[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

AGENCY: National Institutes of Health, HHS.

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 Patents and Patent Applications listed in the Supplementary Information section of this notice to NeoImmune Tech, Inc. (NeoImmune), located in Rockville, Maryland.

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: David Lambertson, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 3W610 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-6467; E-mail: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 62/795,415 entitled "High Affinity Monoclonal Antibodies Targeting Glypican-1 For Treating Pancreatic Cancer" [HHS Ref. E-028-2019-0-US-01], PCT Patent Application PCT/US2020/013739 entitled "High Affinity Monoclonal Antibodies Targeting Glypican-1 For Treating Pancreatic Cancer" [HHS Ref. E-028-2019-0-PCT-02], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

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 research, development and commercialization of a bispecific antibody having the following elements:

(A) a first antibody component that binds to glypican 1 (GPC1), comprised of:

1) an antibody having the complementary determining region (CDR) sequences of the antibody known as HM2, or

2) an antibody having the CDR sequences of the antibody known as D4; and

(B) a second antibody component that binds to CD3;

For the treatment of GPC1-expressing human cancers.

The Licensed Field of Use specifically excludes any unconjugated mono-specific therapeutic antibodies and non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, recombinant immunotoxins, and antibody-drug conjugates (ADCs).

This technology discloses antibodies that are specific for the cell surface domain of GPC1. GPC1 is a protein that is aberrantly expressed on several forms of cancer, including pancreatic cancer. The antibodies can be used either as unconjugated agents, or in the form of immunoconjugates (such as bispecific antibodies, CARs, ADCs and immunotoxins) to specifically target diseased cells that express GPC1, These agents can be used for the selective destruction of the diseased cells, resulting in treatment that may not have severe deleterious effects seen with less specific therapeutic modalities.

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: March 24, 2020. Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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