[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of Glucocerebrosidase Activators for the Treatment of Gaucher Disease and Central Nervous System Proteinopathies, including Parkinson's Disease

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to Lysosomal Therapeutics, Inc., a company having a place of business in Boston, Massachusetts, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/420,946, filed December 8, 2010 (HHS Ref. No. E-257-2010/0-US-01) and PCT Patent Application No. PCT/US2011/063928, filed December 8, 2011 (HHS Ref. No. E-257-2010/0-PCT-02), both entitled "Substituted Pyrazolopyrimidines as Glucocerebrosidase Activators." The patent rights in these inventions have been assigned to the United States of America. The prospective exclusive evaluation option license territory may be "worldwide", and the field of use may be limited to "Treatment of Gaucher disease and human central nervous system proteinopathies, including without limitation Parkinson's disease." Upon the expiration or termination of the exclusive evaluation option license, Lysosomal Therapeutics, Inc. will have the right to execute an exclusive patent

commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the evaluation license.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application(s), inquiries, and comments relating to the contemplated exclusive license should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4426; Facsimile: (301) 402-0220; E-mail: tarak@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: Gaucher disease is a rare lysosomal storage disease caused by mutations in the glucocerebrosidase (GCase) gene; GCase is localized in the lysosome and is responsible for the breakdown of glucocerebroside, an intermediate in glycolipid metabolism. This technology provides small molecule activators of GCase that facilitate the proper folding of GCase and its transport to the lysosome, without inhibiting its activity in the lysosome. Thus, these compounds are extremely promising candidates for the development of a small molecule drug to treat Gaucher disease. Mutations in the GCase gene have also been associated with the development of Parkinson's disease, and therefore, these compounds may also

be useful for the treatment of Parkinson's disease. It is also possible that these compounds could be utilized to treat other proteinopathy-based diseases.

The prospective exclusive evaluation option license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license may be granted unless within fifteen (15) days from the date of this published notice, the NIH 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 404.7.

Only applications for a license in the field of use set forth in this notice and filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

July 18, 2012
Date

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Richard U. Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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