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 552(b)(4) and 552(b)(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; Small Business: Cell and Molecular Biology.

Date: November 29, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The St. Regis Washington DC, 923 16th Street NW., Washington, DC 20006.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Neuroscience Assay, Diagnostics and Animal Model Development.

Date: November 29, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Nephropathy.

Date: November 29–30, 2016.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psychosocial, Mental Health, Substance Abuse.

Date: November 21–22, 2016.
Time: 10:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psycho/Neuropathology, Lifespan Development, and STEM Education.

Date: November 29, 2016.
Time: 12:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Musculoskeletal, Oral and Skin Sciences Continuous Submission.

Date: November 21, 2016.
Time: 1:00 p.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, ingrahamr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Neuroscience Assay, Diagnostics and Animal Model Development.

Date: November 29, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Nephropathy.

Date: November 29–30, 2016.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biological Chemistry and Macromolecular Biophysics.

Date: November 29, 2016.
Time: 1:30 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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biological Chemistry and Macromolecular Biophysics.

Date: November 29, 2016.
Time: 1:30 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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biological Chemistry and Macromolecular Biophysics.

Date: November 29, 2016.
Time: 12:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biological Chemistry and Macromolecular Biophysics.

Date: November 29, 2016.
Time: 12:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Wind Cowles, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, Bethesda, MD 20892, cowlesw@mail.nih.gov.

ADDRESSES:

Notes:

SUMMARY: 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. 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.

AGENCY: National Institutes of Health, HHS.
ACTION: Notice.

Dated: October 25, 2016.
Natasha M. Copeland,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

NOTICE: 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 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. 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.

ADDRESS: 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 nctechtransfer@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
Small Molecule Inhibitors of Drug Resistant Forms of HIV–1 Integrase

Description of Technology
Integrase strand transfer inhibitors (“INSTIs”) are currently in use as a component of prophylactic antiretroviral therapy for preventing HIV–1 infection from progressing to AIDS. Three INSTIs are approved by the FDA for inclusion in antiretroviral regimens: Raltegravir (RAL), elvitegravir (EVG) and dolutegravir (DTG). Clinicians have already identified several HIV–1 integrase mutations that confer resistance to RAL and EVG, and additional mutations that confer resistance to all three INSTIs has been identified in the laboratory.

Researchers at the National Cancer Institute discovered small-molecule compounds containing 1-hydroxy-2-oxo-1,8-naphthyridine moieties whose activity against HIV–1 integrase mutants confer resistance to currently approved INSTIs. These new compounds exhibit potent and selective activity against comprehensive and varied panels of INSTI-resistant mutants of HIV–1 integrase. Preliminary rodent efficacy, metabolic, and pharmacokinetic studies have been completed by the NCI researchers. The National Cancer Institute (NCI) seeks partners to in-license or co-develop this class of compounds for therapeutic use. Parties interested in licensing the technology should submit an Application for Licensing, and seek detailed information from the Licensing and Patenting Manager indicated below.

Co-development partners would apply under a Cooperative Research and Development (CRADA) to conduct pre-clinical studies that include lead optimization, in vitro and in vivo evaluation and preclinical development of a novel series of INSTIs for the treatment of infection by HIV–1 strains with resistance to currently available integrase inhibitors, including raltegravir and elvitegravir. Under the CRADA, further in vitro and in vivo ADME, as well as activity studies, will be conducted by the partner on current and optimized lead compounds using rodent and non-rodent models. Efficacy studies in non-human primates of select compounds are needed and will be part of the CRADA program. The CRADA scope will also include all aspects of toxicity studies, and synthesis scale up under GMP of optimized lead compounds to support submission of a successful IND application.

Interested potential CRADA collaborators can receive detailed information by contacting the Licensing and Patenting Manager (see below). Interested parties will receive detailed information on the current status of the project after signing a confidentiality disclosure agreement (CDA) with NCI. Interested candidate partners must submit a statement of interest and capability to the NCI point of contact for consideration by 5:00 p.m. Eastern Standard Time, December 30, 2016.

Guidelines for the preparation of a full CRADA proposal will be communicated to all respondents with whom initial confidential discussions have been established. Licensing of background technology related to this CRADA opportunity, specifically HHS Reference No.: E–093–2013/0,1,2, entitled “Compounds For Inhibiting Drug-Resistant Strains of HIV–1 Integrase”, is also available to potential collaborators. All proposals received by the above date will be considered. NCI reserves the right to consider additional proposals or none at all if no partner is selected from the initial response.

Further information about the NCI Technology Transfer Center can be found on its Web site http://techtransfer.cancer.gov.

