Billing Code 4040-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Modification of Exclusive Patent License Potent and Selective Analogues of: Monamine Transporters; Methods of Making; and Uses Thereof

Agency: National Institutes of Health,

Action: Notice

SUMMARY: The National Institute of Drug Abuse, an institute of the National Institutes of Health, Department of Health and Human Services is contemplating the modification of grant of an Exclusive Patent License to EncepHeal Therapeutics, Inc., located in Winston-Salem, North Carolina, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the National Institute on Drug Abuse's Technology Transfer Office on or before **[INSERT 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

Addressees: Requests for copies of the patent application, inquiries, and comments relating to the contemplated modification of the Exclusive Patent License should be directed to Martha Lubet, Ph.D., Technology Transfer Manager, NCI TTC, 9609 Medical Center Drive, Room IE350, MSC 9702 Rockville, MD 20850. Telephone: 240 276-5508. Facsimile: 240 276-5505. Email:lubetm@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

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

US provisional application 61/774,878, filed March 8, 2013 entitled "Potent and Selective Inhibitors of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-US-01];

PCT application PCT/US2014/021514, filed March 7, 2014 entitled "Potent and Selective Analogues of: Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-PCT-02];

US application 14/772,486, filed September 3, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-US-06];

EPO application 14714043.8, filed September 1, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-EP-05];

Australian application 2014225550, filed September 8, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-AU-03];

Australian application 2017202849, filed April 28, 2017 entitled Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-AU-07];

Canadian application 2903746, filed September 2, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-CA-04];

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

The Government previously announced its intention to grant an exclusive license to EncepHeal at Fed. Reg 80:245 (December 22, 2015), pp. 79595-79596.
The Notice of Intent to Grant (NOITG) specified a Field of Use as "Use of analogues of monamine transporters to treat substance use disorders and sleep disorders within the scope of the Licensed Patent Rights". Comments/Objections were not received in response to the NOITG. After consideration, an exclusive license was granted to EncepHEal with a Licensed Field of Use of: "Use of analogues of monamine transporters to treat substance use disorders within the scope of the Licensed Patent Rights". This Notice advises the public that the NIH intends to modify the Licensed Field of Use originally granted to EncepHEal. Specifically, the National Institute on Drug Abuse is proposing to modify the Licensed Field of Use to be "use of a lead compound to treat one or more of the following: substance use disorders, cognitive deficits, sleep disorders, attention deficit hyperactivity disorder and depressive disorders. The modification to the

Licensed Field of Use in the Exclusive Patent License requires EncepHeal to select a lead compound for each of the disorders listed in the Field of Use and that upon selection of a lead compound for a disorder, the other compounds of the technology will become available for licensing to other companies.

The technology is directed to novel analogues of modafinil. Modafinil (marketed as Provisil in United States) is approved by FDA to treat narcolepsy and other sleep disorders. Modafinil has been studied as a possible treatment for cognitive dysfunction in disorders such as attention-deficit hyperactivity disorders (ADHD) as well as cocaine and methamphetamine addiction. However, it has a relatively low affinity for dopamine transporter (DAT) and is water-insoluble, thus requiring large doses to achieve pharmacological effects. Early studies indicated that modafinil reduced cocaine intake more effectively than placebo; however, subsequent larger studies reported only modest effectiveness in reducing cocaine intake. The library of compounds in the technology are analogs of modafinil and are designed to have higher affinities for DAT and improved water solubility. The National Institute on Drug Abuse has conducted preliminary experiments on many of the compounds and has identified several compounds that have higher affinities than modafinil for the DAT and lower affinity than modafinil for several other off target receptors. Preliminary studies at the National Institute on Drug Abuse indicate that some of the compounds have *in vivo* activity in rodents to inhibit cocaine taking behavior and are not selectively self-administered themselves (i.e. have low abuse liability).

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404 and incorporates by reference: "Prospective Grant of Exclusive Option License: Potent and Selective Analogues of: Monamine Transporters; Methods of Making; and Uses Thereof" Fed. Reg 80:245 (December 22, 2015), pp. 79595-79596. The prospective modification of the Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from date of this published notice, the National Institute on Drug Abuse receives written evidence and argument that establishes that the grant of modification to the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFT Part 404.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated modification to Exclusive Patent 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.

Dated: September 22, 2107.

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Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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