[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Antibodies Against TL1A, a TNF-Family Cytokine, for the Treatment and Diagnosis of Crohn's Disease, Ulcerative Colitis, Asthma, Psoriasis and Biliary Cirrhosis.

AGENCY: National Institutes of Health

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute ("NHLBI"), an institute of the National Institutes of Health; an agency within the Department of Health and Human Services, is contemplating the grant of an exclusive patent license to commercialize the invention(s) embodied in the intellectual property estate stated in the Summary Information section of this notice to Precision IBD, Inc., located in San Diego, California, and incorporated under the laws of Delaware**.**

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Cristina Thalhammer-Reyero, PhD, MBA, Senior Licensing and Patenting Manager, NHLBI Office of Technology Transfer and Development, 31 Center Drive Room 4A29,

MSC2479, Bethesda, MD 20892-2479; Telephone: +1-301-435-4507; Fax: +1-301-594-3080; E-mail: thalhamc@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement:

US Provisional Patent Application No. 61/488,671, filed May 20, 2011; PCT Application. No. PCT/US2012/028926, filed March 13, 2012; U.S. Patent No. 9,068,003, issued June 30, 2015; U.S. Patent No.9,896,511, issued February 20, 2018; and US Patent Application No. 15/872,592, filed January 16, 2018, "Antibodies Against TL1A, a TNF-Family Cytokine, for the Treatment and Diagnosis of Autoimmune Inflammatory Diseases", NIH Reference No. E-073-2011/0,1,2.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, 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 and commercialization of antibodies against TL1A for the treatment and diagnosis of Crohn's Disease, Ulcerative Colitis, Asthma, Psoriasis and Biliary Cirrhosis"

The subject technology is based on the use of antibodies against TL1A, a TNF-Family cytokine, for the treatment and diagnosis of autoimmune inflammatory diseases. Autoimmune inflammatory diseases occur in greater than five percent of the US population. Treatments generally include immunosuppressants or anti-inflammatory drugs, which can have serious side effects. Recently, more specific immunomodulatory

therapies such as TNF-alpha antagonists have been developed. In experiments with mice, NIAMS inventors have shown that the interaction between the TNF family ligand TL1A with its receptor, DR3, is critical for development of disease in asthma, inflammatory bowel disease and multiple sclerosis. They have also developed anti-TL1A antibodies that prevent disease in mouse models of rheumatoid arthritis and inflammatory bowel disease. This invention describes anti-human TL1A monoclonal antibodies that may be useful for the development of diagnostics and therapeutics for autoimmune inflammatory diseases, as well as methods of treating such diseases by blocking the interaction between TL1A and DR3 by the described antibodies. This specific immunomodulatory effect provides potential for potent therapy without inducing global immunosuppression.

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 NHLBI Office of Technology Transfer and Development 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.

The public may file comments or objections in response to this Notice. 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 U.S.C. 552.

Dated: April 27, 2018.

Cristina Thalhammer-Reyero

Senior Licensing and Patenting Manager

Office of Technology Transfer and Development

National Heart, Lung, and Blood Institute

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