

## Standard License Agreement

THIS AGREEMENT is made between:

Transgenomic, Inc., a Delaware corporation providing laboratory services, genetic assays and platforms, with corporate headquarters at 12325 Emmet Street, Omaha, Nebraska, USA 68164 (hereinafter “Transgenomic”)

and

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(hereinafter “Licensee”)

In exchange for good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, Transgenomic and Licensee agree as follows:

### 1. Preliminary Matters

#### 1.1 Background

1.1.1 Transgenomic and Licensee intend that, through this Agreement, Licensee will be permitted to provide Long QT Testing under the Long QT Patents, as herein defined, on a not-for-profit basis to persons entitled to healthcare under the Canadian healthcare system and to carry out not-for-profit patient care and research.

#### 1.2 Definitions

1.2.1 When used in this Agreement:

1.2.2 “at a profit” means any performance for which funding or reimbursement, as the case may be, is not at or below cost;

1.2.3 “at or below cost” has the meaning set out in Section 2.2 of this Agreement;

1.2.4 “Health Authority” means, in singular or plural usage as required by the context, an agent of the Canadian government or of a Canadian provincial or territorial government that regulates, oversees, funds or reimburses the performance of gene testing or any other medical services, directly or indirectly, by authority of statute, including but not limited to:

- a. any body administering a “health care insurance plan” within the meaning of the *Canada Health Act*, RSC 1985, c C-6, including but not limited to entities listed in Schedule A;
- b. any governmental entity that replaces the function of the aforementioned bodies; and

- c. any entity of the Canadian government or of a Canadian provincial or territorial government under the control of any of the aforementioned bodies.

1.2.5 “Long QT Patent”, in singular or plural usage as required by the context, means:

- a. Canadian Patent No. 2 240 737, titled “A LONG QT SYNDROME GENE WHICH ENCODES KVLQT1 AND ITS ASSOCIATION WITH MINK”;
- b. Canadian Patent No. 2 336 236, titled “MUTATIONS IN AND GENOMIC STRUCTURE OF HERG- A LONG QT SYNDROME GENE”;
- c. Canadian Patent No. 2 337 491, titled “HUMAN MINK GENE MUTATIONS ASSOCIATED WITH ARRHYTHMIA”;
- d. Canadian Patent No. 2 369 812, titled “MINK-RELATED GENES, FORMATION OF POTASSIUM CHANNELS AND ASSOCIATION WITH CARDIAC ARRHYTHMIA”; and/or
- e. Canadian Patent No. 2 416 545, titled “COMMON POLYMORPHISM IN SCN5A IMPLICATED IN DRUG-INDUCED CARDIAC ARRHYTHMIA”.

1.2.6 “Long QT Genes” means the following genes as embodied in nucleic acids, in a mutated or unmutated state:

- a. KCNQ1, also called KVLQT1, KCNA9 or KCNA8;
- b. KCNH2, also called HERG, ERG1 or KV11.1;
- c. KCNE1, also called MINK or ISK;
- d. KCNE2, also called MIRP1; and
- e. SCN5A, also called NAV1.5;

1.2.7 “Long QT Test”, in singular or plural usage as required by the context, means any process, machine, manufacture or composition of matter used for:

- a. research concerning the Long QT Genes or their associated RNAs or polypeptides,
- b. screening for any mutations within one or more of the Long QT Genes or their functional products (*e.g.*, RNAs or proteins), and/or
- c. diagnosis relating to the screening set forth,

whether or not the research, screening or diagnosis also involves genes other than the Long QT Genes;

- 1.2.8 “Party” and “Parties” mean:
- a. Licensee, and/or
  - b. Transgenomic.
- 1.2.9 “Territory” means the whole of Canada; and
- 1.2.10 “Unexpired Claim”, in singular or plural usage as required by the context, means any claim in an unexpired Long QT Patent, which has not been held void or invalid by a decision of a Canadian court or other governmental agency that is unappealable or unappealed within the time allowed for appeal.

