

THE FONDAZIONE TELETHON MATERIAL TRANSFER AGREEMENT

This Agreement is made by and between:

- (1) **Fondazione Telethon**, a not-for-profit organization, whose mission is to advance biomedical research toward the diagnosis, cure and prevention of genetic diseases, having its registered address at Via C. Spinola, 16 - 00154 Roma, Italy ("Provider") on the one side; and
- (2), having its registered address at,
....., ("Institution") and the investigator ("Scientist") on the other side (collectively, "Recipient(s)").

In consideration of Provider supplying certain of its tangible materials and related confidential information to Recipients, the parties hereby agree as follows:

1. Definitions

In this Agreement:

- 1.1 "Reagent" shall mean **OA1 (Gpr143) knockout mice**
- 1.2
.....
generated by **Dr Enrico Surace** ("Provider Scientist") and published in ***Oa1 knock-out: new insights on the pathogenesis of ocular albinism type 1. Incerti B, Cortese K, Pizzigoni A, Surace EM, Varani S, Coppola M, Jeffery G, Seeliger M, Jaissle G, Bennett DC, Marigo V, Schiaffino MV, Tacchetti C, Ballabio A. Hum Mol Genet. 2000 Nov 22;9(19):2781-8.***
(if applicable)].
- 1.3 "Material(s)" shall mean Reagent, Progeny, Unmodified Derivatives (as defined below) and any related information and know-how.
- 1.4 "Progeny" shall mean any descendant from the Reagent such as virus from virus, cell from cell, or organism from organism.
- 1.5 "Unmodified Derivatives" shall mean substances and genetic material created by the Recipient which constitute an unmodified functional subunit or product expressed by the Reagent. Some examples include: subclones of unmodified cell lines, recombinant constructs, subcultures, mutations, proteins expressed by DNA/RNA supplied by Provider, sub-sets of the original Reagent such as novel plasmids or vectors, monoclonal antibodies secreted by a hybridoma cell line, and/or purified or fractioned sub-sets of the original Reagent; DNA, RNA, proteins, cells, tissues and organs either directly derived from Reagent, or reproduced by any means, specifically including cloning, PCR, cell or organ culture.
- 1.6 "Modification(s)" shall mean substances created by Recipients as a result of the Research which contain and/or incorporate the Material.
- 1.7 "Research" shall mean the experimental, non-commercial, scientific research described in Annex 1 to be performed by Recipients.
- 1.8 "Confidential Information" shall mean the Material and any unpublished information related to the Material disclosed by the Provider to the Recipients, which is either labelled as "confidential" or which is confidential by its nature.

2. Use of Material

- 2.1 Provider agrees to supply the Materials to Recipients, at no cost (except for the provision set out under following Section 9.2), for the purpose of the Research and hereby grants Recipients a non-exclusive, non-transferable, non sub-licensable license to use the Materials for the sole purpose of performing the Research and for no other purpose (including, without limitation, product development, preclinical or clinical testing purposes or any commercial purpose).

- 2.2 The Research shall be carried out under the direct supervision and responsibility of Scientist.
- 2.3 The Materials shall remain in the premises of the Institution, only in the Scientist's laboratory and under the direction of the Scientist.
- 2.4 Recipients shall use Materials only *in vitro* or in a laboratory for animal experiments.
- 2.5 Recipients shall not use the Materials in human subjects, in clinical trials involving human subjects, or for diagnostic purposes involving human subjects without the prior written consent of the Provider.
- 2.6 Recipients shall use the Materials only in compliance with all applicable laws, governmental regulations and guidelines, including any regulations or guidelines pertaining to research with animals or recombinant DNA that may be applicable to the Materials, in the country where the Research is carried out.
- 2.7 Except as otherwise permitted by this Agreement, Recipients shall not transfer or otherwise make available, without Provider's written consent, any Materials and/or Modifications to any third party other than Scientist and the Institution's employees who are working under the supervision of Scientist and who: (i) need to have access to Materials and/or Modifications for the purpose of performing the Research; (ii) are apprised of the proprietary nature of the Materials and/or Modifications and are bound to use the Materials and/or Modifications only in the manner permitted under this Agreement.
- 2.8 Recipients shall refer any request received by any third parties for the Materials to Provider. To the extent the Material is available, Provider will evaluate and decide, at its own discretion, whether to make the Materials available to third parties indicated by Recipients, on condition that such third parties are other Institution's scientists or other scientists at non-profit or governmental institutions and on condition that a proper Material Transfer Agreement is signed by each of these third parties with Provider.

