[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of an Anti-TSLPR Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Provisional Patent Application 61/912,948 entitled "Thymic Stromal Lymphopoietin Receptor-Specific Chimeric Antigen Receptors and Methods Using Same" [HHS Ref. E-008-2014/0-US-01], U.S. Provisional Patent Application 61/991,697 entitled "Thymic Stromal Lymphopoietin Receptor-Specific Chimeric Antigen Receptors and Methods Using Same" [HHS Ref. E-008-2014/1-US-01], PCT Patent Application PCT/US2014/063096 entitled "Thymic Stromal Lymphopoietin Receptor-Specific Chimeric Antigen Receptors and Methods Using Same" [HHS Ref. E-008-2014/2-PCT-

01], and all related continuing and foreign patents/patent applications for the technology family, to Lentigen Technology, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to:

"The development of a TSLPR-CAR-based immunotherapy using chimeric antigen receptors (CARs) having:

1) the complementary determining region (CDR) sequences of either
    a) the anti-TSLPR antibody known as 2D10 or
    b) the anti-TSLPR antibody known as 3G11; and
2) a T cell signaling domain

for the prophylaxis and treatment of cancer."

DATES: Only applications for a license which are received by the NIH Office of Technology Transfer on or before [**INSERT DATE 30 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER**] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325,

Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: lambertsond@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns an anti-TSLPR (Thymic Stromal Lymphopoietin Receptor) chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of TSLPR-expressing cancers, including B cell malignancies.

TSLPR is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly rare cancers of B cell origin such as acute lymphoblastic leukemia (ALL). The anti-TSLPR CARs of this technology contain (1) antigen recognition sequences that bind specifically to TSLPR and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-TSLPR CAR can be transduced into T cells that are harvested from a cancer patient; from there, T cells expressing the anti-TSLPR CAR are selected, expanded and then be reintroduced into the patient. Once the anti-TSLPR CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to TSLPR-expressing cancer cells through its antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective

exclusive license may be granted unless the NIH 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 within thirty (30) days from the date of this published notice.

Complete applications for a license in an appropriate field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 22, 2015.

Richard U. Rodriguez, M.B.A.,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

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