## 2. License

### 2.1 Grant of License

- 2.1.1 Subject to the terms and conditions of this Agreement, Transgenomic hereby grants to Licensee, solely to the extent of Transgenomic’s legal right to do so, a personal, non-exclusive, non-transferable, non-sublicensable license solely under the Long QT Patents to: (i) undertake or make (but not to have undertaken or made) Long QT Tests in the Territory; (ii) use the Long QT Tests undertaken or manufactured pursuant to Section 2.1.1(i) to (a) conduct internal, not-for-profit research concerning the Long QT Genes or their associated RNAs or polypeptides (provided that, for clarity, such research may not be carried out for any commercial purposes or carried out on behalf of or for the benefit of any third party other than a patient as provided below), (b) screen for any mutations within one or more of the Long QT Genes or their functional products (e.g. RNAs or proteins), and (c) carry out diagnoses based on the screening set forth in Section 2.1.1(ii)(b) hereof; (iii) advertise the screening and diagnosis services set forth in Sections 2.1.1(ii)(b) and 2.1.1(ii)(c) hereof solely in the Territory; and/or (iv) sell the screening and diagnosis services set forth in Sections 2.1.1(ii)(b) and 2.1.1(ii)(c) solely in the Territory, in all cases only where all of the following conditions are met:
- a. the Long QT Tests are performed by Licensee and otherwise sold by Licensee at or below cost;
  - b. the screening and diagnosis services set forth in Sections 2.1.1(ii)(b) and 2.1.1(ii)(c) are performed on research subjects or patients who are citizens or residents of Canada, who are refugees in Canada, or who are present in Canada for reasons other than receiving medical services, purchasing medical or pharmaceutical products or services, or otherwise receiving the benefit of the Canadian healthcare system; and
  - c. the Long QT Tests are performed pursuant to a healthcare professional’s recommendation or direction.
- 2.1.2 **No Exclusivity.** The licenses granted herein are non-exclusive, and subject to the terms of this Agreement, Transgenomic reserves all rights to use, commercialize,

license, and otherwise exploit all aspects of the Long QT Patents for any use or purpose.

- 2.1.3 Licensee will not be obliged to pay any fee or royalty to Transgenomic under the license set forth in Section 2.1.1.
- 2.1.4 Licensee shall not commence a legal proceeding challenging the validity or enforceability of any of the Long QT Patents or Transgenomic's exclusive ownership of the Long QT Patents, nor will Licensee assist any other entity in challenging the validity or enforceability of any of the Long QT Patents or Transgenomic's exclusive ownership of the Long QT Patent. In the event Licensee commences a legal proceeding challenging or assists any third party in challenging the validity, enforceability or exclusive ownership by Transgenomic of any Long QT Patent, Transgenomic may terminate this Agreement effective immediately upon notice to Licensee.
- 2.1.5 There are no implied rights or licenses granted under this Agreement, whether by implication, estoppel or otherwise. All rights not expressly granted herein by Transgenomic are reserved by Transgenomic. For emphasis, there are no have made, have used, or similar rights granted hereunder, and, as a part of the foregoing, Licensee shall have no right to have any of its rights exercised by or on its behalf by any third party. Without limiting the foregoing, Licensee acknowledges and agrees that it may not (and that no right or license is granted under this Agreement to) (i) use any third party to undertake or manufacture the Long QT Tests, (ii) perform the Long QT Tests for or on behalf of a third-party testing provider that is not a not-for-profit entity in the Territory, and/or (iii) use or perform the Long QT Tests for any commercial purpose.
- 2.1.6 Transgenomic covenants not to bring a claim of infringement of the Long QT Patents against Licensee alleging infringement of the Long QT Patents based solely on activities coming within the scope of the license granted under Section 2.1.1. If Transgenomic commences a legal proceeding to enforce the Long QT Patents against Licensee in respect of activities not coming within the scope of the license granted under Section 2.1.1, Licensee reserves the right to challenge the validity, enforceability or ownership of the Long QT Patents in such proceeding.
- 2.1.7 The license granted to Licensee hereunder does not diminish or otherwise affect the rights of Licensee or any third-party to conduct activities exempt from patent infringement in accordance with section 55.2 of the *Patent Act* and/or the common law exemption from patent infringement for non-commercial use of patented inventions.