3. Confidentiality

- 3.1 During the term of this Agreement and for a 5 (five) year period after its expiration or early termination for any reason whatsoever, Recipients agrees to maintain in strict confidence and not to disclose to any third party any Confidential Information, whether disclosed to Recipients in written, oral, graphic or electronic form, subject to following Section 3.2. Institution may disclose Confidential Information to its employees and officers requiring access thereto for the purpose of performing the Research provided that each such employee or officer is bound by a written agreement containing nondisclosure and non-use provisions no less restrictive than those set forth in this Agreement. It is understood and agreed that Institution shall be liable to Provider for any breach of the confidentiality obligations by any such employees and officers.
- 3.2 Recipients' confidentiality obligations under Section 3.1 above shall not apply to any Confidential Information which, at the time it is received or obtained by Recipients, and to the extent that the Recipient can establish by written proof, (a) is lawfully known by or available to Recipients without binder of secrecy; or (b) is generally available to the public; (c) is lawfully received or obtained by Recipients, without a binder of secrecy, from a third party who, at the best knowledge of the Recipients, did not receive the same, directly or indirectly, from Provider; or (d) becomes generally available to the public through no fault or omission on the part of Recipients; or (e) is independently generated by Recipients. In the event that Confidential Information is required to be disclosed pursuant to a valid court order or as required by law or regulation, Recipients may disclose such Confidential Information, provided that Recipients shall give reasonable prior written notice to Provider and shall make a reasonable effort to obtain a protective order requiring that the Confidential Information be disclosed only to the extent required by such order, law or regulation, and that it be used only for the purposes for which the order, law or regulation requires such disclosure to be made.
- 3.3 The Institution shall be primarily responsible to Provider for any breach by the Scientist of its obligations hereunder.

4. Ownership of Materials and Inventions

- 4.1 Recipients acknowledge and agree that Material represents a significant investment to the Provider and that Provider shall solely own all rights, title and interest, including any intellectual property rights, in the Materials, including any Materials incorporated in any Modifications. Provider shall decide, at its

sole discretion, to prepare, file, prosecute and maintain in its name patent and/or patent applications covering the Material.

- 4.2 Except as expressly set forth hereunder, no express or implied licenses or other rights are granted to Recipients under any patents, patent applications, know-how, trade secrets or other proprietary rights of Provider. In particular, no express or implied licenses or other rights are provided to use the Materials, Modifications, or any related patents of Provider for, *inter alia*, commercial purposes.
- 4.3 If the Research involving the Materials hereunder results in a Modification or any other invention, whether patentable or not, related to the Materials that could not have been invented but for Recipients' use of the Materials ("Invention"), Institution shall promptly communicate it in writing to Provider and shall promptly supply Provider with a written description of the relevant Invention ("Report").
- 4.4 Ownership or co-ownership of any Invention shall be determined in good faith by Provider and Institution pursuant to the applicable law and on the basis of the effective contribution in the achievement of such Invention.
- 4.5 Recipient shall not (and shall not attempt or purport to) file or prosecute in any country any patent application which claims or uses, or purports to claim or use, or relies for support upon Material and/or Invention, or any use thereof, without the prior express written consent of the Provider.
- 4.6 Recipient shall grant Provider an exclusive right to negotiate in good faith, under reasonable commercial terms, an exclusive, worldwide, sub-licensable license under Recipient's ownership in Invention pursuant to Section 4.4 (the "License"). Provider shall have three (3) months (hereinafter the "Option Period"), starting from the receipt of the Report or the Final Report (as defined in Section 5.1 below), to inform Recipient by written communication ("Communication") of its interest in negotiating the License. The parties shall have six (6) months from the receipt by the Recipient of the Communication (hereinafter the "Negotiation Period") to negotiate and execute the License in good faith under reasonable commercial terms. It is understood that (i) in case of failure by Provider to inform Recipient within the Option Period of its will to negotiate the License and/or (ii) in case of failure by the parties to execute the License within the Negotiation Period, Provider shall have a non-exclusive, royalty-free license on such Recipient's ownership in Invention for research activities and non-commercial purposes only.
- 4.7 Either party shall, at no cost to the other, execute (or cause to execute) such documents, and provide (or cause to provide) any assistance to the extent reasonable, as may be required, to the vesting in either party of the relevant right, title and interest in any Invention and in relation to the filing and prosecution of relevant patent rights.

5. Results and publication

- 5.1 Recipients shall keep complete and accurate records of the results of the Research and shall make them available to Provider upon request. Recipients agree to communicate in confidence to Provider a summary of the results of the Research, promptly after the conclusion thereof ("Final Report"). Recipients agree that Provider shall have the right to use any result of the Research for its research activities and non-commercial purposes.
- 5.2 Recipients shall be free to publish the results of the Research, provided that (i) Recipient may not disclose any Confidential Information and/or Invention that may jeopardize Provider's right to file a patent application (pursuant to Section 4.4 above) and (ii) Recipient shall first submit to Provider for its review, a copy of any proposed publication or other presentation of some or all of the results at least thirty (30) days prior to submission for publication and/or oral disclosure. During the thirty (30) day review period, the Provider will have the right to review such manuscript and to have it amended by deleting from the publication and/or oral disclosure reference to all such data and information (including Confidential Information and/or Invention) that may jeopardize Provider's right to file a patent application pursuant to Section 4.4 above.
- 5.3 Recipients shall acknowledge Provider in any such publication and/or oral disclosure, as the source of the Materials, in accordance with scientific custom.

