

*This is a license agreement to use patented inventions, processes, etc. to develop new drugs.*

## EXCLUSIVE PATENT LICENSE AGREEMENT

THIS AGREEMENT made effective as of the \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

**BETWEEN:**

[NAME OF OWNER OF PATENT]

[address]  
(the "Licensor")

- and -

[NAME OF LICENSEE]

[address]  
(the "Licensee")

### RECITALS

- A. Licensor is the holder of several patents related to various inventions, discoveries and processes ("Licensed Subject Matter") within the field of \_\_\_\_\_ [describe the field of research].
- B. Licensor desires to have the Licensed Subject Matter developed and used for the benefit of Licensee, Licensor, and the public.
- C. Licensee wishes to obtain a license from Licensor to use the Licensed Subject Matter in furtherance of the parties' intentions under this Agreement.

NOW THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties agree as follows:

#### 1. Effective Date

This Agreement is effective the \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

#### 2. Definitions

Wherever used throughout this Agreement, the following words and phrases shall have the meanings indicated:

**Affiliate** means any business entity of which Licensee owns at least 51%, any business entity which owns at least 51% of Licensee, or any business entity that is at least 51% owned by a business entity that owns at least 51% of Licensee.

**FDA** means United States Food and Drug Administration.

**Field** means \_\_\_\_\_ [describe the field of research]

**Licensed Product** means any product or service which is created, produced and/or developed using Licensed Subject Matter pursuant to this Agreement.

**Licensed Subject Matter** means inventions, discoveries and processes covered by the Patent Rights and/or Technology Rights within the Field.

**Net Sales** means the gross revenues received by Licensee, an Affiliate and/or any sublicensee from the Sale of Licensed Products, less applicable sales and/or use taxes actually paid, import and/or export duties actually paid, outbound transportation prepaid or allowed, and amounts allowed or credited due to returns (not to exceed the original billing or invoice amount).

**Patent Rights** means Licensor's rights in information or discoveries covered under the patents and/or patent applications listed in the attached Exhibit 1, and all divisionals, continuations, and letters patent that issue thereon and reissues, reexaminations or extensions thereof, and any corresponding foreign patents and patent applications, subject to any limitations set forth therein.

**Phase 1 Clinical Studies** means (a) that portion of the drug development and review process which provides for the initial introduction of an investigational new drug into humans, as more specifically defined by the rules and regulations of the FDA; or (b) a similar development milestone in any national jurisdiction.

**Phase 2 Clinical Studies** means (a) that portion of the drug development and review process which provides for early controlled clinical studies conducted to obtain preliminary data on the effectiveness of an investigational new drug for a particular indication, as more specifically defined by the rules and regulations of the FDA; or (b) a similar development milestone in any national jurisdiction.

**Phase 3 Clinical Studies** means (a) that portion of the drug development and review process in which expanded clinical studies are conducted to gather the additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of an investigational new drug, as more specifically defined by the rules and regulations of the FDA; or (b) a similar development milestone in any national jurisdiction.

**Sale** means the transfer or disposition of a Licensed Product for value to a party other than Licensee.

**Technology Rights** means Licensor's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, software, designs, drawings or data created by \_\_\_\_\_ *[name of party]* prior to the Effective Date hereof and relating to \_\_\_\_\_ which are not covered by Patent Rights but which are necessary for practicing the Patent Rights.

**Territory** means \_\_\_\_\_ *[list countries]*. *[if worldwide, use: all countries throughout the world.]*

### 3. **Warranty; Superior Rights**

3.1 *[delete this first part, if not applicable:]* Except for the rights of the government of the United States of America ("Government"), as set forth below, Licensor represents and warrants to Licensee as follows:

- (a) that it is the owner of the entire right, title, and interest in and to the Licensed Subject Matter,
- (b) that it has the sole right to grant the license granted hereunder, and
- (c) that, to the best of its knowledge and belief, it has not knowingly granted a license to any other entity that would restrict the rights granted to Licensee under this Agreement, except as specifically stated herein.

3.2 *[delete if not applicable:]* Licensee understands that the Licensed Subject Matter may be developed under a funding agreement with the Government and that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to any rights of the Government under any agreement and any applicable law or regulation. If there is a conflict between any agreement, applicable law or regulation and this Agreement, the terms of the Government agreement, applicable law or regulation shall prevail. Licensee agrees that Licensed Products used or sold in the United States will be manufactured substantially in the United States, unless a written waiver is obtained in advance from the Government.

3.3 Licensee understands and acknowledges that Licensor, by this Agreement, makes no representation as to the operability or fitness for any use, safety, efficacy, approval by regulatory

authorities, time and cost of development, patentability, and/or breadth of the Licensed Subject Matter. Licensors, by this Agreement, also makes no representation as to whether there are any patents now held, or which will be held, by others or by Licensors which may be dominant or subordinate to the Patent Rights, nor does Licensors make any representation that the inventions contained in the Patent Rights do not infringe any other patents now held or that will be held by others or by Licensors.

3.4 Licensee, by execution hereof, acknowledges, covenants and agrees that it has not been induced in any way by Licensors or its employees to enter into this Agreement, and further warrants and represents that:

- (a) it has conducted sufficient due diligence with respect to all items and issues pertaining to this Agreement; and
- (b) Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and agrees to accept all risks inherent herein.

#### **4. License**

4.1 Licensors hereby grants to Licensee a royalty-bearing, exclusive license under the Licensed Subject Matter to manufacture, have manufactured, use and/or sell Licensed Products within the Territory for use within the Field. This grant is subject to the payment by Licensee to Licensors of all consideration as provided herein, and is further subject to rights retained by Licensors to: