[Billi

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of Natural Killer (NK) Cell Kita-Kyushu Lung Cancer Antigen 1 (KK-LC-1) T Cell Receptor (TCR) Therapy for the Treatment of KK-LC-1 Expressing Human 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 Zelluna Immunotherapy (Zelluna), located in Oslo, Norway.

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, at Telephone: (240)-276-6154 or at E-mail: abritee.dhal@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 62/327,529 entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Ref. E-153-2016-0-US-01], PCT Patent Application PCT/US2017/027865 entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Ref. E-153-2016-

0-PCT-02], Australian Patent Application 2017258745 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-AU-03], Canadian Patent Application 3021898 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-CA-04], European Patent Application 1733120.4 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-EP-05], United States Patent Application 16/096,118, entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-US-06], 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 development, manufacture and commercialization of a T-Cell Receptor (TCR) Therapy for the treatment of Kita-Kyushu Lung Cancer Antigen 1 (KK-LC-1) expressing cancers, using modified or unmodified natural killer (NK) cells transduced using viral vectors (including lentivirus or retrovirus) to express an anti-KK-LC-1 TCR wherein:
>
> 1) the TCR has:
>
> a) A single antigen specificity; and
>
> b) a binding domain with complementary determining region (CDR) sequences of CASSLGTGGYNEQFF (beta chain) and CAGQLVYGNKLVF (alpha chain); and
>
> 2) The modified allogeneic NK cells can be modified to express one or more of the following:
>
> a) CD3 subunits;
>
> b) CD8 co-receptor subunits;
>
> c) truncated CD34 tag;

d) a chemokine receptor; or

e) IL15.

For the sake of clarity, unmodified NK cells would mean cells that are modified only by the expression of the TCR without any additional modification.

This technology discloses TCRs that are specific for the cell surface domain of KK-LC-1. KK-LC-1 is a cancer germline antigen, that in adults, is reported to be expressed only by germ cells and by certain cancers, including gastric cancer, triple-negative breast cancer, and non-small cell lung cancer. Currently, there for no effective immunotherapies for patients with these various solid tumors. The NK-TCRs can potentially be used for the treatment of triple negative breast cancer, gastric cancer, and lung cancer. In the subject situation, the TCRs can lead to the selective destruction of the cancerous cells. The development of a new therapeutic targeting KK-LC-1 will benefit public health by providing an effective treatment for patients with solid tumors.

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 11, 2021. _____

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2021-06475 Filed: 3/29/2021 8:45 am; Publication Date: 3/30/2021]