting documentation [***] of the Moderna Development Costs, Moderna Commercialization Costs and Costs of Goods Sold incurred by or on behalf of Moderna (or its Affiliate or Sublicensee) in such [***], as applicable for Financial PCVs (each, a "<u>Moderna Costs Report</u>"). [***]
- 5. Reporting of Net Sales. On a [***] basis, Moderna will provide to Merck an estimate of gross sales and Net Sales in U.S. dollars during the prior [***] of such Financial PCVs and units of such Financial PCV sold during such period according to Moderna's sales reporting system, which will be consistent with the financial planning, accounting and reporting procedures set forth in this **Exhibit E**. Each such report will be provided as early as possible, but no later than [***] days after the last day of the [***] in question, and will separately provide [***] figures. The Parties understand that all Net Sales of Financial PCVs will be booked in accordance with GAAP and otherwise in accordance with the definition of Net Sales.

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6. <u>Recording of Costs; Reports</u>. All Moderna Development Costs, Cost of Goods Sold and Moderna Commercialization Costs pursuant to this **Exhibit E** shall be recorded and reported consistent with GAAP (except [***]), consistently applied.



11. <u>Credit Against Profits Mechanism</u>. The Credit Against Profits Mechanism with respect to the Non-Participation PCV Net Profit Share shall operate as follows:

11.1 [***] 11.2 [***] 11.3 [***] 12. [***] 12.1 [***] 12.1.1 [***] 12.1.2 [***]

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13. [***]

13.1 [***]

B. Merck Cessation of Collaboration Activities for the PCV Program

The provisions of this Section B of **Exhibit E** (*i.e.*, Paragraphs 14-15 of this **Exhibit E**) shall apply only to Financial PCVs.

- 14. Allocation of Moderna Net Profits and Costs.
- 14.1 In the event of a Merck Cessation Election for the PCV Program pursuant to Section 10.10 of the Agreement, subject to the remainder of this **Exhibit E**[***], for each [***] following the effective date of the Merck Cessation Election for the PCV Program, Merck shall be entitled to [***] (the "PCV Cessation Net Profit Share").

15. <u>General</u>. The provisions of Paragraphs 2 through 13 of this **Exhibit E** shall apply to the PCV Cessation Net Profit Share, *mutatis mutandis*; [***].

C. Merck Non-Participation for a Given Joint SAV Program

The provisions of this Section C of **Exhibit E** (*i.e.*, Paragraph 16 of this **Exhibit E**) shall apply only to Financial SAVs and shall be calculated on a Joint SAV Program-by-Joint SAV Program basis.

16. Allocation of Moderna Net Profits and Costs.

16.1 In the event of a Merck Non-Participation for a given Joint SAV Program pursuant to Section 3.7(a) of the Agreement, subject to [***] this **Exhibit E**, Merck shall be entitled to [***] of Moderna Net Profits of Financial SAVs for a given [***] up to an aggregate amount equal to the Merck SAV Program Costs for such Joint SAV Program (at which point, such SAVs for such Joint SAV Program shall cease to be Financial SAVs with no further action required by either Party)[***] (the "Non-Participation SAV Net Profit Share").

16.2 *General*. Paragraphs 2 through 13 of this **Exhibit E** shall apply to a given Joint SAV Program and the Financial SAVs, *mutatis mutandis*.

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D. Merck Cessation of Collaboration Activities for a Given SAV Program

The provisions of this Section D of **Exhibit E** (*i.e.*, Paragraph 17 of this **Exhibit E**) shall apply only to Financial SAVs and shall be calculated on a Joint SAV Program-by-Joint SAV Program basis.

17. Allocation of Moderna Net Profits and Costs

17.1 In the event of a Merck Cessation Election for a given Joint SAV Program pursuant to Section 10.10 of the Agreement [***], then, for each [***] following the effective date of the Merck Cessation Election for such Joint SAV Program, Merck shall be entitled to [***] of Moderna Net Profits of Financial SAVs for a given [***] up to an aggregate amount equal to the Merck SAV Program Costs (at which point, such SAVs for such Joint SAV Program shall cease to be Financial SAVs with no further action required by either Party); [***] (the "SAV Cessation [***] Capped Net Profit Share").

