

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850, 240-276-5085, tandlea@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP-B.

Date: February 6-7, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: E. Tian, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850, 240-276-6611, tiane@mail.nih.gov.

Name of Committee: National Cancer Institute Initial Review Group; Institutional Training and Education Study Section (F).

Date: February 21-22, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240-276-6368, Stoicaa2@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP-A.

Date: February 21-22, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W120, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W120, Rockville, Maryland 20850, 240-276-6457, mh101v@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP-C.

Date: February 22-23, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room

7W126, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Mukesh Kumar, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W126, Rockville, Maryland 20850, 240-276-6611, mukesh.kumar3@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) Review SEP-IV.

Date: February 28, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W522, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NCI, 9609 Medical Center Drive, Room 7W522, Rockville, Maryland 20850, 240-276-5413, klaus.piontek@nih.gov.

Name of Committee: National Cancer Institute Initial Review Group; Career Development Study Section (J).

Date: February 28-29, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W624, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Tushar Deb, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W624, Rockville, Maryland 20850, 240-276-6132, tushar.deb@nih.gov.

(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 30, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-24225 Filed 11-1-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as

amended, notice is hereby given of a meeting of the National Center for Advancing Translational Sciences Advisory Council.

This meeting is being held virtually only. The open session will be videocast and may be accessed by the public from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>). Individuals who 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 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 Center for Advancing Translational Sciences Advisory Council.

Date: January 18, 2024.

Closed: 11:00 a.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, 9th Floor, Conference Room 987/989, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Open: 12:30 p.m. to 6:00 p.m.

Agenda: Report from the Center Director, Program Update(s), Clearance of Concept(s), Special Topic presentation.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, 9th Floor, Conference Room 987/989, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, One Democracy Plaza, Room 1072, Bethesda, MD 20892, (301) 435-0809, anna.ramseyewing@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice no later than 15 days after the meeting at NCATSCouncilInput@mail.nih.gov. 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 procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles

will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility 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.

(National Center for Advancing Translational Sciences, National Institutes of Health, HHS Assistance Listing Number (formerly Catalog of Federal Domestic Assistance (CFDA) numbers) No. 93.350.)

Dated: October 30, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-24224 Filed 11-1-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Center for Advancing Translational Sciences, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this Notice to Platform Pharmaceuticals, Inc. ("Platform Pharma"), headquartered in New York, NY.

DATES: Only written comments and/or applications for a license which are received by the National Center for Advancing Translational Sciences' Office of Strategic Alliances on or before November 17, 2023 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Strategic Alliances, Telephone: (301)-642-0460; Email: sury.vepa@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application No. 62/095,322 filed on 12/22/2014 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" (HHS Ref. No. E-243-2014-0-US-01);
2. International Patent Application No. PCT/

- US2015/067406 filed on 12/22/2015 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" (HHS Ref. No. E-243-2014-0-PCT-02);
3. Australian Patent Application No. 2015369712 filed on 12/22/2015 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 2015369712 on 8/20/2020 (HHS Ref. No. E-243-2014-0-AU-03);
4. Canadian Patent Application No. 2971872 filed on 12/22/2015 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" (HHS Ref. No. E-243-2014-0-CA-04);
5. Chinese Patent Application No. 2015800763284 filed on 12/22/2015 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. ZL2015800763284 on 4/13/2021" (HHS Ref. No. E-243-2014-0-CN-05);
6. European Patent Application No. 15823901.2 filed on 12/22/2015 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which issued as Patent No. 3237385 on 11/24/2021 and validated in Germany, Spain, France, Great Britain, and Italy (HHS Ref. No. E-243-2014-0-EP-06);
7. Japanese Patent Application No. 2017534314 filed on 6/22/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 6901394 on 6/21/2021 (HHS Ref. No. E-243-2014-0-JP-07);
8. U.S. Patent Application No. 15/538,570 filed on 12/12/2015 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which issued as Patent No. 10,703,746 on 7/7/2020 (HHS Ref. No. E-243-2014-0-US-08);
9. U.S. Provisional Patent Application No. 62/353,298 filed on 6/22/2016 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" (HHS Ref. No. E-189-2016-0-US-01);
10. International Patent Application No. PCT/US2017/038549 filed on 6/21/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" (HHS Ref. No. E-189-2016-0-PCT-02);
11. Australian Patent Application No. 2017281088 filed on 6/21/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 2017281088 on 9/9/2021 (HHS Ref. No. E-189-2016-0-AU-04);
12. Canadian Patent Application No. 3028999 filed on 6/21/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" (HHS Ref. No. E-189-2016-0-CA-05);
13. Chinese Patent Application No. 2017800514100 filed on 6/21/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 201780051410.0 on 9/20/2022 (HHS Ref. No. E-189-2016-0-CN-06);
14. European Patent Application No. 17735296.0 filed on 6/21/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which issued as Patent No. 3475276 on 3/31/2021 and

validated in Germany, Spain, France, Great Britain, and Italy (HHS Ref. No. E-189-2016-0-EP-07);

15. Japanese Patent Application No. 2018-567108 filed on 6/21/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 6987798 on 12/3/2021 (HHS Ref. No. E-189-2016-0-JP-08); and
16. U.S. Patent Application No. 16/312,206 filed on 12/20/2018 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 10,836,759 on 11/17/2020 (HHS Ref. No. E-189-2016-0-US-03).

The patent rights in these inventions have been either assigned and/or exclusively licensed to the government of the United States of America and the University of North Carolina at Chapel Hill.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

"Use of mutant isocitrate dehydrogenase 1 (mIDH1) inhibitors, as claimed in the licensed patent rights, for the treatment of cancers (such as acute myeloid leukemia, glioma, cholangiocarcinoma, glioblastoma multiforme (GBM) and other solid tumors) and rare diseases."

The inventions relate to a series of novel compounds that potentially 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.

Thus, the compounds of the subject inventions can be used individually or in combination to develop new therapies to treat diseases which result from mutant IDH1 activity. The diseases caused by mutant IDH1 activity include cancer (e.g., acute myeloid leukemia, glioma, cholangiocarcinoma and potentially other solid tumors) and selected rare diseases, such as Ollier Disease.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National