## **2.2 Determining Use At or Below Cost**

- 2.2.1 For the purposes of this subsection only, "Fee" means a payment that reimburses or funds Licensee's performance of a Long QT Test.
- 2.2.2 A Long QT Test is performed at or below cost if the Fee charged by Licensee for the Long QT Test is less than or equal to the sum of all costs it incurs in

association with the Long QT Test. Such costs may include one or more of but are not limited to the following:

- a. payment, direct and indirect, for the labour required to administer and perform the Long QT Test and analyze test results;
- b. the cost of acquiring, storing, and disposing of necessary disposable materials;
- c. the allocable cost of validating the Long QT Test;
- d. the allocable cost of equipment used, directly or indirectly, in the Long QT Test;
- e. the allocable cost of any infrastructure necessary to conduct and validate the Long QT Test; and
- f. reasonably allocable overhead, whether calculated directly or based on a reasonable estimate when assessed in accordance with Generally Accepted Accounting Principles (GAAP).

2.2.3 If a Health Authority pays Licensee a Fee for performance of a Long QT Test that is intended to cover only some or all of the costs laid out in the previous paragraph, then the Fee paid is deemed to be less than or equal to the costs incurred, and the Long QT Test is deemed to be at or below cost.

2.2.4 Where Licensee has been deemed to provide a Long QT Test at or below cost in accordance with the prior paragraph, subsequent provision of a substantially similar Long QT Test by Licensee for the same or lower Fee shall be deemed to be at or below cost, whether the Fee is paid by a Health Authority or some other person.

2.2.5 A Long QT Test is also deemed to be “at or below cost” if Licensee is paid no Fee for that Long QT Test, including but not limited to:

- a. if Licensee pays for costs out of a publicly-funded operating budget rather than accepting reimbursement at a rate per test, or
- b. if Licensee or its associated researchers receive grant or other funding to conduct research.

2.2.6 If Licensee intends to perform a Long QT Test at a profit, the Parties may negotiate reasonable terms before the Long QT test is undertaken.

### **2.3 No Sublicensing**

2.3.1 Licensee will have no right to sublicense any of the rights granted under this Agreement to any third party.

## **3. Accessory Rights and Obligations**

### **3.1 Assignment**

- 3.1.1 Licensee may not assign, transfer, or otherwise delegate any of its rights or obligations under this Agreement, in part or in whole, whether directly or indirectly, and whether by operation of law, change of control, acquisition, sale, or any other similar process, to any third party without Transgenomic's prior written consent, which may not be unreasonably withheld.
- 3.1.2 If Transgenomic assigns any of the Long QT Patents, it shall require that the assignee agree to abide by all terms of this Agreement as a condition of the assignment.

## **4. Representations and Warranties**

### **4.1 Representations and Warranties**

- 4.1.1 Transgenomic and Licensee each represent and warrant to the other that:
  - a. each is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized;
  - b. each has the legal power and authority to execute, deliver and perform this Agreement;
  - c. the execution, delivery and performance by each of this Agreement has been duly authorized by all necessary corporate action;
  - d. this Agreement constitutes the legal, valid and binding obligation of each, enforceable against each other in accordance with its terms; and
  - e. the execution, delivery and performance of this Agreement will not cause or result in a violation of any law, or of any contract by which each is bound.

### **4.2 Warranty Disclaimers**

- 4.2.1 Nothing in this Agreement is or shall be construed as:
  - a. A warranty or representation by Transgenomic as to the validity or scope of any claim or patent within the Long QT Patents;
  - b. A warranty or representation by Transgenomic that the performance of the Long QT Tests or the exercise of any of the license rights under this Agreement is or will be free from infringement of any patent rights or other intellectual property right of any third party;
  - c. A grant by Transgenomic, whether by implication, estoppel, or otherwise, of any licenses or rights under any patents other than the Long QT Patents;

- d. An obligation on Transgenomic to bring or prosecute any suit or action against a third party for infringement of any of the Long QT Patents; or
- e. A representation or warranty of the ownership of the Long QT Patents.

4.2.2 **TRANSGENOMIC MAKES NO, AND HEREBY DISCLAIMS ANY, WARRANTIES, EXPRESS OR IMPLIED, IN CONNECTION WITH THE LONG QT PATENTS, WHICH ARE LICENSED “AS IS” AND “WITH ALL FAULTS.” AND, EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, TRANSGENOMIC, ON BEHALF OF ITSELF AND ITS AFFILIATES, AND THEIR LICENSORS, OFFICERS, DIRECTORS, EMPLOYEES, AND AGENTS, SPECIFICALLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WARRANTIES AS TO VALIDITY, ENFORCEABILITY, NON-INFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE.**

## **5. Indemnification**

5.1 Licensee shall defend, indemnify and hold harmless Transgenomic, the Children’s Hospital of Eastern Ontario, and their affiliates, and their officers, directors, shareholders, employees and agents from and against any and all claims, suits, allegations, liabilities, damages, costs and expenses, including reasonable attorneys’ fees arising out of or relating to: (i) the exercise of the license rights granted to Licensee hereunder, including, without limitation, any claims based on Licensee’s manufacture, use, or performance of the Long QT Tests or any diagnoses made using the Long GT Tests, or (ii) the negligence, misconduct, or violation of law by Licensee or any of its officers, directors, employees, or agents with respect to this Agreement or the Long QT Tests.

