DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Chimeric Antigen Receptors Targeting GPC3

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 Cytovia Therapeutics (''Cytovia'') located in New York, NY.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before August 14, 2020 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 Technology Transfer Manager, NCI Technology Transfer Center at Telephone: (240) 276–5530 or Email: *david.lambertson@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

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 62/584,421 entitled ''Chimeric Antigen Receptors Targeting Tumor Antigens'' [HHS Reference E–016–2018–0–US–01], PCT Patent Application PCT/US2018/059645 entitled ''Chimeric Antigen Receptors Targeting Tumor Antigens'' [HHS Reference E–016–2018–0–PCT–02], Chinese Patent Application (Application number currently unavailable) entitled ''Chimeric Antigen Receptors Targeting Tumor Antigens'' [HHS Reference E–016–2018–0–CN–03], European Patent Application 18822526.2 entitled ''Chimeric Antigen Receptors Targeting Tumor Antigens'' [HHS Reference E–016–2018–0–EP–04], South Korean Patent Application 10–2020–7014565 entitled ''Chimeric Antigen Receptors Targeting Tumor Antigens'' [HHS Reference E–016–2018–0–KR–05] and U.S. Patent Application 16/762,459 entitled ''Chimeric Antigen Receptors Targeting Tumor Antigens'' [HHS Reference E–016–2018–0–US–06], and all continuing U.S. and foreign patents/patent applications for the technology family.

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 following:

''The development, production and commercialization of a monospecific anti-GPC3 chimeric antigen receptor (CAR)-based allogeneic immunotherapy using either (A) unmodified Natural Killer (NK) cells or (B) induced pluripotent stem cells (iPSC), where the NK cells or iPSC are transduced using a viral vector to express an anti-GPC3 CAR, and where the CAR has at least:

(1) The complementary determining region (CDR) sequences of the anti-GPC3 antibody known as YP7 or hYP7; and

(2) a T cell co-stimulatory domain;

for the treatment of GPC3-expressing human cancers.

The Licensed Field of Use specifically excludes the use of autologous T cells or T cells that have been genetically modified to become allogeneic.''

This technology discloses the development of chimeric antigen receptors that recognize the glypican3 (GPC3) cell surface protein. GPC3 is expressed on the cell surface of several solid tumors, including liver cancers (such as hepatocellular cancer (HCC)), certain ovarian cancers, and neuroblastomas. Although the FDA has approved certain therapies for the treatment of liver cancer, those therapies only provide a minimal increase in the life expectancy of patients. The development of a new therapeutic targeting GPC3 will benefit public health by providing an improved and more effective treatment for patients.

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 completed 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 U.S.C. 552.

Dated: July 23, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020–16486 Filed 7–29–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: August 25, 2020.

Closed: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Room 206–Q, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206–Q, Bethesda, MD 20892, (301) 827–5517, *moenl@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 27, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–16509 Filed 7–29–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Development and Commercialization of CD22–Targeting Chimeric Antigen Receptor (CAR) T-Cell Therapies for Children and Young Adults With Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia (ALL)

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 seeking statements of capability and interest from prospective licensees and potential Collaborators interested in participating in collaborative research under a Cooperative Research and Development Agreement (CRADA) to develop autologous CD22 CAR T-cells (m971BBZ lentivirus transduced) for the treatment of B-cell ALL.

DATES: Statements of capability and interest should be submitted via email by September 1, 2020, with a formal proposal due by October 15, 2020.

ADDRESSES: Statements of capability and interest should be directed to: Jim Knabb, Ph.D., Senior Technology Transfer Manager, NCI, at 240–276–7856 or Email: *knabbjr@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Collaboration Opportunity

NCI is seeking a pharmaceutical or biotechnology company that can effectively and efficiently collaborate on the scientific and commercial development of CD22–CAR. The goal of the collaboration will be the successful transfer of clinical development of CD22–CAR from NCI to the Collaborator, which will be responsible for the rapid scale-up and clinical manufacture of the agent to support the pivotal clinical trial and subsequent BLA. The selected Collaborator will be responsible for the manufacture and provision of CD22–CAR lentivirus (m971BBZ lentivirus) and autologous CD22–CAR T-cell therapy product in sufficient quantities to complete the pivotal clinical trial. The selected Collaborator will prepare and submit a BLA to the FDA for CD22–CAR following the completion of the pivotal trial.

Subject to federal statutes and NIH guidelines including those governing the establishment of CRADAs (15 U.S.C. 3710a) and the licensing of federally owned inventions (35 U.S.C. 207), it is anticipated that the Collaborator will pursue an exclusive or nonexclusive commercialization license to the CD22–CAR. Additionally, NCI is able to offer a CRADA Collaborator the right to use any and all data developed during the course of the collaboration for commercial development of the agent, as well as access to existing CD22–CAR clinical study data and regulatory documents for commercial development of the agent.

Interested parties may sign a confidential disclosure agreement to obtain additional clinical data for its evaluation of the collaboration.

Roles of Collaboration Partners:

The roles of the National Cancer Institute in the CRADA may include but are not limited to the following:

1. NCI will provide intellectual, scientific, and technical expertise and experience related to the ongoing development of CD22–CAR.

2. NCI will continue to support clinical manufacture and development of CD22–CAR pending transition of manufacturing to an appropriate site by the commercial partner and will make data available to the Collaborator as appropriate.

3. NCI will collaborate in the design of protocols and the evaluation of results.

4. NCI will provide all clinical data in its possession to Collaborator to support FDA regulatory filings.

The roles of the CRADA Collaborator will include, but are not limited to the following:

1. The Collaborator will provide clinical development strategy and financial and other support for the collaborative development leading to BLA filing and FDA approval of CD22–CAR.

2. The Collaborator will provide intellectual, scientific, and technical expertise or experience to the development of CD22–CAR.

3. The Collaborator will provide sufficient clinical supply of autologously-derived CD22 CAR T-cell therapy product for all clinical trials under the CRADA; this includes additional trials that may be needed for licensing as well as trials required to meet clinical need for pediatric patients prior to licensing.

4. The Collaborator will prepare and submit regulatory documents to FDA, culminating in the submission of a BLA for CD22–CAR.

5. The Collaborator will demonstrate its capability of providing a commercial supply of CD22–CAR in a timely manner.

Selection Criteria

Interested parties should notify the NCI of their interest in filing a formal proposal no later than September 1, 2020. Potential licensees/CRADA Collaborators will have until October 15, 2020 to submit a formal proposal. Additional proposals will be considered after the posted deadline in the event that a Collaborator, meeting the necessary criteria, is not found during the initial posted time period. Selection criteria for choosing the CRADA Collaborator shall include, but not be limited to:

1. Possession of or access to the resources needed to support and perform the activities required to expeditiously commercially develop CD22–CAR (*e.g.,* facilities, personnel and expertise), including preparation and submission of regulatory documents;

2. Demonstrated ability to access the expertise required for successful