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Dated: May 10, 2017.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government.

FOR FURTHER INFORMATION CONTACT:

Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC 2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: The following inventions are available for licensing in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Technology description follows.

T-Cells Transduced With HLA A11 Restricted CT-RCC HERV-E Reactive TCR To Treat Patients With ccRCC

Description of Technology: We isolated an allogeneic T cell clone 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. We found that 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. We observed that more than 80% of ccRCC tumors express CT-RCC HERV-E provirus, which makes it an ideal target for T cell based immunotherapy. We have sequenced and cloned the genes for a T cell receptor (TCR) that specifically recognizes an HLA-A11 restricted CT-RCC-1 antigen. We then created 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. Phase I/II clinical trials are currently being planned in patients with metastatic ccRCC using normal patient's T-cells transduced with this vector.

Potential Commercial Applications: The vector can be used to transduce and expand normal T cells from HLA-A11 patients with metastatic ccRCC with the TCR recognizing HLA-A11-restricted CT-RCC HERV-E antigen that specifically expressed on clear cell type of kidney cancer. 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. Despite progress in treating kidney cancer with IL-2 and inhibitors of immune checkpoints, metastatic ccRCC is generally lethal, with mean survival being less than a year. Patients with melanoma and other malignancies can now benefit from adoptive T cell transfer. One of the limitations of this approach for metastatic kidney cancer is a lack of identified tumor restricted antigens for this tumor. We show that the CT-RCC HERV-E is expressed in most ccRCC tumors but not in normal tissues which makes the antigens encoded by this provirus ideal targets for T cell-based immunotherapy of ccRCC.

Development Stage: Early-stage; In vitro data available.

Inventors: Richard W. Childs and Elena Cherkasova (NHLBI), Michael Nishimura (Loyola University Chicago).

Publications:

1. Takahashi Y. et al. 2008. Regression of kidney cancer following allogeneic stem-cell transplantation associated with T-cells recognizing a HERV-E antigen. *J. Clin. Invest.* 118:1099-109.

2. Cherkasova E. et al. 2011. Inactivation of the von Hippel-Lindau tumor suppressor leads to selective expression of a human endogenous retrovirus in kidney cancer. *Oncogene* 30:4697-706.

3. Cherkasova E. et al. 2013. Endogenous retroviruses as targets for antitumor immunity in renal cell cancer and other tumors. *Front. Oncol.* 3:243-247.

4. Cherkasova E. et al. 2016. Detection of a HERV-E envelope with selective expression in clear cell kidney cancer. *Cancer Res.* 76:2177-2185.

Intellectual Property: NIH Reference No. E-120-2016/0—US Application No. 62/357,265, filed June 30, 2016.

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301-435-4507; thalhamc@mail.nih.gov.

Dated: May 2, 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; AMSC Review Conflict Meeting.

Date: June 8, 2017.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 6701 Democracy Boulevard, Conference Room 803, Bethesda, MD 20892.

Contact Person: Yin Liu, Ph.D., M.D., Scientific Review Officer, Scientific Review Branch, NIH/National Institute of Arthritis, Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Suite 824, Bethesda, MD 20892, 301-451-4838, yin.liu@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)