

Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-28605 Filed 11-28-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that a meeting of the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will take place. This meeting will be open to the public.

DATES: Thursday, January 12, 2017, from 12:00 p.m. to 5:00 p.m. ET, and Friday, January 13, 2017, from 9:00 a.m. to 5:00 p.m. ET.

ADDRESSES: Individuals may attend this meeting in person and/or by utilizing virtual technology. Information for in-person attendance will be posted on the CFSAC Web site, <http://www.hhs.gov/ash/advisory-committees/cfsac/meetings/index.html>. Registration is required for in-person attendance. Information on the procedure to follow for registration will be included on the CFSAC Web site. For individuals wishing to attend the meeting virtually, a webinar will be offered. Information about accessing the webinar will be included on the CFSAC Web site.

FOR FURTHER INFORMATION CONTACT: Gustavo Seinos, MPH, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Department of Health and Human Services, 200 Independence Avenue SW., Room 712E, Washington, DC 20201. Please direct all inquiries to cfsac@hhs.gov.

SUPPLEMENTARY INFORMATION: The CFSAC is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health on topics related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The issues can include factors affecting access and care for persons with ME/CFS; the science and definition of ME/CFS; and broader public health, clinical, research, and educational issues related to ME/CFS.

The agenda for this meeting, call-in information, and location will be posted on the CFSAC Web site <http://www.hhs.gov/ash/advisory-committees/cfsac/meetings/index.html>.

Thirty minutes will be allotted for public comment via telephone or in person on each day of the meeting. Each individual will have three minutes to present their comments. Priority will be given to individuals who have not provided public comment within the previous year. We are unable to place international calls for public comments. Individuals are required to register to participate in the public comment sessions. To request a time slot for public comment, please send an email to cfsac@hhs.gov by January 5, 2017. The email should contain the speaker's name and the telephone number at which the speaker can be reached for the public comment session.

Individuals who would like for their testimony to be provided to the Committee members should submit a copy of the testimony prior to the meeting. It is preferred, but not required, that the submitted testimony be prepared in digital format and typed using a 12-pitch font. Copies of the written comment must not exceed 5 single-space pages, and it is preferred, but not required that the document be prepared in the MS Word format. Please note that PDF files, charts, and photographs cannot be accepted. Materials submitted should not include sensitive personal information, such as Social Security number, birthdate, driver's license number, passport number, financial account number, or credit or debit card number. If you wish to remain anonymous, then document must specify this.

The Committee welcomes input on any topic related to ME/CFS.

Gustavo Seinos,

Designated Federal Officer, CDR, USPHS.

[FR Doc. 2016-28723 Filed 11-28-16; 8:45 am]

BILLING CODE 4150-42-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing and Collaboration

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Genetically Engineered Mouse-Derived Allograft for Use in Preclinical Studies of Metastatic Melanoma Therapies.

Keywords: Melanoma, GDA, Allograft, Genetically Engineered Mouse, immunological response.

Description of Technology: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. 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.

Before testing drugs in humans, drug developers are required to demonstrate a reasonable expectation of safety and efficacy by performing so-called pre-clinical studies. A key element of such trials is the use of animal models,

typically mice or rats that are selected for demonstrating hallmarks of a given disease. For cancer research, while many mouse models exist to simulate the response of the cancer to a particular drug, all of the current models have some limitations in their ability to fully predict the concomitant physiological or immunological response that might result when the drug progresses to clinical trials. This is problematic both in models in which the cancer spontaneously develops in the animal as well as models in which cancerous cells or tumors, *i.e.*, allografts (derived from cells of the same organism) or xenografts (derived from cells of different organism, usually humans), are transplanted into an otherwise cancer-free animal.

To address these issues, researchers at NCI developed a means of more closely simulating in mouse models both melanoma cancer itself and the resulting physiological and immunological response by creating a genetically engineered mice (GEM)-derived allograft (GDA). This allograft both resembles human-like melanoma and has features that will stimulate a normal immunological response in the mouse. Thus, when transplanted into a host, the resulting tumor-containing mouse may be used to test conventional cancer therapies (*e.g.*, chemotherapy and radiotherapy), targeted drugs (*e.g.*, kinase inhibitors), and immunotherapies with an expectation that the response in the mouse will more closely mimic the types of responses expected in humans if the therapy progresses to clinical trials. Further this melanoma-based GDA approach may represent a new standard for building or improving preclinical models of other types of cancer.

Potential Commercial Applications:

- This is a novel mouse allograft model that provides a preclinical model of human-like advanced-stage melanoma.

- This allograft model may be useful for preclinical testing of conventional therapies, targeted therapies, and immunotherapies.

Value Proposition:

- Hgf-tg;Cdk4R24C C57BL/6 mouse-derived melanoma allograft with humanized pathogenetics allows adoption of clinically relevant procedures and endpoints, facilitating clinical translation.

- Features a constitutively activated MET/MAPK pathway and disrupted CDKN2A pathway.

- Expresses typical diagnostic markers of human melanoma such as DCT and TRP1.

- Exhibits progression patterns relevant to human disease.

Development Stage: Basic (Target ID).
Inventor(s): Chi-Ping Day, Glenn T. Merlino, Zoe Weaver Ohler, Rajaa El Meskini, Terry A. Van Dyke (all of NCI), and Thomas Tüting (University Hospital Bonn).

Intellectual Property: HHS Reference Number E-291-2015/0. This is a Research Tool. Following the policy of the National Institutes of Health, patent protection will not be sought.

Publications:

1. Day CP, *et al.* "Glowing head" mice: A genetic tool enabling reliable preclinical image-based evaluation of cancers in immunocompetent allografts. *PLoS One* 2014; 9(11):e109956. [PMID 25369133]
2. Day CP, *et al.* Preclinical mouse cancer models: A maze of opportunities and challenges. *Cell*. 2015;163(1):39-53. [PMID 26406370]

Contact Information: Inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: November 22, 2016.

John D. Hewes,

Technology Transfer and Patenting Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-28624 Filed 11-28-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; PA-16-194: Mentored Quantitative Research Development Award.

Date: December 12, 2016.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, rubertm@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Novel Strategies for Targeting HIV-CNS Reservoirs without Reactivation.

Date: December 13, 2016.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: Dimitrios Nikolaos Vatakis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, Bethesda, MD 20892, 301-827-7480.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-28623 Filed 11-28-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Center for Advancing Translational Sciences.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should