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: Sylvia Neal, PhD, National Center for Advancing Translational Sciences, NIH, 6701 Democracy Blvd., Building One, Room 818, Bethesda, MD 20892, 301–594–5033, syvia.neal@mail.nih.gov.

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


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.

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 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 Pragati, Jason Rohde, Li Liu, Surendra Karavadhi, Daniel Urban, Min Shen, Anton Simeonov, Aij 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


Dated: October 5, 2016.

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

[FR Doc. 2016–25468 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.
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 of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Ancillary Studies Review Meeting  
**Date**: November 9, 2016  
**Time**: 9:30 a.m. to 12:30 p.m.  
**Agenda**: To review and evaluate grant applications  
**Place**: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting)  
**Contact Person**: Xincheng Zheng, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 820, Bethesda, MD 20892, 301–451–4838, xincheng.zheng@nih.gov.

**Name of Committee**: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; AMS Member Conflict Meeting  
**Date**: November 9, 2016  
**Time**: 2:00 p.m. to 3:00 p.m.  
**Agenda**: To review and evaluate grant applications  
**Place**: National Institutes of Health, Bethesda, MD 20892 (Telephone Conference Call)  
**Contact Person**: Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, mak2@mail.nih.gov.

**Name of Committee**: National Institute of Child Health and Human Development Special Emphasis Panel; AMS  
**Date**: November 9, 2016  
**Time**: 9:00 a.m. to 2:00 p.m.  
**Agenda**: To review and evaluate grant applications  
**Place**: National Institutes of Health, Bethesda, MD 20892 (Teleconference Call)  
**Contact Person**: Rita Anand, Ph.D., Scientific Review Officer, Division of Scientific Review, National Institute of Child Health And Human Development, NIH, 6710B Rockledge Drive, Room 2131C, Bethesda, MD 20892, 301–496–1477, anandr@mail.nih.gov.

**Name of Committee**: National Institute of Child Health and Human Development Special Emphasis Panel  
**Date**: December 7, 2016  
**Time**: 11:00 a.m. to 2:30 p.m.  
**Agenda**: To review and evaluate grant applications  
**Place**: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call)  
**Contact Person**: Carla T. Walls, Ph.D., Scientific Review Administrator, Scientific Review Branch, National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2131C, Bethesda, MD 20892, 301–435–6898, wallscc@mail.nih.gov.

**Name of Committee**: National Institute of Child Health and Human Development Special Emphasis Panel  
**Date**: December 15, 2016  
**Time**: 9:00 a.m. to 2:30 p.m.  
**Agenda**: To review and evaluate grant applications  
**Place**: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call)  
**Contact Person**: Michelle Trout, Program Analyst, Office of Federal Advisory Committee Policy  
**Date**: October 17, 2016.