



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Allogeneic Therapy for the Treatment of Autoimmune Disease Using Chimeric Antigen Receptors Targeting CD19

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 Kyverna Therapeutics (“Kyverna”) located in Berkeley, 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 at (240)-276-5530 or E-mail: 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 62/006,313 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-01], PCT Patent Application PCT/US2015/033473 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-PCT-02], Australian Patent 2015270912 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-AU-03], Canadian Patent Application 2951045 entitled

“Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-CA-04], Chinese Patent Application 201580033802.5 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-CN-05], European Patent 3149044 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-EP-06] (validated in Germany [HHS Ref. E-042-2014-0-DE-19], Spain [HHS Ref. E-042-2014-0-ES-20], France [HHS Ref. E-042-2014-0-FR-21], the United Kingdom [HHS Ref. E-042-2014-0-GB-22], Italy [HHS Ref. E-042-2014-0-IT-23], and Ireland [HHS Ref. E-042-2014-0-IE-24], and lodged in Hong Kong [E-042-2014-0-HK-16]), Israeli Patent Application 249305 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-IL-07], Indian Patent Application 291647041047 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-IN-08], Japanese Patent Application 2016-571017 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-JP-09], South Korean Patent Application 2016-7036828 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-KR-10], Mexican Patent Application MX/a/2016/015834 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-MX-11], New Zealand Patent Application 727167 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-NZ-12], Saudi Arabian Patent Application 516380406 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-SA-13], Singaporean Patent Application 11201609960Q entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-SG-14], United States Patent 10,287,350 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-15], United States Patent Application 16/360,281 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-17], New Zealand Patent Application 764530 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-NZ-18], European Patent Application 20197459.9 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-EP-25], Australian Patent Application 2020267211 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-AU-26], and Japanese Patent Application XXX entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-JP-27], 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 an anti-CD19 targeting chimeric antigen receptor (CAR)-based immunotherapy using CRISPR/Cas9-edited allogeneic (where donor and recipient are different) T lymphocytes, wherein the CAR expresses at least:

- (1) the complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;
- (2) a CD8a hinge and transmembrane domain*;
- (3) and a CD28z T cell signaling domain*;

for the treatment of autoimmune diseases.”

This technology discloses the development of chimeric antigen receptors that recognize the CD19 cell surface protein. CD19 is expressed on the cell surface of several autoimmune disease cells, including lupus nephritis. For many autoimmune diseases there are no FDA-approved therapies, underscoring that there is an unmet need. The development of an autoimmune disease therapeutic targeting CD19 will benefit public health by providing a treatment for patients who may not have any options.

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: February 4, 2021.

Richard U. Rodriguez,
Associate Director,
Technology Transfer Center,
National Cancer Institute.

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