Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20

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 Kite Pharma, Inc. ("Kite") located in Santa Monica, CA**.**

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 [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION 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 Technology Transfer 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

United States Provisional Patent Application No. 62/732,263, filed 17 September 2018 and entitled "Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 and Their Uses"

[HHS Reference No. E-205-2018-0-US-01]; and U.S. and foreign patent applications claiming priority to the aforementioned application.

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 commercializaiton of an anti-CD19 anti-CD20 dual targeting chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) immune cells transfected with either a viral or non-viral vector, wherein the vector expresses a CAR having at least:

1) a dual antigen specificity;
2) the complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;
3) the complementary determining region (CDR) sequences of the anti-CD20 antibody known as 2.1.2; and
4) a T cell signaling domain;

for the treatment of B-cell derived human cancers."

This technology discloses the development of chimeric antigen receptors that recognize both the CD19 and CD20 cell surface proteins. CD19 and CD20 are expressed on the cell surface of several hematological malignancies, including Non-Hodgkins Lymphoma (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). Although the FDA has recently approved CAR-based therapies which target only CD19 (Yescarta, Kymriah), tumors are capable of undergoing tumor antigen escape (the downregulation of target antigen expression on tumor cells), which results in gradual resistance to "single target therapies." As a result, patients

receiving single target CAR therapies are susceptible to relapse. This has prompted investigators to pursue dual targeting CAR therapies to provide as a means of overcoming tumor antigen escape, thereby providing a more comprehensive therapeutic alternative. The development of a new therapeutic targeting both CD19 and CD20 will benefit public health by offering up an improved treatment for patients that would otherwise be subject to relapse due to tumor antigen escape.

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 USC 552.

Dated: July 2, 2019.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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