17.2 In the event of a Merck Cessation Election for a given Joint SAV Program pursuant to Section 10.10 of the Agreement [***], Merck shall be entitled to [***] of Moderna Net Profits of Financial SAVs for a given [***] (each "SAV Cessation [***] Net Profit Share").

17.3 In the event of a Merck Cessation Election for a given Joint SAV Program pursuant to Section 10.10 of the Agreement [***], then, for each [***] following the effective date of the Merck Cessation Election for such Joint SAV Program, Merck shall be entitled to [***] of Moderna Net Profits of Financial SAVs for a given [***] (each, a "SAV Cessation [***] Net Profit Share", and together with each SAV Cessation [***] Capped Net Profit Share and each SAV Cessation [***] Net Profit Share, the "SAV Cessation Net Profit Share").

17.4 SAV Cessation Net Profit Share Term. Payments to Merck related to the Moderna Net Profits of Financial SAVs under Paragraphs 17.1, 17.2 or 17.3 of this **Exhibit E** will be payable following the effective date of the Merck Cessation Election, on the Moderna Net Profits of Financial SAVs and shall continue until the last day of the month following the effective date of the expiration of the Agreement.

17.5 *General*. Paragraph 2-13, 14.2 of this **Exhibit E** shall apply to a given Joint SAV Program and the Financial SAVs, *mutatis mutandis*; [***].

E. Business Combination.

[***]

EXHIBIT F

In-Licenses

1 Third Party In-Licenses.

(a) <u>Moderna Pre-Existing In-Licenses</u>. Promptly following the Amended Effective Date, the Parties shall discuss in good faith whether any Patents or Know-How in-licensed under a Moderna Pre-Existing In-License should be made available for use by the Parties, on a Program-by-Program basis, for the performance of Collaboration Activities under this Agreement, including the Research, Development, Manufacture or Commercialization of a Collaboration Product with respect to such Program pursuant to the terms of this Agreement and, if the Parties mutually agree in writing, then, subject to and in accordance with the terms of this Agreement and to the extent permitted under the applicable Moderna Pre-Existing In-License, the Patents and Know-How in-licensed under such Moderna Pre-Existing In-License shall be deemed to be Moderna Technology with respect to such Program and such Moderna Pre-Existing In-License shall be deemed an "Included Moderna Pre-Existing In-License" with respect to such Program.

(b) Moderna New In-Licenses.

(i) Negotiation and Disclosure of Moderna New In-Licenses. After the Amended Effective Date, if Moderna identifies any Patents or Know-How of a Third Party to which Moderna (and its Affiliates) does not have rights and that may be[***] for the performance of existing or future Collaboration Activities under this Agreement, including for the Research, Development, Manufacture or Commercialization of mRNA Cancer Vaccines pursuant to the terms of this Agreement, Moderna may independently negotiate and enter into an agreement to obtain a license or other rights to such Patents or Know-How (each such agreement, a "Moderna New In-License"); provided that (1) Moderna will [***] and (2) Moderna will use [***]. If Moderna (or its Affiliate) enters into such a Moderna New In-License, Moderna will disclose to Merck the terms of such Moderna New In-License (including by providing a copy of such Moderna New In-License to Merck), subject to applicable confidentiality obligations and reasonable redaction of provisions that do not relate to the potential use of Patents and Know-How in-licensed under such Moderna New In-License for the performance by the Parties of such existing or future Collaboration Activities, including the Research, Development, Manufacture or Commercialization of any mRNA Cancer Vaccines, and otherwise provide Merck with [***] to assess whether or not any Patents or Know-How in-licensed under such Moderna New In-License should made available for use as set forth herein.

(ii) Included Moderna New In-Licenses. Subject to Section 1(d) of this **Exhibit F**, if the Parties mutually agree in writing that any Patents or Know-How in-licensed under a given Moderna New In-License should be made available for use by the Parties for the performance of any Collaboration Activities under this Agreement with respect to any Program, including for the Research, Development, Manufacture or Commercialization of any Collaboration Product subject to and in accordance with the terms of this Agreement and to the extent permitted under such Moderna New In-License, then such Patents or Know-How, as applicable, will be deemed Moderna Technology with respect to such Program (but subject to

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[***]) and such Moderna New In-License shall be deemed an "<u>Included Moderna New In-License</u>" with respect to such Program. If the Parties cannot agree whether any Patent or Know-How licensed to Moderna or its Affiliate pursuant a Moderna New In-License should be made available for use by either Party for the performance of Collaboration Activities, or made available for the Research, Development, Manufacture or Commercialization of any Collaboration Product, in each case, pursuant to the terms of this Agreement then (1) the Patents and Know-How in-licensed under such Moderna New In-License [***], (2) such Moderna New In-License [***], (3) [***], (4) Merck will not [***], and (5) Merck will have no [***].

(c) <u>Merck In-Licenses</u>. In the event that, during the Collaboration Term for a given Program, Merck identifies any Patents or Know-How of a Third Party to which Merck (and its Affiliates) does not have rights and that may be [***] for the performance of Collaboration Activities under this Agreement for such Program, including the Research, Development, Manufacture or Commercialization of any Collaboration Product as a part of such Program pursuant to this Agreement, Merck may independently negotiate and enter into an agreement to obtain a license or other rights to such Patents or Know-How (each such agreement, a "<u>Merck In-License</u>") provided that (1) Merck will [***] and (2) Merck will use [***]. In addition, if Merck (or its Affiliates) has

other Patents or Know-How that may be [***] for the performance of Collaboration Activities for a given Program under this Agreement, including the Research, Development, Manufacture or Commercialization of any Collaboration Product pursuant to this Agreement and that Merck desires to bring into the Collaboration for such Program, but such Patents or Know-How are licensed to Merck (or its Affiliate) from a Third Party pursuant to an agreement between Merck (or its Affiliate) and such Third Party (even if the agreement with the Third Party was entered into prior to the Effective Date), then, such agreement shall also be considered a "Merck In-License". Solely to the extent Merck determines that the rights in-licensed under a Merck In-License should be made available for use by the Parties for the performance of Collaboration Activities for a given Program under this Agreement, including for the Research, Development, Manufacture or Commercialization of any Collaboration Product, then Merck will provide Moderna written notice thereof, which written notice shall include the terms of such Merck In-License, subject to applicable confidentiality obligations and reasonable redaction of provisions that do not relate to the potential use of Patents and Know-How in-licensed under such Merck In-License for the performance by the Parties of such Collaboration Activities with respect to a Program, including the Research, Development, Manufacture or Commercialization of any Collaboration Product as a part of such Program, and otherwise provide Moderna with [***] to assess whether or not any Patents or Know-How in-licensed under such Merck In-License should be made available for use as set forth herein. Following Moderna's receipt of such notice from Merck disclosing a given Merck In-License, the Parties shall discuss in good faith whether any Patents or Know-How in-licensed under such Merck In-License should be made available for use by the Parties for the performance of Collaboration Activities with respect to a Program under this Agreement, including for the Research, Development, Manufacture or Commercialization of any Collaboration Product as a Party of such Program and, if the Parties mutually agree in writing, then, in each case, pursuant to the terms of this Agreement and to the extent permitted under the applicable Merck In-License, then such Patents and Know-How, as applicable, shall be deemed to be Merck Technology and such Merck In-License shall be deemed an "Included Merck In-License".

