[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of 5T4 Antibodies in Human Cancer Therapeutics and Diagnostics

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Cancer Institute, 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 following U.S. Patents and Patent Applications to Ovensa, Inc. ("Ovensa") located in Ontario, Canada**.**

Intellectual Property

U.S. Provisional Patent Application No. 62/034,995 filed August 8, 2014 entitled "Human Monoclonal Antibodies Specific for 5T4 and Methods of Their Use" [HHS Ref. No. E-158-2014/0-US-01];

PCT Application No. PCT/US2015/044253 filed August 8, 2015 entitled "Human Monoclonal Antibodies Specific for 5T4 and Methods of Their Use" [HHS Ref. No. E-158-2014/0-PCT-02].

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 the Licensed Patent Rights in combination with the Licensee's proprietary or exclusively in-licensed platforms and technologies for the treatment, prevention or diagnosis of cancer."

DATE: Only written comments and/or applications for a license which are received by the Technology Transfer Center at the National Cancer Institute 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, inquiries, and comments relating to the contemplated exclusive license should be directed to: Rose Freel, Ph.D. Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 8490 Progress Drive, Riverside 5, Suite 400, Frederick, MD 21702; Telephone: (301) 624-1257; E-mail: rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION: 5T4 is an antigen expressed on many different types of cancers, especially solid tumors. Its expression is limited in normal

tissue, but is prevalent in malignant tumors throughout their development making it an attractive target for cancer immunotherapy. 5T4 is often found in colorectal, ovarian, and gastric tumors and as a result, has been used as a prognostic aid for these cancers. The role of 5T4 in antibody-directed immunotherapy has been studied using murine monoclonal antibodies (mAbs). In addition, the cancer vaccine TroVax (currently in clinical trials for multiple solid tumors) targets 5T4. The present invention describes the identification and characterization of two fully human mAbs (m1001 and m1002) that bind to 5T4. Since the mAbs are fully human, they could have less immunogenicity and better safety profiles than the existing mouse and humanized antibodies. These mAbs have the potential to be cancer therapeutics as naked mAbs, chimeric antigen receptors (CARs) or antibody-drug conjugates (ADCs).

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 National Cancer 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 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive 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.

Dated: March 29, 2016 _____

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

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