

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of General Medical Sciences; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following 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: NIGMS Initial Review Group Training and Workforce Development Study Section-C; Review of MARC and U-RISE T34 Applications.

Date: October 21–22, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Video Meeting).

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institutes of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18A, Bethesda, MD 20814, 301-435-0807, slicelw@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 17, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-17875 Filed 8-19-21; 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: The Development of an Epidermal Growth Factor Receptor Variant III (EGFRvIII) Antibody-Drug Conjugate (ADC) for the Treatment of EGFRvIII-Expressing Human Cancers**

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, 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 ADC Therapeutics Ltd (ADCT), located in Lausanne, Switzerland.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before September 7, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Abritee Dhal, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276-6154; Email: abritee.dhal@nih.gov.

SUPPLEMENTARY INFORMATION:**Intellectual Property**

U.S. Provisional Patent Application 62/869,956 entitled "Monoclonal Antibodies that Bind EGFRvIII and Their Use" [HHS Ref. E-103-2019-0-US-01], PCT Patent Application PCT/US2020/040544 entitled "Monoclonal Antibodies that Bind EGFRvIII and Their Use" [HHS Ref. E-103-2019-0-PCT-02], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

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

The use, development, manufacturing and commercialization of an antibody-drug conjugate (ADC) having:

(1) The CDR sequences of the 40H3 monoclonal antibody

(2) a DNA-damaging or immunostimulant payload including, but not limited to, pyrrolbenzodiazepines, camptothecins, ecteinascidins, TLR/STING agonists, for the treatment of EGFR-overexpressing tumors including, but not limited to glioblastoma, head and neck cancer, non-small cell lung cancer (NSCLC) and colorectal cancer. The license field of use excludes any (a) non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, ADCs with payloads that are not DNA-damaging, and (b) unconjugated antibodies."

Epidermal growth factor receptor (EGFR) is a transmembrane receptor for members of the epidermal growth factor (EGF) family of extracellular protein ligands. There is substantial evidence that aberrant EGFR activity is involved in the pathogenesis and progression of various types of cancers including glioblastoma multiforme (GBM). Aberrant EGFR activity is frequently associated with genetic alterations in EGFR expression (such as gene amplification) or activity (such as activating mutations). A particularly prominent activating mutation is caused by the loss of exons 2–7 to produce EGFR variant III (EGFRvIII). This constitutively active variant of EGFR is expressed in cancer cells only. Currently, there for no effective therapy for patients with GBM. The EGFRvIII ADC can potentially be used for the treatment of GBM and other EGFR expressing cancers such as head and neck cancer, NSCLC and colorectal cancer, the ADCs can lead to the selective destruction of the cancerous cells. The development of a new therapeutic targeting EGFR will benefit public health by providing an effective treatment for patients with GBM and other solid tumors.

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 Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 16, 2021.

Richard U. Rodriguez,
Associate Director, Technology Transfer
Center, National Cancer Institute.

[FR Doc. 2021-17849 Filed 8-19-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, September 09, 2021, 10:00 a.m. to September 10, 2021, 12:45 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD, 20892 which was published in the **Federal Register** on August 09, 2021, FR Doc 2021-16952, 86 FR 43557.

The meeting notice is amended to change and adjust the Opening and Closing times on the Subcommittees and Executive Sessions. The meeting is partially Closed to the public.

Dated: August 17, 2021.

Miguelina Perez,
Program Analyst, Office of Federal Advisory
Committee Policy.

[FR Doc. 2021-17876 Filed 8-19-21; 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, 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 of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; AMP AIM Technology and Analytic Cores Review.

Date: September 15, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Blvd, Bethesda, MD 20892 (Virtual Meeting).

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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; AMP- AIM Disease Team Review.

Date: September 17, 2021.

Time: 10:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yin Liu, Ph.D., MD Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, and Musculoskeletal and Skin Diseases, National Institute of Health, Bethesda, MD 20892, 301-496-0505 liuy@mail.nih.gov.

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

Dated: August 17, 2021.

Miguelina Perez,
Program Analyst, Office of Federal Advisory
Committee Policy.

[FR Doc. 2021-17873 Filed 8-19-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and

need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open sessions will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

A portion of 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: Council of Councils.

Open: September 17, 2021.

Time: 10:00 a.m. to 12:10 p.m.

Agenda: Call to Order and Introductions; Announcements and Updates; NIH Program Updates; Scientific Talks and Other Business of the Committee.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Name of Committee: Council of Councils.

Closed: September 17, 2021.

Time: 12:10 p.m. to 1:10 p.m.

Agenda: Review of Grant Applications.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Open: September 17, 2021.

Time: 1:30 p.m. to 5:10 p.m.

Agenda: NIH Program Updates; Scientific Talks and Other Business of the Committee.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert W. Eisinger, Ph.D., Executive Secretary, Council of Councils, Senior Scientific Advisor, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, Building 1, Room 258, One Center Drive, Bethesda, MD 20892, robert.eisinger@nih.gov, 301-451-0455.

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.

Information is also available on the Council of Council's home page at <http://dpcpsi.nih.gov/council/> where an agenda will be posted before the meeting date.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired