4.1. **Compliance with Legal Requirements.**

Licensee shall conduct, and shall ensure that its Affiliates, Sublicensees and Subcontractors, conduct, all activities hereunder, including all Development and Commercialization of the Product, in compliance with all Applicable Laws.

In addition, Licensee hereby certifies that (i) to its reasonably knowledge or belief, neither Licensee nor its Affiliates has been, prior to the Effective Date debarred under United States law, including Section 21 U.S.C. 335a (or any foreign equivalent thereof), and (ii) neither
Licensee nor its Affiliates will, from and after the Effective Date, employ or otherwise use in any capacity, the services of any Person, who to the knowledge or belief of Licensee or any of its Affiliates is, debarred under United States law, including Section 21 U.S.C. 335a (or any foreign equivalent thereof) to perform any portion of the activities hereunder, including any Development and Commercialization of the Product.

Licensee shall notify Sub-Licensor in writing promptly upon becoming aware of any such debarment of any such Person, and shall, upon becoming so aware, promptly remove such Person from performing any such activities and from any function or capacity related to any such activities.

4.2. **Compliance with Ethical Business Practices.**

(a) **Compliance with Laws and Policies.**

Licensee shall conduct the activities contemplated herein, and shall ensure that its Affiliates, Sublicensees and Subcontractors, conduct the activities contemplated herein, in a manner which is consistent with all Applicable Laws in Korea including, as applicable, Good Clinical Practices, Good Laboratory Practices, the U.S. Foreign Corrupt Practices Act which generally
prohibits the promise, payment or giving of anything of value either directly or indirectly to any Official for the purpose of obtaining or retaining business or any improper advantage, and the UK Bribery Act of 2010 which additionally includes the prohibition on the making of any bribe to a foreign public official with the intention of influencing such person in order to obtain or retain business or an advantage in the conduct of business, and good business ethics.

(b) **Governments and International Public Organizations.**

Licensee warrants that, in connection with this Agreement and Licensee's business relating thereto, Licensee, its directors, employees, officers, and anyone acting on Licensee's behalf or with Licensee's knowledge, shall not offer, make or promise any payment, and shall ensure that its Affiliates, Sublicensees and Subcontractors, do not offer, make or promise any payment (either directly or indirectly, of money or other assets) to any government officials (including any government-owned or controlled commercial enterprise), 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 (either directly or
indirectly of money or other assets) would constitute a violation of any Applicable Law.

In addition, Licensee shall make no payment (either directly or indirectly of money or other assets), and shall ensure that its Affiliates, Sublicensees and Subcontractors, make no payment in connection with this Agreement or Licensee's business relating thereto, either directly or indirectly to Officials if such payment (either directly or indirectly of money or other assets) is for the purpose of (i) influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of either Party's business; (ii) inducing such Official to do or omit to do any action in violation of the lawful duty of such Official; (iii) securing any improper advantage; or (iv) inducing such Official to use his/her position to affect or influence any decisions or actions of government or any legislative, administrative, public agency or other public body with respect to any activities undertaken relating to this Agreement.

Additionally, Licensee will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to the extent they relate to the subject of this Agreement, to enable Licensor to ensure compliance with any
applicable anti-corruption laws.

(c) **Disclosure.**

Where Licensor requests reasonable information regarding disclosure of any officers, employees, owners, or persons directly or indirectly retained by Licensee who are Officials or relatives of Officials of any governmental authority with oversight over the performance of Licensee's obligations under this Agreement or any Regulatory Documentation, if such persons are engaged to perform Licensee's obligations under this Agreement, Licensee shall provide complete and accurate information and documentation to Licensor with respect thereto. Licensee shall update such disclosures upon request of Licensor from time to time as necessary to ensure the information provided remains complete and accurate for the Term of this Agreement.

(d) **Books and Records.**

Licensee represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of
transactions and expenditures. Licensee further represents, warrants and agrees that no "off the books" or similar funds will be maintained or used in connection with this Agreement.

(e) **Compliance Training.**

Licensee agrees to ensure that all of Licensee’s employees involved in performing the obligations under this Agreement are made specifically aware of the compliance requirements under Sections 4.2(a), (b), (d), (e) and (f).

(f) **Exclusions Lists.**

Licensee shall not use (and shall cause its Affiliates not to use) any Person (including any employee, officer, director, Sublicensee or Third Party contractor) who is (or has been) on the Exclusions List, or who is (or has been) in Violation, in the performance of any activities hereunder. Licensee certifies to Sub-Licensor that as of the Effective Date, Licensee has screened itself, and its officers and directors (and its Affiliates, Sublicensees and Third Party contractors and their respective officers and directors) against the Exclusions Lists and that it has informed Licensor whether Licensee, or any of its officers or directors (or any of its
(g) **Obligation to Notify.**

Licensee shall promptly notify Licensor upon becoming aware of any violation of any anti-corruption laws by Licensee or its Affiliate or those acting on Licensee’s behalf in connection with the matters that are the subject of this Agreement and the performance by Licensee of its obligations hereunder.

(h) **Compliance Audits.**

Licensee shall maintain books and records that are complete and accurate in all material respects relating to its compliance by Licensee and its Affiliates that is engaged in carrying out activities in connection with this Agreement with anti-corruption laws and with respect to its obligations under this Agreement (collectively, the “Compliance Records”) for a period of two (2) years after the period to which such records relate or such longer period as required by Applicable Laws, which Compliance Records shall include: (a) its policies and
procedures including those of Licensee and its Affiliates concerning compliance with anti-corruption laws with respect to its obligations under this Agreement, (b) records of any investigations and remedial and disciplinary actions undertaken to address material violations of anti-corruption laws with respect to its obligations under this Agreement and (c) records of any payments made by it or Licensee and its Affiliates in connection with this Agreement. Upon reasonable advance written notice to Licensee, Licensor shall be entitled, at its cost and expense, to have access to and audit the Compliance Records of Licensee and any of its Affiliates (to the extent such Compliance Records are not subject to attorney-client privilege) for a period of two (2) years after the period to which such records relate or such longer period as required by applicable anti-corruption laws. Licensor may not exercise this audit right more frequently than once during any twelve (12)-month period; provided, however, that if any audit by Licensor under this Section 4.2(h) reveals that Licensee or any of its Affiliates is or was not in material compliance with applicable anti-corruption laws in relation to the performance of its obligations under this Agreement, Licensor shall have the right to conduct such additional audits (for clarity, such additional audits shall apply only to the applicable Licensee and its Affiliates which was so determined during the initial audit in such twelve (12)-month period to not be in material compliance) during such twelve (12)-month period as may be reasonably required to determine whether
Sub-Licensee and its Affiliates have appropriately remedied such non-compliance.

4.3. **Termination for Non-Compliance.**

Any uncured violation by Licensee or any of its Affiliates of any applicable anti-corruption laws in connection with its obligations under this Agreement shall be a material breach of this Agreement entitling Sub-Licensor to terminate this Agreement pursuant to Section 11.2(c).

4.4. **Responsibility for Compliance.**

Licensee acknowledges and agrees that neither Licensor, nor or any of its Affiliates or Licensor’s or its Affiliates’ officers, directors, employees, agents and representatives is authorized to waive compliance with the provisions of Section 4.3 and/or to give any direction, either written or oral, relating to the making of any commitment by Licensee or its agents to any Third Party in violation of the terms of this ARTICLE 4, and that Sub-Licensee shall be solely responsible for its compliance with all applicable anti-corruption laws irrespective of any act or omission of Merck or any of Merck’s Affiliates or Merck’s or its Affiliates’ officers, directors, employees, agents and representatives.
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