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(d) <u>Permitted In-Licenses</u>. Notwithstanding anything to the contrary set forth herein, in the event that, during the POC Term for a given Program, to the extent Moderna reasonably determines that any Patents or Know-How in-licensed under a given Moderna New In-License [***] (such Moderna New In-License, a "<u>Permitted In-License</u>") should be made available for use by either Party for the performance of Collaboration Activities for such Program, including for the Research, Development, Manufacture or Commercialization of any Collaboration Product as a part of such Program under this Agreement, subject to and in accordance with the terms of this Agreement and to the extent permitted under such Permitted In-License, then Moderna shall notify Merck in writing, which notice shall include a copy of the applicable Permitted In-License (subject to confidentiality obligations and reasonable redaction) and specifically identify the applicable Patents or Know-How to be made available for use by the Parties for such use and, upon Merck's receipt of such notice, then such Patents or Know-How (as applicable) will be deemed Moderna Technology (subject to any limitations set forth in such Permitted In-License as disclosed by Moderna in such notice to Merck) with respect to such Program and such Permitted In-License shall be deemed an "<u>Included Permitted In-License</u>" with respect to such Program, unless [***].

(e) Included In-License Requirements.

- (i) *Scope*. The sublicenses granted under any Included In-License (and further rights to sublicense) shall be [***].
- (ii) Sublicense Party. Each Party will abide, and will cause all its Affiliates and applicable Sublicensees to abide, by all requirements of each Included In-License under which it is granted a sublicense hereunder (including with respect to the Research, Development, Manufacture or Commercialization of any Collaboration Products) in all material respects [***], to the extent applicable to sublicensees thereunder and to the extent disclosed by the contracting Party to the other Party pursuant to Section 1(b), Section 1(c) or Section 1(d) of this **Exhibit F**, as applicable, prior to the Parties' determination as to whether such In-License should be an Included In-License, with the understanding that disclosure by a Party of any In-License to the other Party will be deemed disclosure of such requirements of such In-License so disclosed to such other Party.
- (iii) Maintenance of Included In-Licenses. The contracting Party to any Included In-License (the "Contracting Party") (A) will duly perform and observe all of its obligations under such Included In-Licenses in all material respects and maintain in full force and effect such Included In-License and (B) will not, without the other Party's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), [***] in each case ((A) and (B)) to the extent such action [***] would reasonably be expected to

materially adversely affect the Research, Development, Manufacture or Commercialization of any Collaboration Product hereunder or the rights of the other Party under this Agreement. The Contracting Party to any Included In-License will provide the other Party with written notice as promptly as practicable after becoming aware of any of the following: [***]. If the Contracting Party fails to pay any amounts due under such Included In-License and if such nonpayment would permit the counterparty to such Included In-License to terminate or suspend the same or any rights thereunder, then, to the extent permitted under the Included In-License, the other Party will have the right, but not the obligation, in its sole discretion, to pay such amounts on the

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Contracting Party's behalf, and any amounts so paid by the other Party may, to the extent that, as between the Parties, the Contracting Party is responsible for payment of such amounts in accordance with Section 2 and Section 3 of this **Exhibit F**, be taken by such other Party as [***].

