[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 Siglec-6-specific chimeric antigen receptor (CAR) for the Treatment Acute Myeloid Leukemia (AML), Chronic Lymphocytic Leukemia (CLL), and other forms of Acute and Chronic B- and T-Cell Leukemia and Lymphoma

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 T-CURX GmbH (T-CURX), located in Würzburg, Germany.

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: Abritee Dhal, Ph.D., 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)-276-6154; Facsimile: (240)-276-5504; E-mail: abritee.dhal@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 61/178,688 entitled "A Panel Of Fully Human Monoclonal Antibodies To The Same Epitope Of An Unknown Cell Surface Antigen Expressed In B-cell Lymphocytic Leukemia (B-CLL)" [HHS Ref. E-163-2009-0-US-01], PCT Patent Application PCT/US2010/034491 entitled "B-cell Surface Reactive Antibodies" [HHS Ref. E-163-2009-0-PCT-02], and United States Patent 8,877,199, entitled "B-cell Surface Reactive Antibodies" [HHS Ref. E-163-2009-0-US-03].

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, production, and commercialization of a Siglec-6-specific chimeric antigen receptor (CAR) based immunotherapy using autologous (meaning one individual is both the donor and recipient) T cells modified by virus-free Sleeping Beauty (SB)-based gene transposition compromising of at least:
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> a. a single antigen specificity; and
>
> b. comprising at least:
>
> i. The complementary determining region (CDR) sequences of the Siglec-6 antibody known as JML-1, and

ii. a CD3ζ activation module and either a CD28 or a 4-1BB co-stimulation moiety

for the treatment of acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), and other forms of acute and chronic B- and T-cell leukemia and lymphoma.

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

This technology discloses monoclonal antibodies that are specific for the cell surface domain of Siglec-6. The antibodies can potentially be used for the treatment of acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), and other forms of acute and chronic B-and T-cell leukemia and lymphoma cells. In the subject situation, the antibodies can be used in a CAR, 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: December 5, 2019. _____

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2019-27002 Filed: 12/13/2019 8:45 am; Publication Date: 12/16/2019]