



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: Small molecule therapeutic compounds encompassed within the Licensed Patent Rights for the treatment of thioesterase deficiency disorder

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to practice the inventions embodied in the following Patent Applications to Circumvent Pharmaceuticals Inc.

(“Circumvent”) located in Pasadena, California, USA:

Intellectual Property

United States Provisional Patent Application No. 61/473,692, filed April 8, 2011, titled “Small molecule therapeutic compounds targeting thioesterase deficiency disorders and methods of using the same” [HHS Reference No. E-157-2011/0-US-01], status: expired;

International Patent Application No. PCT/US2012/32772 filed April 9, 2012 titled “Small molecule therapeutic compounds targeting thioesterase deficiency disorders and methods of using the same” [HHS Reference No. E-157-2011/0-PCT-02], status: converted;

European Patent Application No. 12716889.6, filed November 7, 2013, titled “Small molecule therapeutic compounds targeting thioesterase deficiency disorders and methods of using the same” [HHS Reference No. E-157-2011/0-EP-03], status: pending; and

United States Patent Application No. 14/110,393, filed October 7, 2013, titled “Small molecule therapeutic compounds targeting thioesterase deficiency disorders and methods of using the same” [HHS Reference No. E-157-2011/0-US-04], status: pending.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The territory of the prospective Start-Up Exclusive Evaluation Option License Agreement may be worldwide and the field of use may be limited to: “Small molecule therapeutic compounds encompassed within the Licensed Patent Rights for the treatment of thioesterase deficiency disorders”

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, Circumvent will have the exclusive right to execute a Start-Up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

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, inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Surekha Vathyam, Ph.D., Senior Licensing and Patenting Manager, National Cancer Institute Technology Transfer Center, 9609 Medical Center Drive, Rm 1E-530 MSC9702, Rockville, MD 20850-9702, E-mail: vathyams@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The subject technology describes methods of using derivative compositions of hydroxylamine, including N-t-butyl hydroxylamine (NtBuHA), for the treatment of thioesterase deficiencies. NtBuHA is small molecule derivative of hydroxylamine which possesses strong anti-oxidant properties and an ability to cleave thioester linkages with high specificity. These capabilities suggest that NtBuHA may be useful as a modulator of intracellular protein palmitoylation dynamics when endogenous mechanisms are insufficient to support normal function.

The compounds disclosed in this invention have potential therapeutic applications for both the management of diseases driven by excess accumulation or malfunction of palmitoylated proteins. Target disorders may therefore include neuronal ceroid lipofuscinoses (also known as Batten Disease), amyotrophic lateral sclerosis, and Ras-driven cancers.

The prospective Start-Up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective Start-Up Exclusive Evaluation Option License Agreement may be granted unless the NIH receives written evidence and argument that establishes that the grant of the contemplated Start-Up Exclusive Evaluation

Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in an appropriate field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement. 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.

Dated: August 8, 2016

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

[FR Doc. 2016-19418 Filed: 8/15/2016 8:45 am; Publication Date: 8/16/2016]