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 an Anti-GPC3 Radionuclide Immunoconjugate for the Treatment of GPC3-Expressing Cancers

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 Xsto BioSciences, Inc. (Xsto), located in San Carlos, California.

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 A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 61/477,020 entitled "Human Monoclonal Antibody Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011-0-US-01], PCT Patent Application

PCT/US2012/034186 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-PCT-02], Chinese Patent 201280029201.3 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-CN-03], European Patent 2699603 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-EP-04], and validated in France [HHS Ref. E-130-2011-0-FR-09], Germany [HHS Ref. E-130-2011-0-DE-08] and the United Kingdom [HHS Ref. E-130-2011-0-GB-10] and lodged in Hong Kong [HHS Ref. E-130-2011-0-HK-11], United States Patent 9,206,257 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-US-05], United States Patent 9,394,364, entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-US-06], European Patent 2998320 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-EP-07], and validated in France [HHS Ref. E-130-2011-0-FR-23], Germany [HHS Ref. E-130-2011-0-DE-22] and the United Kingdom [HHS Ref. E-130-2011-0-GB-24], United States Patent 9,932,406 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-US-12], Chinese Patent Application 201610290837.3 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-CN-13], European Patent 3070104 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-EP-14], and validated in France [HHS Ref. E-130-2011-0-FR-18], Germany [HHS Ref. E-130-2011-0-DE-16], the United Kingdom [HHS Ref. E-130-2011-0-GB-19], Italy [HHS Ref. E-130-2011-0-IT-20] and Spain [HHS Ref. E-130-2011-0-ES-17] and lodged in Hong Kong [HHS Ref. E-130-2011-0-HK-15], United States Patent Application 15/843,256 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011-0-US-21], 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

(I) The development and commercialization of glypican-3 (GPC3) antibody-based radionuclide conjugates comprising of at least:

a. The complementary determining region (CDR) sequences of the anti-GPC3 antibody known as HN3, and

b. A radionuclide, including but not limited to an alpha, beta, positron, gamma or auger emitting radionuclide,

for the treatment of GPC3-expressing cancers.

(II) The development of an FDA-approved *in vivo* radiopharmaceutical, using a binder having the CDR sequences of the anti-GPC3 antibody known as HN3, for the diagnosis and monitoring of GPC3-expresing cancers.

The licensed field of use excludes any (a) non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, immunotoxins, and antibody drug conjugates, and (b) unconjugated antibodies.

This technology discloses monoclonal antibodies that are specific for the cell surface domain of GPC3. These antibodies can potentially be used for the treatment of GPC3-expressing cancers such as HCC. In the subject situation, the antibodies can be used in conjunction to target a radionuclide specifically to GPC3-expressing cells, leading to the selective destruction of the cancerous 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: October 23, 2019.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2019-23481 Filed: 10/25/2019 8:45 am; Publication Date: 10/28/2019]