[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

AGENCY: National Institutes of Health

ACTION: Notice.

SUMMARY: The National Cancer 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 U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to Atara Biotherapeutics Inc. ("Atara") located in South San Francisco, CA**.**

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center 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 an Exclusive Patent License should be directed to: Rose M. Freel, Ph.D., Licensing and Patenting Manager, NCI Technology Transfer Center, 8490 Progress Drive, Suite 400, Frederick MD 21701 Telephone: (301)-624-8775; Facsimile: (240)-276-5504 E-mail: rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 61/040,005, filed March 27, 2008 and entitled "Human Monoclonal Antibodies Specific for Mesothelin" [HHS Reference No. E-079-2008/0-US-01];

PCT Patent Application PCT/US2009/038228, filed March 25, 2009 and entitled "Human Monoclonal Antibody Against Mesothelin" [HHS Reference No. E-079-2008/0-PCT-02]; and US Patent No. 8,357,783, filed September 22, 2010, Issued January 22, 2013 and entitled "Human Anti-Mesothelin Monoclonal Antibodies" [HHS Reference No. E-079-2008/0-US-06].

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 development of a mesothelin chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic T cells either transduced with a retroviral vector (including lentiviral vectors) or modified using a gene-editing technology, wherein the vector expresses a CAR comprising:

1) single antigen specificity for binding to mesothelin, and

2) at least a) the complementary determining region (CDR) sequences of the anti-mesothelin antibody known as m912, and b) a T cell signaling domain;

for the prophylaxis and treatment of mesothelin-expressing human cancers."

This technology discloses a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, stomach/gastric cancer, ovarian cancer, and pancreatic cancer. The specific antibody covered by this technology is designated as m912, which is a fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer. The m912 antibody selectively binds to the mesothelin on the surface of cancer cells and induces cell death of those cancer cells while leaving healthy cells unharmed. This selectivity may lead to fewer side effects due to decreased non-specific killing of cells.

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 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.

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: June 21, 2018

Richard U. Rodriguez,

Associate Director

Technology Transfer Center

National Cancer Institute

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