6. Indemnification

- 6.1 PROVIDER MAKES NO REPRESENTATIONS, AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE MATERIALS, AND SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.
- 6.2 RECIPIENTS ACKNOWLEDGE THAT MATERIALS ARE EXPERIMENTAL IN NATURE AND ARE NOT INVESTIGATED REGARDING THEIR POTENTIAL RISKS; PROVIDER DOES NOT PROVIDE ANY WARRANTY CONCERNING THE SAFETY OF USING SUCH MATERIALS, NOT ASSUMING ANY RISK OF HARM TO PROPERTY OR PERSONS WITH RESPECT TO THE MATERIALS. IN NO EVENT PROVIDER SHALL BE LIABLE FOR ANY USE OF THE MATERIALS BY RECIPIENTS OR FOR ANY DAMAGE SUFFERED BY RECIPIENTS OR ITS OFFICERS, EMPLOYEES, SCIENTISTS, OR LABORATORY PERSONNEL. RECIPIENTS THEREFORE ASSUME ALL RISK OF HARM TO PROPERTY OR PERSONS WITH RESPECT TO RECIPIENT'S USE, STORAGE, AND DISPOSAL OF THE MATERIALS. IN NO EVENT WILL PROVIDER BE LIABLE FOR ANY USE OF THE MATERIALS BY SCIENTISTS, OR LABORATORY PERSONNEL UNDER SCIENTIST'S IMMEDIATE AND DIRECT CONTROL, OR RECIPIENTS, OR OF ANY LOSS, CLAIM DAMAGE OR LIABILITY OF ANY KIND OR NATURE, THAT MAY ARISE FROM OR IN CONNECTION WITH RECIPIENT'S USE, HANDLING, STORAGE, OR DISPOSITION OF THE MATERIALS.
- 6.3 TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE INSTITUTION AGREES TO INDEMNIFY, DEFEND, AND HOLD HARMLESS PROVIDER AND ITS TRUSTEES, OFFICERS, REPRESENTATIVES, EMPLOYEES, AND AGENTS AGAINST ALL LOSSES, EXPENSES (INCLUDING WITHOUT LIMITATION ANY LEGAL EXPENSES), CLAIMS, DEMANDS, SUITS, OR OTHER ACTIONS ARISING FROM THE USE, STORAGE, OR DISPOSAL OF THE MATERIALS BY RECIPIENTS, EXCEPT TO THE EXTENT CAUSED BY THE GROSS NEGLIGENCE OR WILFUL MISCONDUCT OF PROVIDER.

7. Term and Termination

- 7.1 This Agreement shall enter into effect on the date of signature by parties ("Effective Date") and shall terminate upon completion of the Research.
- 7.2 Provider shall have the right to terminate this Agreement in case of material breach of this Agreement by the Recipients and if the Recipients fail to cure such breach within thirty (30) days from Provider's written notice ordering Recipients to comply with the Agreement.
- 7.3 The provisions under Sections 3, 4, 6 and 8 shall survive expiration or early termination of this Agreement for any reason whatsoever.
- 7.4 Upon expiration or early termination of this Agreement for any reason whatsoever, or upon written request of Provider, Recipients shall at the instruction of Provider either destroy or return any unused Materials. Recipients will also either destroy Modifications or remain bound by the terms of this Agreement as they apply to Modifications.

8. Law and jurisdiction

This Agreement shall be construed and governed pursuant to the Italian law. The Court of Milan shall have exclusive jurisdiction for any controversy arising from or related to the present Agreement.

9. Miscellaneous

- 9.1 This Agreement is not assignable by Recipients, in any way, without the prior written consent of Provider.
- 9.2 The Materials may be provided with a fee that is solely intended to reimburse Provider for its production, shipping and distribution costs.
- 9.3 This Agreement can be modified only by written agreement duly signed by authorised representatives of the parties.
- 9.4 This Agreement does not imply nor shall it be construed to imply any obligation for Recipients or Provider to enter into any further agreement.

The parties hereby execute this Agreement effective as of the date last written below.

Agreed by: _____

Institution: _____

By: _____

Name: _____

Title: _____

Date: _____

Read and Understood by:

Scientist:

By: _____

Name: _____

Title: _____

Date: _____

Fondazione Telethon

Provider Scientist:

By: _____

Name: Francesca Pasinelli

Title: Managing Director

Date: _____

By: _____

Name: _____

Title: _____

Date: _____

Ref. FT MTA_

Annex 1

Research