- (f) /***/
- (g) /***/
- 2 Upfront Payments for New In-Licenses.
- (a) [***] The Parties acknowledge that if the Contracting Party to a given New In-License has, prior to the date that such New In-License becomes an Included In-License hereunder, paid to the licensor party thereto an upfront fee or other license fee to acquire rights to the applicable Included In-License IP (an "In-License Upfront Payment"), then, prior to including such New In-License as an Included In-License hereunder, the Parties will agree on [***] of such In-License Upfront Payment [***].
- (b) [***] In addition to [***] set forth in Section 2(a) of this **Exhibit F**, prior to including such In-License as an Included In-License hereunder, the Parties will agree on [***].
 - 3 Included In-License Payments. Except as set forth above in Section 2 of this Exhibit F:
- (a) <u>POC Program</u>. With respect to a given POC Program, if and to the extent that any Included In-License Payments become due during the POC Term for such POC Program, the Contracting Party will pay the same; provided that, (1) if Merck exercises the Merck Participation Election for such POC Program, then the amount(s) of any [***], will, in each case [***], as of the Merck Participation Election Date for such Program at Merck's election, be deemed [***], unless the non-Contracting Party elects to [***], and (2) if Merck does not exercise the Merck Participation Election for such POC Program, then [***] Program will, in each case [***].
- (b) <u>Joint Development Programs Allowable Development Costs</u>. If and to the extent that any Included In-License Payment becomes due with respect to activities under a Joint Development Program or an Additional Research Plan, the Contracting Party will pay the same, and such amount will be [***].
- (c) <u>Independent Additional Studies</u>. If and to the extent that any Included In-License Payment becomes due with respect to activities under an Independent Additional Study Development Plan, the Party sponsoring or conducting such Independent Additional Study will pay the same, and such amount will be [***].
- (d) <u>Commercialization</u>. If and to the extent that any Included In-License Payment becomes due with respect to the performance of Commercialization Activities in the Territory, the Contracting Party will pay the same and such payment will be treated as [***].
- (e) <u>Manufacturing</u>. If and to the extent that any Included In-License Payment becomes due with respect to Manufacturing activities undertaken pursuant to the activities described in clause (a), (b), (c) or (d) above, then the Parties' respective responsibilities for such Included In-License Payment will be as set forth in such clause (a), (b), (c) or (d), as applicable.

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EXHIBIT G_

Confidential CMC Document Review Procedures

1. In connection with any review conducted pursuant to Section 6.1(d), the Merck Representatives (as defined below) shall have the right to review [***] (i) Confidential CMC Data or (ii) [***] (collectively, "Confidential

- <u>CMC Documents</u>"), solely for the purposes of assisting Merck in determining [***]. Merck's participation in any such review of Confidential CMC Documents is strictly limited to the Merck Representatives. In no event will Merck permit any Merck personnel other than the Merck Representatives to participate in any such review of any Confidential CMC Documents. For the purposes of this **Exhibit G**, "<u>Merck Representatives</u>" shall mean Merck employees that [***].
- 2. At Merck's election, Confidential CMC Documents [***] for review pursuant to this **Exhibit G** will be made available for review by the Merck Representatives either in [***].
- 3. [***]
- 4. Except as otherwise set forth herein, in no event will (a) the Merck Representatives disclose or make available (directly or indirectly) any information learned from such review of, or otherwise pertaining to, the Confidential CMC Documents to anyone other than providing to Merck's (or its Affiliate's) employees that [***], and (b) any Merck personnel who have received or who have access to (directly or indirectly) any such information pursuant to this **Exhibit G** use such information for any purpose other than to [***]. Merck will ensure that any such individual having access to such information will be made aware of its highly confidential nature and will cause such individuals to comply with this **Exhibit G**.

EXHIBIT J

Patent Prosecution and Maintenance; Patent Enforcement

1. Patent Committee.

- 1.1 Composition. The IP Committee shall comprise [***] representatives of Merck and [***] representatives of Moderna. Each Party may change its representatives to the IP Committee from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate expertise, seniority, decision-making authority and ongoing familiarity with the Collaboration, and each Party's representatives collectively will have relevant expertise in intellectual property portfolio management and licensing matters. With the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), each Party may invite employees and consultants to attend meetings of the IP Committee, subject to their agreement to be bound to the same extent as a permitted subcontractor under Section 10.4. The IP Committee may change its size from time to time by mutual consent of its members; provided that the IP Committee will consist at all times of an equal number of representatives of each of Merck and Moderna.
- 1.2 Meetings. The IP Committee will meet as necessary to carry out its duties under Paragraph 1.1, but at least [***] per Calendar Quarter during the Collaboration Term, unless otherwise agreed by its members. The IP Committee will meet in-person at Moderna or Merck or, alternatively, by means of teleconference, videoconference or other similar communications equipment.
- 1.3 *IP Committee Responsibilities*. The IP Committee will provide input regarding the strategy of Prosecuting and Maintaining [***] with respect to a given Program, including the following activities:

 1.3.11 [***]
- 1.4 *Decision-Making Authority*. The IP Committee will be an advisory committee for the Collaboration and to the Parties and will make recommendations by consensus. The IP Committee will not have any final decision-making power, and its discussions with not be subject to review or approval by the JSC.

