[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The development of MRI-1569, MRI-2213 and MRI-2214 as a therapeutic to treat obesity, diabetes, fatty liver disease and liver fibrosis.

AGENCY: National Institutes of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Public Health Service, PHS

ACTION: Notice

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the following inventions embodied in the following patent applications, entitled "CB1 receptor mediating compounds":

1. U.S. Provisional Patent Application No.: 61/991,333
   HHS Ref. No.: E-140-2014/0-US-01
   Filed: May 09, 2014

2. PCT Application No.: PCT/US2015/029946
   HHS Ref. No.: E-140-2014/0-PCT-02
   Filed: May 08, 2015

3. U.S. Provisional Patent Application No.: 61/725,949
   HHS Ref. No.: E-282-2012/0-US-01
   Filed: November 13, 2012

4. PCT Application No.: PCT/US2013/069686
   HHS Ref. No.: E-282-2012/0-PCT-02
   Filed: November 12, 2013

5. U.S. Patent Application No.: 14/442,383
   HHS Ref. No.: E-282-2012/0-US-03
   Filed: May 12, 2015

6. Canadian Patent Application No.: 2889697
   HHS Ref. No.: E-282-2012/0-CA-04
   Filed: April 27, 2015

7. European Patent Application No.: 13802153.0
   HHS Ref. No.: E-282-2012/0-EP-05
   Filed: June 01, 2015

8. Indian Patent Application No.: 3733/DELNP/2015
   HHS Ref. No.: E-282-2012/0-IN-06
   Filed: May 01, 2015

9. Japanese Patent Application No.: 2015-542015
   HHS Ref. No.: E-282-2012/0-JP-07
   Filed: May 11, 2015

10. Chinese Patent Application No.: 201380069389.9
    HHS Ref. No.: E-282-2012/0-CN-08
    Filed: July 3, 2015

11. US Provisional Application No.: 62/171,179
    HHS Ref. No.: E-282-2012/1-US-01
    Filed: June 04, 2015

to Kalytera Therapeutics Inc., ("Kalytera"), a company incorporated under the laws of Delaware and having an office in Hermosa Beach, California. The patent rights in these inventions have been assigned to the United States of America. This license may be worldwide. The field of use may be limited to the use of the Licensed Patent Rights to the development of select compounds from the patents listed above.

DATES: Only written comments and/or applications for a license which are received by the Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases 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, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Betty Tong, Ph.D., Sr. Licensing and Patenting Manager, Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892,; E-mail: betty.tong@nih.gov. A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

This technology, and its corresponding patent applications, is directed to methods of treating fibrosis, obesity and associated diseases such as type 2 diabetes by administering an agent that reduces appetite, body weight, hepatic steatosis, and insulin resistance. This technology may be useful as a means for treating various fibrotic diseases and metabolic syndromes without serious adverse neuropsychiatric side effects.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this

published notice, the Technology Advancement Office 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 404.7.

Properly filed competing applications for a license 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.

Dated: April 13, 2016

Anna Amar
Acting Deputy Director, Technology Advancement Office
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health

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