

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA AA-2 & AA-3 Member Conflict Applications.

Date: November 16, 2016.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Conference Room 2098, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ranga V. Srinivas, Ph.D., Chief Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2085 Rockville, MD 20852, (301) 451-2067, srinivar@mail.nih.gov.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict Applications—Behavioral and Clinical Studies.

Date: November 22, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Conference Room 2098, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ranga V. Srinivas, Ph.D., Chief Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451-2067, srinivar@mail.nih.gov

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs;

93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: October 17, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-25471 Filed 10-20-16; 8:45 am]

BILLING CODE 4140-01-P

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.

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Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Molecular and Cellular Biology Study Section.

Date: November 14, 2016.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Implementation Science.

Date: November 15, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Suites Old Town Alexandria, 801 N. St. Asaph Street, Alexandria, VA 22314.

Contact Person: Jose H. Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1137, guerrierj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: AIDS and AIDS-related Applications.

Date: November 17, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, Bethesda, MD 20892, 301-451-5953, tuo@csr.nih.gov.

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

Date: November 17-18, 2016.

Time: 9:00 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 (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240-498-7546, diramig@csr.nih.gov.

(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: October 17, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-25469 Filed 10-20-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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.

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Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal

and Skin Diseases Clinical Trials Review Committee.

Date: October 25–26, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Kathy Salaita, SCD, Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Blvd., Building One, Room 818, Bethesda, MD 20892, 301–594–5033, kathy.salaita@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: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS Institutional Training Grants (T32) Review Meeting.

Date: October 28, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 6701 Democracy Boulevard, Building One, Conference Room 807, Bethesda, MD 20892.

Contact Person: Yin Liu, Ph.D., MD, Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Blvd., Building One, Room 824, Bethesda, MD 20892, 301–594–8919, liuy@mail.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 17, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–25472 Filed 10–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Availability of License; Mutant IDH1 Inhibitors Useful for Treating Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention Mutant IDH1 Inhibitors Useful for Treating Cancer is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S.

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: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301–217–9197, Fax: 301–217–5736, or email NCATSPartnerships@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This notice is made 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.

Intellectual Property

Description of Technology: Isocitrate dehydrogenase 1 (IDH1) is an enzyme whose normal function is to convert isocitrate to α -ketoglutarate. Mutated forms of this enzyme (mIDH1) are common in a variety of cancers including acute myeloid leukemia (AML), glioma, cholangiocarcinoma, chondrosarcoma and melanoma. The IDH1 mutation at position 132 and similar IDH1 mutations result in the enzyme gaining the ability to catalyze the NADPH-dependent reduction of the wild type enzyme's product, α -ketoglutarate to R–2-hydroxyglutarate (2–HG). 2–HG is an oncometabolite, and its elevated levels have been shown to lead to de-differentiation of cells. Mutant IDH1 is an attractive target for anti-cancer therapeutics as inhibition reduces levels of 2–HG. It is expected that lower 2–HG levels will result in fewer undifferentiated cancer cells. Furthermore, inhibition of mutant IDH1 is expected to have little effect on non-cancerous cells, as these cells do not express the IDH1 mutation resulting in lower toxicity than typical cytotoxic anticancer agents.

In collaboration with the University of North Carolina, the National Center for Advancing Translational Sciences (NCATS) investigators have discovered a series of novel compounds that potently and selectively inhibit mIDH1. These compounds reduce 2–HG levels in cell lines *in vitro* as well as in human cancer cells grown in mouse xenografts *in vivo*. These compounds show greater than 250-fold selectivity for the mutant enzyme over the wild-type, show favorable *in vitro* stability (in mouse, rat, dog and human hepatocyte exposure studies), are AMES negative, and exhibit

no significant metabolic CYP liabilities. These compounds possess very favorable *in vivo* rodent pharmacokinetics and bioavailability and are well tolerated in rodents, even when dosed at high levels.

Potential Commercial Applications

- Potential treatment of cancer (AML or other solid tumors listed above).
- Potential treatment of rare diseases including Maffucci Syndrome and Ollier Disease.

Value Proposition

- Novel mutant IDH1 inhibitors are effective at lowering the oncometabolite, 2–HG in *in vivo* mouse proof-of-concept studies and are well suited for IND enabling studies.

Development Stage: Pre-clinical (*in vivo* validation).

Inventor(s): Matt Boxer, Kyle Brimacombe, Mindy Davis, Rajan Pragani, Jason Rohde, Li Liu, Surendra Karavadi, Daniel Urban, Min Shen, Anton Simeonov, Ajit Jadhav (NCATS) Xiaodong Wang and Andrew McIver (Univ. of North Carolina at Chapel Hill)

Intellectual Property:

1. International Application No. PCT/US15/067406 filed on 12/22/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No: E–243–2014/0–PCT–02), and

2. U.S. Provisional Application No. 62/353298 filed on 06/22/2016 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No. E–189–2016/0–US–01).

Dated: October 5, 2016.

Pamela McInnes,

Deputy Director, Office of the Director, National Center for Advancing Translational Sciences.

[FR Doc. 2016–25468 Filed 10–20–16; 8:45 am]

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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 Meetings

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