



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development and Use of a Therapeutic STAT3 Inhibitor, GLG-302, in All Proliferative Diseases, Where STAT3 is Present

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, 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.) Patents and Patent Applications listed in the Supplementary Information section of this notice to GLG Pharma LLC located in Jupiter, Florida, USA.

DATES: Only written comments and/or applications for a license which are received by the 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 an Exclusive Patent License should be directed to: Sidra Ahsan, Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business

mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: ahsans@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No.62/481,960, filed April 5, 2017 and entitled “Improved STAT3 Inhibitor Formulation” [HHS Reference No. E-035-2017/0-US-01];

PCT Patent Application No. PCT/US2018/026228, filed April 5, 2018 and entitled “STAT3 Inhibitor Formulation” [HHS Reference No. E-035-2017/0-PCT-02]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

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

The prospective exclusive license territory may be worldwide and the field of use may be limited to: “The development and commercialization of a therapeutic STAT3 inhibitor, GLG-302, in all proliferative diseases, where STAT3 is present.”

This technology discloses the use of the STAT3 inhibitor GLG-302 with Trizma salts for preclinical anti-cancer and cancer preventive activity. GLG-302 is a proprietary compound developed by GLG Pharma LLC. Trizma salts allow GLG-302 to remain in solution for oral administration. This formulation has been demonstrated to be effective in the modulation of STAT3 signaling and proliferation in normal mammary ductal epithelium, and this formulation has demonstrated mammary cancer preventive efficacy in rat (ER+) and mouse (ER-) models. The technology provides improved sample

handing and oral bioavailability suggesting that a therapeutic product derived from this technology would be applicable for the treatment of cancer where STAT3 is present.

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 Cancer Institute 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 USC 552.

Dated: May 15, 2019.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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