[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: A3 Adenosine Receptor (A3AR) Agonists as an Orally-administered Analgesic for Treatment of Chronic Neuropathic Pain

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is 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 BioIntervene, Inc., a company having a place of business in Saint Louis, Missouri to practice the inventions embodied in the following patent applications and patents:

1. U. S. Patent 8,735,407, issued May 27, 2014, titled “Purine Derivatives As A3 Adenosine Receptor-Selective Agonists” [HHS Ref. No. E-140-2008/0-US-06];
2. European Patent Application 09728154.7, filed March 24, 2009, titled “Purine Derivatives As A3 Adenosine Receptor-Selective Agonists” [HHS Ref. No. E-140-2008/0-EP-05];

3. Canadian Patent Application 2720037, filed March 24, 2009, titled “Purine Derivatives As A3 Adenosine Receptor-Selective Agonists” [HHS Ref. No. E-140-2008/0-CA-04];
4. Australian Patent 2009231978, issued February 20, 2014, titled “Purine Derivatives As A3 Adenosine Receptor-Selective Agonists” [HHS Ref. No. E-140-2008/0-AU-03];
5. U. S. Patent Application 13/371,081, filed February 10, 2012, titled “A3 Adenosine Receptor Agonists And Antagonists” [HHS Ref. No. E-140-2008/1-US-01];
6. U. S. Provisional Application 61/909,742, filed November 27, 2013, titled “A3 Adenosine Receptor Agonists” [HHS Ref. No. E-742-2013/0-US-01]; and
7. U. S. Provisional Application 62/033,723, filed August 6, 2014, titled “A3 Adenosine Receptor Agonists” [HHS Ref. No. E-210-2014/0-US-01].

The patent rights in these inventions either have been assigned to the Government of the United States of America, or have been granted exclusive rights 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: “The use of an A3 Adenosine Receptor (A3AR) agonist as an orally-administered analgesic, either as monotherapy or as an add-on analgesic, for treatment of chronic neuropathic pain conditions”.

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, BioIntervene 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 patents, patent applications, inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Betty B. Tong, 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) 594-6565; Facsimile: (301) 402-0220; E-mail: tongb@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: The subject inventions describe selective A3 Adenosine Receptor (A3AR) agonists, and their *in vivo* activity reducing or preventing development of chronic neuropathic pain in an animal model. The A3AR subtype was linked with helping protect the heart from ischemia, controlling inflammation, and regulating cell proliferation. The compounds claimed are consistently highly selective

and have smaller molecular weight, thus can offer greater oral bioavailability. Hence, the subject inventions may provide a new treatment for chronic neuropathic pain.

The prospective Start-up Exclusive Evaluation Option License Agreement and a subsequent Start-up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, 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.

Complete applications for a license in the prospective 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 in response 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: December 3, 2014

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

[FR Doc. 2014-28749 Filed 12/08/2014 at 8:45 am; Publication Date: 12/09/2014]