



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Delivery of a corrective glucose-6-phosphatase-alpha gene to treat glycogen storage disease type 1a (GSD-Ia) in humans.

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Child Health and Human Development, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and foreign Patents and Patent Applications listed in the Supplementary Information section of this notice to Panacea Opportunity, Ltd..

DATES: Only written comments and/or applications for a license which are received by the National Institute of Child Health and Human Development c/o National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Alan Hubbs, Ph.D., Senior Technology Transfer Manager at Telephone: (240)-276-5530 or Email: hubbsa@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement:

Intellectual Property

1. Priority Application, U.S.P.T.O. No. 62/096,400, filed December 23, 2014 [HHS Reference No. E-039-2015/0-US-01];
2. PCT Patent Application No. PCT/US2015/067338, filed December 22, 2015 [HHS Reference No. E-039-2015-0-PCT-02];
3. Pending Canadian Patent Application No. 2972038, filed on December 22, 2015, [HHS Reference No. E-039-2015-0-CA-03];
4. Issued China Patent No. ZL201580076462.4, filed on December 22, 2015, Issued December 11, 2020 [HHS Reference No. E-039-2015-0-CN-04];
5. Issued European Patent No. 2182936, filed December 22, 2015, Issued July 22, 2020 [HHS Reference No. E-039-2015-0-EP-05];
6. Issued Israeli Patent No. 253103, filed on December 22, 2015, Issued April 1, 2020 [HHS Reference No. E-039-2015-0-IL-06];
7. Issued Japan Patent No. 6824169, filed June 22, 2017, Issued January 14, 2021 [HHS Reference No. E-039-2015-0-JP-07];
8. Issued United States Patent No. 10,415,044, filed September 17, 2019, Issued September 17, 2019 [HHS Reference No. . E-039-2015-0-US-08]
9. Pending United States Patent Application No. 16/526,327, filed July 30, 2019, [HHS Reference No. . E-039-2015-0-US-08]

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: “Delivery of a corrective glucose-6-phosphatase-alpha gene to treat glycogen storage disease type 1a (GSD-Ia) in humans.”

This technology discloses a gene therapy to treat glycogen storage disease type 1a (GSD-Ia) in humans using adeno-associated virus mediated delivery of a corrective glucose-6-phosphatase-alpha (G6Pase- α) gene nucleic acid sequence that codes for a protein having an amino acid sequence that differs from the wildtype human amino acid sequence at amino acid position 293.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Child Health and Human Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 11, 2021.

Richard U. Rodriguez,
Associate Director,
Technology Transfer Center,
National Cancer Institute.