[Billing Code: 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development, manufacture and commercialization of gene therapy products for human gene therapy use to treat and/or prevent Methylmalonic Acidemia (MMA).

AGENCY: National Institutes of Health (NIH).

ACTION: Notice.

SUMMARY: The National Human Genome Research Institute (NHGRI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to practice the inventions embodied in the Patent Applications listed in the Supplementary Information section of this notice License to Selecta Biosciences ("Selecta") located in Watertown, Massachusetts.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center 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., Licensing and Patenting Manager, Technology Transfer Office (TTO)

National Human Genome Research Institute, National Institutes of Health, 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

1. US Provisional Patent Application No.: 61/792,081

   HHS Ref. No.: E-243-2012/0-US-01

2. PCT Patent Application No.: PCT/2014/028045

   HHS Ref. No.: E-243-2012/0-PCT-02

3. EP Patent Application 14729502.6

   HHS Ref. No.: E-243-2012/0-EP-03

4. US Patent Application No.: 14/773,885

   HHS Ref. No.: E-243-2012/0-US-04

5. US Patent Application No.: 15/070,787

   HHS Ref. No.: E-243-2012/1-US-01

and all continuing applications and foreign counterparts. The patent rights in these inventions have been assigned 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:

> Development, manufacture and commercialization of gene therapy products for human gene therapy use to treat and/or prevent Methylmalonic Acidemia (MMA) comprised of the following: all of or fragments of the synthetic methylmalonyl-CoA mutase (MUT) human polynucleotide (synMUT) and/or recombinant synMUT constructs, in combination with the following:

> the Anc80 vector or vectors derived from the Anc80 vectors, wherein the derived Anc80 vectors have capsid sequences possessing 90% or greater sequence identity to the Anc80 capsid sequences.

For purposes of clarity, the above gene therapy products may be combined with Selecta's synthetic vaccine particles (SVP™) technology encapsulating an immunomodulator.

The subject technology discloses a synthetic codon-optimized human methylmalonyl-CoA mutase (MUT) cDNA gene (co-MUT) encoding human MUT protein, co-MUT constructs and uses thereof for treatment of MMA disorders. Such uses, may include the administration of immunomodulator(s) in order to maximize the advantage of the gene therapy, with fewer side effects. MMA is an autosomal recessive disorder caused by defects in the mitochondria-localized enzyme methylmalonyl-CoA mutase (MUT). MUT deficiency, the most common cause of MMA, is characterized by the accumulation of methylmalonic acid. MMA can lead to metabolic instability, seizures, strokes, and kidney failure, and can be lethal even when patients are being properly managed. If successfully developed, this invention would be a first of its kind therapy for MMA, by administering the disclosed nucleic acid, vector, or recombinant virus to a subject, optionally with an immunomodulator.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective Exclusive Patent License will be royalty bearing and 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated 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.

December 27, 2016 _____

Date

Claire T. Driscoll

Director, NHGRI Technology Transfer Office

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