

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Centers for Disease Control and Prevention (CDC)/ Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis and Sexually Transmitted Diseases (STD) Prevention and Treatment; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT).

Date and Time: November 4, 2015, 10:00 a.m.–4:30 p.m.; and November 5, 2015, 10:00 a.m.–12:30 p.m.

Place: This meeting is accessible via audio conference call and Adobe Connect Pro.

Status: This meeting is open to the public. The virtual meeting is available via teleconference line and Adobe Connect Pro Meeting and will accommodate approximately 100 people. Join the meeting by:

1. (Audio Portion) Calling the Toll Free Phone Number 1-800-369-3340 and providing the Public Participant Pass Code 4318075, and

2. (Visual Portion) Connecting to the Advisory Committee Adobe Connect Pro Meeting using the following URL: https://hrsa.connectsolutions.com/cdc-hrsa_ac/.

(Copy and paste the above link into your browser if it does not work directly). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. Call (301) 443-9684 or send an email to sgordon@hrsa.gov if you have any questions, or send an email to CWilliams2@hrsa.gov if you are having trouble connecting to the meeting site.

Purpose: This Committee is charged with advising the Director, CDC, and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS, Viral Hepatitis and other STDs; the support of health care services to persons living with HIV/AIDS; and education of health professionals and the public about HIV/AIDS, Viral Hepatitis and other STDs.

Agenda: Agenda items include: (1) CDC and HRSA Program Updates; (2) HRSA HIV Clinical Workforce Study; (3) Emerging Issues Related to ACA Implementation and Ryan White HIV/AIDS Program Client Level Data; (4)

Impact of Ryan White HIV/AIDS Program on HIV Treatment Outcomes; and (3) CHAC Workgroup Updates (Pre-Exposure Prophylaxis, Hepatitis C Virus, and Data). Agenda items are subject to change.

Public Comment: Persons who desire to make an oral statement may request it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

FOR FURTHER INFORMATION CONTACT:

Shelley B. Gordon, Senior Public Health Analyst, Health Resources and Services Administration, HIV/AIDS Bureau, Division of Policy and Data, 5600 Fishers Lane, Room 7C-26, Rockville, Maryland 20857, telephone (301) 443-9684, fax (301) 443-3343, or email sgordon@hrsa.gov.

Jackie Painter,

Director, Division of the Executive Secretariat.

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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 CFR 404.7, 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 November 2, 2015 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; Email: 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