5.2 Transgenomic shall defend, indemnify and hold harmless Licensee and its affiliates, and, their officers, directors, shareholders, employees and agents from and against any and all claims, suits, allegations, liabilities, damages, costs and expenses, including reasonable attorneys’ fees arising out of or relating to: (i) the assignment of one or more of the Long QT Patents by Transgenomic in breach of this Agreement, including, without limitation, a failure by Transgenomic to require that the assignee of the Long QT Patents agree to abide by all terms of this Agreement as a condition of the assignment; or (ii) the negligence, misconduct, or violation of law by Transgenomic or any of its officers, directors, employees, or agents with respect to this Agreement.

### **5.3 Governing Law**

5.3.1 This Agreement shall be governed in all respects by and construed in accordance with the laws of the Province of Ontario and federal laws of Canada. Transgenomic and Licensee hereby expressly exclude the application of the *United Nations Convention on Contracts for the International Sale of Goods*.

### **5.4 Jurisdiction and Forum**

5.4.1 Licensee and Transgenomic submit to the non-exclusive jurisdiction of the courts of Ontario for all disputes under this Agreement. Licensee and Transgenomic



Fax: 001 402 452 5461

Email: [kgarman@transgenomic.com](mailto:kgarman@transgenomic.com)

To Licensee:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Attn: \_\_\_\_\_

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

Email: \_\_\_\_\_

## **6.5 Further Assurances**

6.5.1 Transgenomic and Licensee shall do all things and sign all documents necessary to give effect to this Agreement.

## **6.6 Severability**

6.6.1 In the event that any term, provision or covenant of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove such invalidity, illegality or unenforceability, and the remaining terms, provisions and covenants shall not in any way be affected or impaired thereby.

## **6.7 Entire Agreement and Amendment**

6.7.1 This Agreement contains the entire understanding of Transgenomic and Licensee with respect to the matter contained herein and replaces any prior oral or written communications between Transgenomic and Licensee.

6.7.2 This Agreement may not be amended, modified, released, discharged or otherwise terminated, in whole or in part, except by an instrument in writing, signed by authorized representatives of the Parties hereto.

## **6.8 Successors**

6.8.1 This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors.

## **6.9 Construction**

6.9.1 This Agreement shall not be construed more strictly against either Party merely by virtue of the fact that the Agreement may have been drafted or prepared by one Party or its counsel.

**6.10 Article Headings**

6.10.1 The Article headings herein are for purposes of convenient reference only and shall not be used to construe or modify the terms written in the text of this Agreement.

**6.11 No Agency Relationship and No Joint Venture**

6.11.1 The relationship between the Parties is that of independent contractor and contractees. Licensee shall not be construed to be an agent of Transgenomic in connection with the exercise of any rights hereunder, and shall not have any right or authority to assume or create any obligation or responsibility on behalf of Transgenomic. This Agreement does not constitute a partnership or joint venture, and neither Party can be bound by the other to any contract, arrangement or understanding except as specifically stated herein.

**6.12 Force Majeure**

6.12.1 Neither Party shall be deemed to be in default of any provision of this Agreement for any failure in performance resulting from acts or events beyond the reasonable control of such Party, such as but not limited to, Acts of God, acts of civil or military authority, civil disturbance, war, strikes, fires, power failures, natural catastrophes or other “force majeure” events.

*[--remainder of page intentionally left blank--]*

Signature Page to Standard License Agreement

In witness whereof Transgenomic and Licensee have set their hands and seals, where applicable, by their duly authorized signing officers.

Executed at \_\_\_\_\_, the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

Licensee

Per: \_\_\_\_\_ c/s

Name:

Title:

Executed at \_\_\_\_\_, the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

Transgenomic, Inc.

Per: \_\_\_\_\_ c/s

Name:

Title: