제약회사의 API 공급, 완제품 생산위탁, 완제품구매 계약서에서 정부의 제조품목허가 관련 계약조항 영문 샘플

7. REGULATORY MATTERS.

7.1 **Ownership of Product Regulatory Approvals and Documentation**. Licensee shall own all Product Regulatory Approvals and Documentation in respect of each country in the Territory.

7.2 Conduct and Management of Regulatory Activities. Licensee will use its Commercially Reasonable Efforts:

(a) to maintain the First Approved NDA in the United States;

(b) to obtain Regulatory Approval for the Product for the Nocturia Indication in each other country in the Territory in accordance with the Development Plan;

and

(c) to obtain Regulatory Approval for the Product for the PNE Indication in each country in the Territory in accordance with the Development Plan.

Any breach by Licensee of its obligations under Section 7.2(a) shall be deemed to be a material breach of this Agreement for purposes of Article 14.

7.3 **Transfer to Licensee of Product Regulatory Approvals and Documentation.** Following the transfer to Licensee of ownership of the Product Regulatory Approvals and Documentation in each such country in the Territory pursuant to Section 2.3(b),

(a) Licensee or its designee shall be the owner of any and all Product Regulatory Approvals and Documentation in each such country in the Territory, subject to the Right of Reference or Use hereby granted by Licensee to Licensor in Section 2.5(c) for purposes of Development and Commercialization of Products outside the Territory;

(b) Except for the Development and Commercialization of Products by Licensor in the Territory pursuant to Section 6.3, Licensee shall have the responsibility, at its expense, for all regulatory activities (including, without limitation, Development Activities undertaken to support obtaining or maintaining Regulatory Approvals) and interactions relating to the Product in each country in the Territory, including without limitation preparing, obtaining, and maintaining Regulatory Approvals in each country in the Territory and all substantive interactions with such Regulatory Authorities relating thereto; and

(c) Licensee shall determine, in its sole discretion, the content of all such submissions and of all correspondence with Regulatory Authorities relating to the Product in the Territory.

(d) To the extent Licensor has not undertaken any Product Development Activities in the Territory under Section 2.5(c), Section 2.6, Section 6.1 and/or Article 14, Licensor hereby grants to Licensee a Right of Reference or Use in all Regulatory Approvals and Regulatory Documentation in respect of the Compound and any Products in respect of which Licensor is the sponsor for purposes of Licensee's Development and Commercialization of Products in the Field and in the Territory. In consideration of such grant, Licensee will make one or more payments to Licensor determined in accordance with the same provisions set forth in clauses (ii) and (iii) in Section 2.5(c) in respect of

Licensee's grant of the Right of Reference or Use set forth in clause (i) of Section 2.5(c).

7.4 **Regulatory Documentation for Generic Products**.

(a) Each Party shall deliver written notice to the other Party of any notice it receives as to the submission, filing, or approval of an application, including, without limitation, an Abbreviated New Drug Application in the United States or the equivalent thereof in any other country in the Territory, in respect of a Generic Product within three (3) days after receipt or such notice thereof.

(b) Licensee shall have the sole right to respond to each such application, provided that Licensee shall consult with Licensor regarding any such application and the response thereto.

7.5 **Audits**. Licensor will have the continuing right during the Term of this Agreement, upon reasonable prior written notice to Licensee, to inspect, audit, and investigate any facilities, equipment, record-keeping procedures, and records utilized by Licensee and its subcontractors in connection with the Manufacture and Commercialization of the Product

and any Development (including, without limitation, the conduct of Clinical Studies) of the Product.

7.6 **Regulatory Authority Communications Received by a Party.**

(a) Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection, or communication by or from any Person, including, without limitation, any Regulatory Authority in any country in the Territory, that may affect the safety or efficacy claims of the Product, have a material adverse effect on the Commercialization of the Product, or that otherwise suggests the Product may be in violation of Applicable Laws in such country.

(b) Upon receipt of such information described in Section 7.7(a), the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for Licensee to take at Licensee's expense.

(c) Each Party shall keep the other Party informed, in a timely manner consistent with the reporting requirements of Regulatory Authorities, of notification of any action by any

Regulatory Authority, or notification or other information that the Party receives (directly or indirectly) from any such Regulatory Authority, and provide to such other Party copies of all documents, if any, it received from such Regulatory Authority.

