[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 an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

AGENCY: National Institutes of Health

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 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: 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. 62/241,896, filed 15 October 2015 and entitled "Anti-CD30 Chimeric Antigen Receptors" [HHS Reference No. E-016-2018/0-US-01]; PCT Patent Application PCT/US2016/056262, filed 10 October 2016 and entitled "Anti-CD30 Chimeric Antigen Receptors" [HHS Reference No. E-016-2018/0-PCT-02]; 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 following:

> "The development of a CD30 chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) T cells transfected with a retroviral vector (including lentiviral vectors), wherein the vector expresses a CAR having:
>
> 1) a single antigen specificity; and
> 2) comprising at least:
>   a) the complementary determining region (CDR) sequences of the anti-CD30 antibody known as 5F11; and
>   b) a T cell signaling domain;
>
> for the prophylaxis and treatment of CD30-expressing human cancers."

This technology discloses the development of chimeric antigen receptors that recognize the CD30 protein (also known as tumor necrosis factor receptor superfamily member 8 (TNFRSF8)). CD30 is expressed on the cell surface of several rare forms of cancer, including Hodgkin lymphoma (HL), Non-Hodgkin's Lymphoma (NHL), diffuse large B

cell lymphoma (DLBCL), peripheral T cell lymphoma not otherwise specified (PTCL-NOS), anaplastic large cell lymphoma (ALCL), and angioimmunoblastic T cell lymphoma (AITL). The development of a new therapeutic targeting CD30 will benefit public health by offering up a treatment for these rare cancers in instances when conventional first line therapies are ineffective.

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: December 8, 2017

Richard U. Rodriguez

Associate Director

Technology Transfer Center

National Cancer Institute

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