[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: T-Cells Transduced with HLA A11 Restricted CT–RCC HERV–E Reactive T-Cell Receptors for the Treatment of Renal Cell Carcinoma

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute ("NHLBI"), an institute of the National Institutes of Health; an agency within the Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to commercialize the invention(s) embodied in the intellectual property estate stated in the Summary Information section of this notice to T-Cure Bioscience, Inc. located in Thousand Oaks, California and incorporated under the laws of Delaware.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development 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 license should be directed to: Cristina Thalhammer-Reyero, PhD, MBA, Senior Licensing and Patenting Manager, NHLBI Office of Technology Transfer and Development, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; Telephone: +1-301-435-4507; Fax: +1-301-594-3080; E-mail: thalhamc@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement:

US Provisional Patent Application No. 62/357,265, filed June 30, 2016; and PCT Patent Application PCT/US2017/040449, filed June 30, 2017, "HERV-E Reactive T Cell Receptors and Methods of Use", NIH Reference No. E-120-2016/0,1.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned 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: "Development and commercialization of T cell receptor based cancer immunotherapy for Renal Cell Carcinoma".

The subject technology is based on an allogeneic T cell clone isolated from a clear cell renal cell carcinoma (ccRCC) HLA-A11 patient who showed prolonged tumor regression after an allogeneic transplant. This clone was found to have tumor specific cytotoxicity, killing patient's tumor cells in vitro. The antigen recognized by this clone is an HLA-A11 restricted peptide (named CT-RCC-1) and it is encoded by a novel human endogenous retrovirus-E (named CT-RCC HERV-E) whose expression was discovered to be restricted to ccRCC, but not observed in normal tissues or other tumor types. More than 80% of ccRCC tumors express CT-RCC HERV-E provirus, which makes it an ideal target for T cell based immunotherapy. The genes for a T cell receptor (TCR) that specifically recognizes an HLA-A11 restricted CT-RCC-1 antigen were sequenced and cloned. A retroviral vector encoding this TCR as well as a truncated CD34 protein lacking the intracellular domain, which can be used to facilitate the isolation of T-cells transduced with this TCR, was created. The vector can be used to transduce and expand normal T cells from HLA-A11 patients with metastatic ccRCC with the TCR. The transduced cytotoxic T cells can then be administered to subjects to treat or inhibit metastatic kidney cancer. Kidney cancer is responsible for approximately 12,000 deaths every year in the United States alone. As with most cancer, when detected at early stages,

surgical intervention is highly effective. Phase I/II clinical trials are currently being planned in patients with metastatic ccRCC using normal patient's T-cells transduced with this vector.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI Office of Technology Transfer and Development 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.

The public may file comments or objections in response to this Notice. 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 in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: November 16, 2017. _____

Cristina Thalhammer-Reyero,
Senior Licensing and Patenting Manager,
Office of Technology Transfer and Development,
National Heart, Lung, and Blood Institute.

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