[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients with Metastatic Cancer

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR404.7, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Intima Biosciences, Inc., which is located in New York City, New York to practice the inventions embodied in the following patent applications and applications claiming priority to these applications:

1. U.S. Provisional Patent Application No. 61/771,251 filed March 1, 2013 entitled "Methods of Producing Enriched Populations of Tumor Reactive T Cells from Peripheral Blood" (HHS Ref No. E-085-2013/0-US-01);
2. PCT Application No. PCT/US2013/038813 filed April 30, 2013 entitled "Methods of Producing Enriched Populations of Tumor Reactive T Cells from Peripheral Blood" (HHS Ref No. E-085-2013/0-PCT-02) and all resulting national stage filings; and
3. PCT Application No. PCT/US2014/058796 filed October 2, 2014 entitled "Methods of Isolating T Cell Receptors Having Antigenic Specificity for a Cancer-Specific Mutation" (HHS Ref No. E-233-2014/0-PCT-01);

The patent rights in these inventions have been assigned to 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 the Licensed Patent Rights with the Licensee's non-viral clustered regularly interspaced short palindromic repeats (CRISPR)/cellular apoptosis susceptibility (Cas) systems and proprietary non-viral constructs for the insertion of genes encoding T-Cell Receptors (TCR) against mutated antigens into peripheral blood lymphocytes for the treatment and prophylaxis of patients with metastatic cancer.

DATES: Only written comments and/or 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: Sabarni K. Chatterjee, Ph.D., M.B.A., Senior Licensing and Patenting 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: chatterjeesa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The first technology describes a process to select highly tumor-reactive T cells from a patient's peripheral blood sample based on the expression of two specific T cell surface markers: programmed cell death protein 1 (PD-1; CD279) and/or T cell Ig- and mucin-domain-containing molecule-3 (TIM-3). After this enriched population of tumor-reactive T cells is selected and expanded to large quantities, it gets re-infused into the patient via an ACT regimen. The enrichment of tumor-reactive cells from a patient's peripheral blood based on these markers provides a simple alternative to the current strategies based on

isolation tumor-reactive cells from the tumor, as it reduces the cost and complications of tumor of resection, as well as provides a T cell product for patients without resectable lesions. The second technology describes a method to identify and generate TCR engineered T cells for personalized cancer therapy. Using tandem mini-gene constructs encoding all of the patient's tumor mutations, T cells that were reactive with the unique mutated antigens expressed only in the patient's tumors are identified, and then the mutation-reactive TCRs and engineered peripheral blood T cells from the same patient are isolated to express these mutation-reactive TCRs. These personalized TCR engineered T cells are expanded and infused back into the same patient with the potential to induce tumor regression.

The prospective exclusive license may be granted unless within thirty (30) 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 field of use 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: September 28, 2015.

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

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