[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This 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 patent license to practice the inventions embodied in the following Patents and Patent Applications and all continuing U.S. and foreign patents/patent applications to Sangamo BioSciences, Inc. located in Richmond, California, USA:

Intellectual Property

U.S. Provisional Patent Application 62/006,313, filed 2 June 2014 and entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014/0-US-01]; and

PCT Patent Application PCT/US2015/033473, filed 1 June 2015 and entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014/0-PCT-02].

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 use of Licensed Patent Rights for the following: "The integration of a monospecific anti-CD19 chimeric antigen receptor (CAR) into genome-edited, allogeneic T cells (where the donor and recipient are different), where the monospecific CAR has at least: a) the complementary determining region (CDR) sequences of the anti-CD19 47G4 antibody; and b) a T cell signaling domain, for the prophylaxis and treatment of CD19-positive malignancies."

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESS: 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, National Cancer

Institute, 9609 Medical Center Drive, Rm 1-E530 MSC9702, Rockville, MD 20850-9702, E-mail: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns an anti-CD19 chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of CD19-expressing cancers, including B cell malignancies. With regard to the proposed license, the CAR covered by the invention will be integrated into a genome-edited allogeneic (where the donor and recipient of the T cell are different individuals) T cell, and the resulting anti-CD19 CAR-expressing genome-edited allogeneic T cell will be introduced into a cancer patient to exhibit a therapeutic effect. CD19 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly cancers of B cell origin such as Non-Hodgkin's Leukemia (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). The anti-CD19 CARs of this technology contain (1) antigen recognition sequences that bind specifically to CD19 and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-CD19 CAR can be integrated into genome-edited allogeneic T cells; from there, genome-edited allogeneic T cells expressing the anti-CD19 CAR are selected, expanded and then introduced into a patient. Once the anti-CD19 CAR-expressing genome-edited allogeneic T cells are introduced into the patient, the T cells can selectively bind to CD19-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 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, 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 404.7.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. 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.

August 31, 2016 _____

Date

Richard U. Rodriguez,

Associate Director

Technology Transfer Center

National Cancer Institute

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