

Ms. Forbes has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on May 6, 2016:

(1) to exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR part 180 (collectively the "Debarment Regulations");

(2) that she will neither apply for nor permit her name to be used on any application, proposal, or other request for funds to the United States Government or any of its agencies, as defined in the Debarment Regulations; Respondent will further ensure that during the period of the voluntary exclusion, she will neither receive nor be supported by funds of the United States Government and its agencies made available through grants, subgrants, cooperative agreements, contracts, or subcontracts, as discussed in the Debarment Regulations; and

(3) to exclude herself from serving in any advisory capacity to the U.S. Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.

Kathryn M. Partin,

Director, Office of Research Integrity.

[FR Doc. 2016-13541 Filed 6-7-16; 8:45 am]

BILLING CODE 4150-31-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Office of the Surgeon General of the United States Public Health Service, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.), notice is hereby given that a meeting is scheduled for the Advisory Group on Prevention, Health Promotion,

and Integrative and Public Health (the "Advisory Group"). This meeting will be open to the public. Information about the Advisory Group and the agenda for this meeting can be obtained by accessing the following Web site: <http://www.surgeongeneral.gov/priorities/prevention/advisorygrp/index.html>.

DATES: The meeting will be held on July 11, 2016, from 3:00 p.m.–5:00 p.m. EST.

ADDRESSES: This meeting will be held via teleconference. Teleconference information and the exact meeting time will be published closer to the meeting date at: <http://www.surgeongeneral.gov/priorities/prevention/advisorygrp/index.html>.

FOR FURTHER INFORMATION CONTACT:

Office of the Surgeon General, U.S. Department of Health and Human Services, 200 Independence Ave. SW.; Washington, DC 20201; 202-205-9517; npcsupport@cdc.gov.

SUPPLEMENTARY INFORMATION: The Advisory Group is a non-discretionary federal advisory committee that was initially established under Executive Order 13544, dated June 10, 2010, to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111-148. The Advisory Group was terminated on September 30, 2012, by Executive Order 13591, dated November 23, 2011. Authority for the Advisory Group to be re-established was given under Executive Order 13631, dated December 7, 2012. Authority for the Advisory Group to continue to operate until September 30, 2017, was given under Executive Order 13708, dated September 30, 2015.

The Advisory Group was established to assist in carrying out the mission of the National Prevention, Health Promotion, and Public Health Council (the Council). The Advisory Group provides recommendations and advice to the Council. It is authorized for the Advisory Group to consist of not more than 25 non-federal members. The Advisory Group currently has 21 members who were appointed by the President. The membership includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine.

A meeting description and relevant materials will be published closer to the meeting date at: <http://>

www.surgeongeneral.gov/priorities/prevention/advisorygrp/.

Members of the public have the opportunity to participate in the meeting and/or provide comments to the Advisory Group on July 11, 2016. Public comment will be limited to 3 minutes per speaker. Individuals who wish to participate in the meeting and/or provide comments must register by 12:00 p.m. EST on July 5, 2016. In order to register, individuals must send their full name and affiliation via email to npcsupport@cdc.gov. Individuals who need special assistance and/or accommodations, *i.e.*, sign language interpretation or other reasonable accommodations, should indicate so when they register. Members of the public who wish to have materials distributed to the Advisory Group members at these scheduled meetings should submit those materials when they register.

Dated: May 23, 2016.

Brigitte Ulin,

Designated Federal Officer, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health, Office of the Surgeon General.

[FR Doc. 2016-13558 Filed 6-7-16; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: The Development of an Anti-GPC3 Chimeric Antigen Receptor (CAR) Based on HN3 for the Treatment of Human Cancers

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in:

Intellectual Property:

U.S. Provisional Patent Application 61/477,020 entitled "Human Monoclonal Antibody Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-US-01], PCT Patent Application PCT/US2012/034186 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-PCT-02], Chinese Patent Application 201280029201.3 entitled "Human

Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-CN-03], European Patent 2699603 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-EP-04], and validated in France, Germany and the United Kingdom, United States Patent 9,206,257 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-US-05], United States Patent Application 14/837,903 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-US-06], European Patent Application 15188264.4 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-EP-07], United States Patent Application 15/090,873 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-US-12], Chinese Patent Application 201610290837.3 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-CN-13], European Patent Application 16166924.7 entitled "Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof" [HHS Ref. E-130-2011/0-EP-14], and all continuing U.S. and foreign patents/patent applications for the technology family, to Lentigen Technology, Inc.

The patent rights to these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be the United States, Australia, Canada, the European Union, Russia, China, Hong Kong, Japan, Taiwan, South Korea and Singapore, and the field of use may be limited to: "The development of a glypican-3 (GPC3) chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) primary human lymphocytes (T cells or NK cells) transfected with a lentiviral or retroviral vector, wherein the vector expresses a CAR having (1) a single antigen specificity and (2) comprising at least: (a) The complementary determining region (CDR) sequences of the anti-GPC3 antibody known as HN3; and (b) a T cell signaling domain; for the prophylaxis and treatment of GPC3-expressing cancers."

DATES: Only written comments and/or applications for a license which are received by the NCI Technology

Transfer Center on or before June 23, 2016 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: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, National Cancer Institute, 9609 Medical Center Drive, Rm. 1-E530 MSC9702, Rockville, MD 20850-9702, Email: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns an anti-GPC3 (Glypican-3) chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of GPC3-expressing cancers. GPC3 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly liver cancers such as hepatocellular carcinoma (HCC). The anti-GPC3 CARs of this technology contain (1) antigen recognition sequences that bind specifically to GPC3 and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-GPC3 CAR can be transduced into T cells that are harvested from a donor, followed by (a) selection and expansion of the T cells expressing the anti-GPC3 CAR, and (b) reintroduction of the T cells into the patient. Once the anti-GPC3 CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to GPC3-expressing cancer cells through its antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless 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 within fifteen (15) days from the date of this published notice.

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: June 3, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-13530 Filed 6-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Clinical Trial Pilot Studies (R34).

Date: June 27, 2016.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892-7924, 301-435-0287, carolko@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS).

Dated: June 2, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-13500 Filed 6-7-16; 8:45 am]

BILLING CODE 4140-01-P