2. Prosecution and Maintenance.

2.1 Moderna Patents.

2.1.1 Moderna General Patents and Moderna Agent Technology. Moderna shall have the sole right, but not the obligation, at its own expense and through counsel of its own choosing, to Prosecute and Maintain the Moderna General Patents and any Patents within the Moderna Agent Technology worldwide.

2.1.2 [***]

2.1.3 /***/

2.1.4 /***/

2.2 Merck Patents.

2.2.1 Merck General Patents and Merck Agent Technology. Merck shall have the sole right, but not the obligation, at its own expense and using counsel of its own choosing, to Prosecute and Maintain the Merck General Patents and any Patents within the Merck Agent Technology worldwide.

2.2.2 [***]

- 2.3 <u>Patent Costs.</u> Patent and Trademark Expenses incurred by the prosecuting Party in connection with Prosecuting and Maintaining [***], as applicable (but not any [***]), shall be treated in accordance with this **Exhibit J** or **Exhibit D** or **Exhibit E**, as follows:
- 2.3.1 for such Patent and Trademark Expenses accrued by the Parties during the applicable POC Term, if (a) Merck exercises the Merck Participation Election for a given Program, then [***], and (b) if Merck does not exercise the Merck Participation Election for the PCV Program, then [***];
- 2.3.2 such Patent and Trademark Expenses incurred by or on behalf of each Party (or its Affiliates) during the Merck Participation Term for a given Program will be treated as [***];
- 2.3.3 such Patent and Trademark Expenses incurred by or on behalf of each Party (or its Affiliates) in the event of a Merck Non-Participation for the PCV Program or a Merck Cessation Election for the PCV Program will be treated as [***]

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- 2.3.4 such Patent and Trademark Expenses incurred by or on behalf of a Party (or its Affiliates) in the event of a Merck Non-Participation for a given SAV Program or a Merck Cessation Election for a given SAV Program will be [***].
- 2.4 <u>Cooperation</u>. The Parties agree to cooperate fully in the Prosecution and Maintenance of the Moderna Patents and Merck Patents in the Territory under this Agreement. Cooperation shall include:
- 2.4.1 executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to (a) effectuate the ownership of intellectual property set forth in Section 11; (b) enable the other Party to apply for and to prosecute Patent applications in the Territory; and (c) obtain and maintain any Patent extensions, supplementary protection certificates, and the like with respect to the Moderna Patents and Merck Patents in the Territory, in each case, to the extent provided for in this Agreement;
- 2.4.2 consistent with this Agreement, assisting in any license registration processes with applicable governmental authorities that may be available in the Territory for the protection of a Party's interests in this Agreement; and
- 2.4.3 promptly informing the other Party of any matters coming to such Party's attention that may materially affect the Prosecution and Maintenance of any such Moderna Patents or Merck Patents in the Territory.
- 3. <u>Patent Extensions</u>. With respect to any election for patent term restoration or extension, supplemental protection certificate or any of their equivalents, (a) Merck will have the sole right to make any such decision relating to the Merck Patents; provided that [***]; (b) Moderna will have the right to make any such decision relating to the Moderna Patents; provided that, [***] and (c) if either Party requests that the other Party make any election for patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to which such other Party has sole decision making authority pursuant to this Paragraph 2, the Parties shall discuss and such other Party shall consider in good faith any such request.
- 4. <u>Patent Listings</u>. With respect to any filings made to Regulatory Authorities with respect to the Moderna Patents or Merck Patents for any Collaboration Product, including as required or allowed in connection with in the United States, the FDA's Orange Book, if applicable, or outside the United States, other international equivalents, [***] will have the sole right to make any such decision. Upon the request by [***], [***] will reasonably cooperate in the implementation of decisions regarding the filing and listing pursuant to this Paragraph 3.
- 5. Patent Enforcement and Defense.

