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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: The Development of a Bispecific, Biparatopic Antibody-Drug Conjugate to GPC3 for the Treatment of Human Liver Cancers

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Salubris Biotherapeutics, Inc. (Salubris), located in Gaithersburg, Maryland, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

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

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated 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)-276-6467; E-mail: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement: (A) U.S. Provisional Patent Application 61/654,232 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012/0-US-01], PCT Patent Application PCT/US2013/043633 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012/0-PCT-02], Chinese Patent Application 201380039993.7 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use

Thereof" [HHS Ref. E-136-2012/0-CN-03], Japanese Patent Application 2015-515243 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012/0-JP-04], South Korean Patent Application 10-2014-7037046 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012/0-KR-05], Singapore Patent Application 11201407972R entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012/0-SG-06], and United States Patent 9,409,994 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012/0-US-07],

and all continuing U.S. and foreign patents/patent applications for the technology family; and (B) 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 Application 15188264.4 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-EP-07], United States Patent Application 15/090,873 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 Application 16166924.7 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-EP-14], and all continuing U.S. and foreign patents/patent applications for the technology family, to Salubris. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

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 Patent License territory may be worldwide for the following field of use:

> "The development and commercialization of a bispecific, biparatopic antibody-drug conjugate (ADC) having:
>
> 1) the CDR sequences of both the hYP7 and HN3 anti-GPC3 monoclonal antibodies; and
> 2) a microtubule inhibitor payload including, but not limited to, auristatin and mertansine;
>
> for the treatment of human liver cancer. The licensed field of use excludes any (a) non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, immunotoxins, ADCs with payloads that are not microtubule inhibitors, and monospecific versions of the aforementioned immunoconjugates, and (b) unconjugated antibodies."

The present inventions to be licensed concern monoclonal antibodies that are specific for the cell surface domain of GPC3: HN3 and hYP7. 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 toxic payload 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 Patent License will be royalty bearing and 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent 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: July 25, 2017 _____

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

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