[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, 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 TeraImmune, Inc. ("TeraImmune") located in Rockville, Maryland.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office 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 Exclusive Patent License should be directed to: Dr. Yogikala Prabhu, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804 Telephone: (301) 496-2644; Facsimile: (240) 627-3117; E-mail: prabhuyo@niaid.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

- U.S. Patent 9,481,866 - issued November 1, 2016, entitled "Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells" [HHS Reference No. E-279-2011/0-US-02]
- U.S. Divisional Application No.15/284,840 - filed October 4, 2016, entitled "Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells'. [HHS Reference No. E-279-2011/0-US-03]

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory will be the United States and the field of use will be limited to: "Human cell-based therapeutics for the treatment of Hemophilia A in patients that have inhibitory Factor VIII antibodies."

The technology is directed to a method for producing or growing cell populations that are enriched for stable, highly suppressive regulatory T cells (Tregs). Tregs are critical in regulating immune system processes that maintain tolerance to self-antigens and prevent immune mediated disease**s.** The method takes a population of cells comprising stable, regulatory T cells and enriched for specific CD markers, cultures these cells in the presence of interleukin-2, an anti-CD3 antibody, an anti-CD28 antibody, and oligodeoxynucleotides of specified length having a phosphorothioate backbone, and yields the expansion of the initial population of regulatory T-cells. The expanded Tregs may then be used for the treatment of immune-mediated diseases.

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 Institute of Allergy and Infectious Diseases 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a 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 from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: January 6, 2020.

Wade W. Green,

Acting Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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