Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: N-Acetyl Mannosamine as a Therapeutic Agent

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Human Genome Research 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 Patents and Patent Applications listed in the Supplementary Information section of this notice to Leadiant Biosciences, Inc, located in Gaithersburg, Maryland. USA.

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

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Eggerton Campbell Ph.D., Senior Licensing and Patenting Manager, Technology Transfer Office (TTO), National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH), 5635 Fishers Lane, Suite 3058, MSC 9307, Bethesda, MD

20892-9307. Telephone: 301-402-1648. Fax: 301-402-9722. email: eggerton.campbell@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

US Provisional Patent Application No.: 60/932,451, [HHS Ref. No.: E-217-2007/0-US-01], Filed May 31, 2007; PCT Patent Application No.: PCT/US2008/006895, [HHS Ref. No.: E-217-2007/0-PCT-02], Filed: May 30, 2008; CA Patent Application 2680842, [HHS Ref. No.: E-217-2007/0-CA-03], Filed: May 30, 2008; EP Patent Application No.: 08767999.9, [HHS Ref. No.: E-217-2007/0-EP-04], Filed: September 14, 2009; IL Patent Application No.: 200872, [HHS Ref. No.: E-217-2007/0-IL-05], Filed: May 30, 2008; JP Patent Application No.: 2010-510363, [HHS Ref. No.: E-217-2007/0-JP-06, Filed: May 30, 2008; US Patent Application No.: 12/530,433, [HHS Ref. No.: E-217-2007/0-US-07], Filed: Sept 8, 2009; US Patent Application No.: 13/791,576, [HHS Ref. No.: E-217-2007/0-US-08], Filed: March 8, 2013; JP Patent Application No.: 2014-208695, [HHS Ref. No.: E-217-2007/0-JP-09], Filed: May 30, 2008; US Patent Application No.: 14/754,304, [HHS Ref. No.: E-217-2007/0-US-10], Filed: June 29, 2015; CA Patent Application No.: 2903133, [HHS Ref. No.: E-217-2007/0-CA-11], Filed: May 30, 2008; IL Patent Application No.: 245026, [HHS Ref. No.: E-217-2007/0-IL-12], Filed: March 8, 2013; JP Patent Application No.: 2016-159061, [HHS Ref. No.: E-217-2007/0-JP-13], Filed: August 15, 2016; EP Patent Application No.: 16196935.7, [HHS Ref. No.: E-217-2007/0-EP-14], Filed: March 8, 2013; US Patent Application No.: 15/702,529, [HHS Ref. No.: E-217-2007/0-US-08], Filed: September 12, 2017; and all continuing applications and foreign counterparts.

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 use of Licensed Patent Rights for the following: "Treating GNE Myopathy (also referred to as distal myopathy with rimmed vacuoles (DMRV), Nonaka myopathy, muscular dystrophy hereditary inclusion body myopathy (HIBM) or inclusion body myopathy type 2 (IBM2)) and kidney disorders due to hyposialylation of the glomerulae or sialic acid deficiency including but not limited to minimal change disease glomerulopathy, focal segmental glomerulosclerosis and membranous nephropathy, in humans with oral formulations of N-acetyl mannosamine (ManNAc) or derivative."

N-Acetyl Mannosamine is a precursor for the synthesis of sugar molecules known as sialic acids which play an important role in specific biological processes such as cellular adhesion, cellular communication and signal transduction. Lack of sialic acids also play an important role in disease processes such as cancer, inflammation and immunity.

This invention relates to methods of administering ManNAc or its derivative (to produce sialic acid in patients who are deficient in the sugar molecule) to treat GNE Myopathy (also referred to as distal myopathy with rimmed vacuoles (DMRV), Nonaka myopathy, muscular dystrophy hereditary inclusion body myopathy (HIBM) or inclusion body myopathy type 2 (IBM2)), and kidney disorders due to hyposialylation of the glomerulae or sialic acid deficiency may be treated by this method as well.

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 Human Genome Research 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: November 30, 2017.

Claire T. Driscoll,

Director,

NHGRI Technology Transfer Office.

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