(d) Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to in this Section 7.7.

7.7 **Adverse Event Reporting and Safety Data Exchange**.

(a) Licensee shall be responsible, at Licensee's expense, in each country in the Territory for the monitoring of all clinical experiences, post-marketing experiences, and filing of all required reports with respect to the Product.

(b) Licensor shall transfer to Licensee the patient database, including without limitation the databases, in their entirety, containing pharmacokinetic, pharmacodynamic, efficacy, and safety information, developed in connection with the conduct of Clinical Studies for the Product under U.S. IND 076667, and all information relating thereto, in the format

requested by Licensee. Licensor shall have the right to retain a copy of any and all such information transferred to Licensee.

(c) Each Party shall (i) notify the other Party immediately, but in no event later than three (3) Business Days, after becoming aware of any information concerning any complaint involving the possible failure of Product to meet any requirement of Applicable Laws, and any Unexpected Adverse Drug Experience or other serious or unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidents associated with the distribution or use of the Product and (ii) with respect to adverse events, comply with the provisions of this Section 7.7, and the applicable agreements described herein. Specific details regarding the exchange and management of information relating to adverse events related to the use of the Product shall be delineated and product labeling personnel of each Party shall work in good faith together during such time to negotiate an agreement that:

(i) identifies which safety information shall be exchanged, which shall include without limitation all adverse events for any Indication or condition;

(ii) identifies when such information shall be exchanged (which SAE information shall be provided within two (2) Business Days after notification of such SAE);

(iii) provides that Licensee shall (i) have regulatory reporting responsibilities, (ii) manage the global safety database, (iii) be obligated to obtain follow-up information on incomplete safety reports, (iv) review the literature for safety report information, and (v) prepare required periodic safety updates;

(iv) sets forth the roles and responsibilities of the Parties related to review and approval of safety information for inclusion in the Product labeling; provided that Licensee shall have the final decision-making authority with respect to any disputes regarding such activities with respect to Product in accordance with the terms and conditions hereof;

(v) identifies any other details required to appropriately manage safety information for the Product; and

(vi) as soon as reasonably practicable following the Effective Date, but in no event later than sixty (60) days thereafter Licensor and Licensee will agree upon the terms and conditions of the Pharmacovigilance Agreement and will thereupon execute and deliver to the other Party a copy of such Agreement.

7.8 **Remedial Actions**.

(a) Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Product in the Field may be subject to a Remedial Action.

(b) The Parties will assist each other in gathering and evaluating such information as is required to determine the necessity of conducting a Remedial Action with respect to the Product in the Field in the Territory; provided, however, that Licensee shall have sole responsibility for collecting information from its customers in the Territory, including, without limitation, customer complaints, in accordance with the terms and conditions hereof.

(c) Each Party will maintain adequate records to permit the Parties to trace the manufacture of the Product in the Field and the distribution and use of the Product in the Field. In the event Licensee determines that any Remedial Action with respect to the Product in the Field in the Territory should be commenced or Remedial Action is required by any Governmental Authority having jurisdiction over the matter, Licensee will control and coordinate all efforts necessary to conduct such Remedial Action, provided that Licensee shall consult with Licensor or its designee regarding any such Remedial Action.

(d) The cost and expense of a Remedial Action (including the Parties' reasonable costs and expenses in conducting such Remedial Action, but excluding claims described in Article 10) shall be allocated as follows:

(i) If such Remedial Action is due to Licensee's gross negligence or willful misconduct, material breach of this Agreement, or material violation of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensee;

(ii) if and to the extent that such Remedial Action is due to Licensor's gross negligence or willful misconduct, Licensor's material breach of this Agreement, or Licensor's material breach of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensor; and

(iii) if and to the extent that such Remedial Action is due to reasons other than as set forth in Sections 7.8(d)(i) and (ii), then: (A) Licensor shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensor, as Licensor's predecessor in interest; and (B) except for the Development and Commercialization of Product in the Territory by Licensor pursuant to Section 6.3, Licensee shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensee and its contractors; provided, however, that nothing in this Section 7.8(d)(iii) is intended to limit or supersede any obligation that Renaissance may have in respect of any such lots of the Product subject to such Remedial Action.

국제계약, 영문계약, 계약분쟁, 손해배상, Claim, License, R&D 제휴계약

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