Potential Commercial Applications
• HIV therapeutic for drug-resistant compounds of HIV–1 integrase

Value Proposition
• Currently, the only INSTI effective against drug resistant mutants of HIV–1 integrase

Development Stage
Pre-clinical (in vivo validation)

Inventor(s)
Terrence Burke, Stephen Hughes, Yves Pommier, Xue Zhao, Mathieu Me´tifiot, Stephen Smith, Barry Johnson, Christophe Marchand (all from NCI)

Intelectual Property
HHS Reference No.: E–093–2013/0,1,2; all entitled “Compounds For Inhibiting Drug-Resistant Strains Of HIV–1 Integrase”

US Provisional App. No.: 61/952,928 filed May 16, 2013
US Provisional App. No.: 61/899,061 filed November 1, 2013
Brazilian App. No.: BR1120150287603 filed May 13, 2014
Canadian App. No.: CA2912064 filed May 13, 2014
Chinese App. No.: 2014–80039611.5 filed May 13, 2014
European App. No.: 14728395.6 filed May 13, 2014
Indian App. No.: 3937/KOLNP/2015 filed May 13, 2014
US Non-Provisional App. No.: 14/891,309 filed May 13, 2014
South African App. No.: ZA2015/08408 filed May 13, 2014

Publications

Contact Information
Requests for copies of the patent application and inquiries about licensing, research collaborations, and co-development opportunities for this invention should be sent to Lauren Nguyen-Antczak, Ph.D., J.D., Senior Licensing & Patenting Manager, NCI Technology Transfer Center, 8490 Progress Drive, Suite 400, Frederick, MD 21701, Tel: (301) 624–8752, email: lauren.nguyen-antczak@nih.gov.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2), notice is hereby given of the joint meeting of the National Cancer Advisory Board (NCAB) and NCI Board of Scientific Advisors (BSA).

The meeting 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 notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (http://videocast.nih.gov).

A portion of the National Cancer Advisory Board meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended, for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board; Ad Hoc Subcommittee on Global Cancer Research.

Open: December 6, 2016, 3:30 p.m. to 5:00 p.m.

Agenda: Discussion of Global Cancer Research.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washington Boulevard, Lakeside 1 Meeting Room, Gaithersburg, MD 20878.

Contact Person: Dr. Caroline Stiles, Senior Program Specialist, NCAB, 9609 Medical Center Drive, Room 3W562, Bethesda, MD 20892, (240) 276-8260, stiles_caroline@mail.nih.gov.

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Open: December 6, 2016, 8:30 a.m. to 4:00 p.m.

Agenda: Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors; NCI Board of Scientific Advisors Concepts Review, NCI acting Director’s report and presentations.

Closed: December 6, 2016, 4:00 p.m. to 5:30 p.m.

Agenda: Review of intramural program site visit outcomes and the discussion of confidential personnel issues.

Open: December 7, 2016, 9:00 a.m. to 12:00 p.m.

Agenda: Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors and presentations.

Place: National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, Room TE406, Bethesda, MD 20892.

Contact Person: Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, Room 7W444, Bethesda, MD 20892, 240–276–6340, grayp@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has implemented stringent procedures for entrance onto the NCI—Shady Grove campus. All visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit. Information is also available on the Institute’s/Center’s home page: NCAB: http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm, BSA: http://deainfo.nci.nih.gov/advisory/bsa/bsa.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 25, 2016.

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[DoCKET NO. USCBP–2016–0066]

Commercial Customs Operations Advisory Committee (COAC)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will meet in Washington, DC. The meeting will be open to the public.

DATES: The Commercial Customs Operations Advisory Committee (COAC) will meet on Thursday, November 17, 2016, from 12:30 p.m. to 4:30 p.m. EST. Please note that the meeting may close early if the committee has completed its business.

Pre-Registration: Meeting participants may attend either in person or via webinar after pre-registering using a method indicated below:

—For members of the public who plan to attend the meeting in person, please register by 5:00 p.m. EST by November 15, 2016 either online at https://apps.cbp.gov/te_reg/index.asp?w=97 by email to tradeevents@dhs.gov; or by fax to (202) 325–4290. You must register prior to the meeting in order to attend the meeting in person.

—For members of the public who plan to participate via webinar, please register online at https://apps.cbp.gov/te_reg/index.asp?w=96 by 5:00 p.m. EST by November 15, 2016. Please feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered and later need to cancel, please do so in advance of the meeting by accessing one (1) of the following links: https://apps.cbp.gov/te_reg/cancel.asp?w=97 to cancel an in person registration, or https://apps.cbp.gov/te_reg/cancel.asp?w=96 to cancel a webinar registration.

ADDRESSES: The meeting will be held at the Washington Marriott Wardman Park Hotel, 2660 Woodley Road NW., Washington, DC 20008. There will be signage posted directing visitors to the location of the meeting room.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Karmeshia Tuck,