[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of methanocarba analogues of purine and pyrimidine nucleosides and nucleotides to treat or prevent cardiac diseases in humans

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 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive evaluation option license, to practice the inventions embodied in U.S. Provisional Patent Application No. 60/176,373, filed January 14, 2000 and currently abandoned [HHS Ref. No. E-176-1999/0-US-01]; PCT Application PCT/US01/00981, filed January 12, 2001 and currently expired [HHS Ref. No. E-176-1999/0-PCT-02]; U.S. Patent Application No. 10/169,975, filed July 12, 2002 and issued as U.S. Patent No. 7,087,589 on August 8, 2006 [HHS Ref. No. E-176-1999/0-US-06]; U.S. Patent Application No. 11/500,860, filed August 8, 2006 and issued as U.S. Patent No. 7,790,735 on September 14, 2006 [HHS Ref. No. E-176-1999/0-US-07]; Australian Patent Application No. 2001230913, filed January 12, 2001 and issued as Australian Patent No. 2001230913 on October 13, 2005 [HHS Ref.

No. E-176-1999/0-AU-03]; Canadian Patent Application No. 2,397,366, filed January 12, 2001 and issued as Canadian Patent No. 2,397,366 on March 15, 2011 [HHS Ref. No. E-176-1999/0-CA-04]; European Patent Application No. 01903043.6, filed January 12, 2001 and issued as European Patent No. 1252160 on August 6, 2006 and currently abandoned [HHS Ref. No. E-176-1999/0-EP-05]; and UK Patent Application No. 01903043.6, filed January 12, 2001 and issued as UK Patent No. 1252160 on August 16, 2006 [HHS Ref. No. E-176-1999/0-GB-08], entitled "Methanocarba Cycloalkyl Nucleoside Analogues" to Cornovus Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware having its headquarters in Farmington, Connecticut. The United States of America is the assignee of the rights of the above inventions. The prospective exclusive evaluation option license territory may be ''worldwide'', and the field of use may be limited to "The use of (1'S,2R,3S,4'R,5'S)-4-(6-amino-2-chloro-9H-purin-9-yl)-1-[phosphoryloxymethyl] bicycle[3.1.0]hexane-2,3-diol) (MRS2339) to treat and/or prevent cardiac diseases in humans." Upon the expiration or termination of the exclusive evaluation option license, Cornovus Pharmaceuticals, 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 received by the NIH Office of Technology Transfer on or before [Insert date fifteen (15) days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Suryanarayana (Sury) Vepa, Ph.D., J.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5020; Facsimile: (301) 402-0220; E-mail: vepas@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 present technology is premised upon the novel combination of adenine and uracil and their derivatives with a constrained cycloalkyl group, typically a cyclopentyl group. The constraint on the cycloalkyl group is introduced by fusion to a second cycloalkyl group. In the case of cyclopentane, the fusion is typically with cyclopropane. The compounds disclosed in this technology retain a surprising binding affinity despite the substitution for the ribose group. Moreover, the absence of the glycosidic bond in the compounds assists in improving the chemical stability of these compounds and aids in overcoming the stability problem associated with the glycosidic bond in previously known P1 and P2 receptor ligands. The compounds of the present technology are useful in the treatment or prevention of various cardiac and other disorders.

The prospective exclusive evaluation option license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive

evaluation option license may be granted unless, within fifteen (15) days from the date of this published notice, 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 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. 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.

December 20, 2011
Date

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Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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