5.1 <u>Notice</u>. With respect to a given Program, each Party will promptly notify the other Party, in writing, upon learning of any [***] (in each case [***], a "<u>Competitive Infringement</u>"), or of [***], would amount to Competitive Infringement, and will, along with such notice, provide any evidence in its possession pertaining thereto, subject to Third Party confidentiality obligations.

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5.2 Competitive Infringement.

5.2.1 /***/

5.2.2 General Patents. [***]

5.2.3 [***]

5.2.4 Neither Party will exercise any of its enforcement rights under Paragraph 5.2.1 without first consulting with the other Party, provided that this consultation requirement will not limit either Party's rights under this Paragraph 5.2.

5.3 Defense.

5.3.1 /***/

5.3.2 [***]

5.3.3 [***]

- 5.4 <u>Withdrawal, Cooperation and Participation</u>. With respect to any infringement or defensive action identified above in Paragraphs 5.2 or 5.3:
- 5.4.1 If the controlling Party ceases to pursue or withdraws from such action, it will promptly notify the other Party (in sufficient time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and such other Party may substitute itself for the withdrawing Party and proceed under the terms and conditions of [***].
- 5.4.2 The non-controlling Party will cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party), including [***]. The Party controlling any such action will keep the non-controlling Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.
- 5.4.3 Each Party will have the right to participate or otherwise be involved in any such action controlled by the other Party, in each case at the non-controlling Party's sole cost and expense. If a Party elects to so participate or be involved, the controlling Party will provide the non-controlling Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party will take into account reasonable requests of the non-controlling Party regarding such enforcement or defense.
- 5.4.4 In all cases, prior to the commencement of any infringement or defensive action identified above in Paragraphs 5.2 or 5.3, the Parties shall reasonably consult with respect thereto, including a discussion of the relevant Patents to be included in any such action.

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- 5.5 <u>Damages</u>. Unless otherwise agreed by the Parties, [***], all monies recovered upon the final judgment or settlement of any such action will be [***]. Unless otherwise agreed by the Parties, [***], all monies recovered upon the final judgment or settlement of any such action shall be treated [***].
- 5.6 <u>Agent Technology</u>. Notwithstanding anything in this Agreement to the contrary, Moderna has the sole right to enforce and defend all Patents within the Moderna Agent Technology, and Merck has the sole right to enforce and defend all Patents within the Merck Agent Technology.

- 6. <u>Third Party Rights</u>. Notwithstanding the foregoing provisions of this **Exhibit J**, each Party's rights and obligations under this **Exhibit J** will be subject to the Third Party rights and obligations under any Included In-License.
- 7. Matters involving General Patents and Agent Technology. Notwithstanding anything in this Agreement to the contrary, as between the Parties and irrespective of Committee involvement or otherwise, (a) Moderna shall have final decision making authority with respect to any and all matters involving the Moderna General Patents and any Patents within the Moderna Agent Technology, and (b) Merck shall have final decision making authority with respect to any and all matters involving Merck General Patents and any Patents within the Merck Agent Technology.
- 8. <u>Third Party Rights</u>. To the extent that a Third Party licensor under a Moderna Included In-License has retained any right to [***], Moderna will use Commercially Reasonable Efforts to cause such Third Party licensor to take the actions specified by this Exhibit J in a manner consistent with the Moderna Included In-License applicable thereto, but Moderna will not be deemed to be in breach of its obligations under this Exhibit J if, after using such Commercially Reasonable Efforts, it is unable to comply with such obligations because of actions taken or not taken by such Third Party licensor.
- 9. <u>Matters involving Joint Patents</u>. The Prosecution and Maintenance, and the enforcement and defense, of any Joint Patents shall be [***].
- 10. Immune Potentiator Patent Application. [***]