

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 to Kyverna Therapeutics (“Kyverna”) located in Berkeley, CA.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before March 5, 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: David A Lambertson, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center at (240)-276-5530 or Email: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:**Intellectual Property**

The following represents the intellectual property to be licensed under the prospective agreement:

(A) U.S. Provisional Patent Application 62/006, 313 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-01], PCT Patent Application PCT/US2015/033473 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-PCT-02], Australian Patent 2015270912 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-AU-03], Canadian Patent Application 2951045 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-CA-04], Chinese Patent Application 201580033802.5 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-CN-05], European Patent 3149044 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-EP-06] (validated in Germany [HHS Ref. E-042-2014-0-DE-19], Spain [HHS Ref. E-042-2014-0-ES-20], France [HHS Ref. E-042-2014-0-FR-21], the United Kingdom [HHS Ref. E-042-2014-0-GB-22], Italy [HHS Ref. E-042-2014-0-IT-23], and Ireland [HHS Ref. E-042-2014-0-IE-24], and lodged in Hong Kong [E-042-2014-0-HK-16]), Israeli Patent Application 249305 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-IL-07], Indian Patent Application 291647041047

entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-IN-08], Japanese Patent Application 2016-571017 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-JP-09], South Korean Patent Application 2016-7036828 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-KR-10], Mexican Patent Application MX/a/2016/015834 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-MX-11], New Zealand Patent Application 727167 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-NZ-12], Saudi Arabian Patent Application 516380406 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-SA-13], Singaporean Patent Application 11201609960Q entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-SG-14], United States Patent 10,287,350 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-15], United States Patent Application 16/360,281 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-17], New Zealand Patent Application 764530 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-NZ-18], European Patent Application 20197459.9 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-EP-25], Australian Patent Application 2020267211 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-AU-26], and Japanese Patent Application XXX entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-JP-27], and all continuing U.S. and foreign patents/patent applications for the technology family.

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 following:

“The development, production and commercialization of an anti-CD19 targeting chimeric antigen receptor (CAR)-based immunotherapy using CRISPR/Cas9-edited allogeneic (where donor and recipient are different) T lymphocytes, wherein the CAR expresses at least:

- (1) The complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;
- (2) a CD8a hinge and transmembrane domain*;

(3) and a CD28z T cell signaling domain*; for the treatment of autoimmune diseases.”

This technology discloses the development of chimeric antigen receptors that recognize the CD19 cell surface protein. CD19 is expressed on the cell surface of several autoimmune disease cells, including lupus nephritis. For many autoimmune diseases there are no FDA-approved therapies, underscoring that there is an unmet need. The development of an autoimmune disease therapeutic targeting CD19 will benefit public health by providing a treatment for patients who may not have any options.

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 completed 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: February 4, 2021.

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

[FR Doc. 2021-03221 Filed 2-17-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of General Medical Sciences Special Emphasis Panel, March 23, 2021, 09:30 a.m. to March 23, 2021, 05:30 p.m., National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD, 20892 which was published in the

Federal Register on February 04, 2021, 86 FR 8211.

The meeting notice is amended to change the date of the meeting from March 19, 2021 to March 23, 2021. The meeting is closed to the public.

Dated: February 11, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-03188 Filed 2-17-21; 8:45 am]

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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 Subcommittee—B Review of Predoctoral Training Grant Applications.

Date: February 25–26, 2021.

Time: 9:30 a.m. to 6:00 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: Lisa A. Newman, SCD, 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) 435-0965, newmanla2@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. 93.375, 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: February 12, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-03253 Filed 2-17-21; 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, 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: Center for Scientific Review Special Emphasis Panel, Member Conflict: Respiratory Science.

Date: March 11, 2021.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Richard D Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, 301-402-3995, richard.schneiderman@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Macromolecular Structure and Function.

Date: March 18–19, 2021.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David R. Jollie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435-1722, jollieda@csr.nih.gov.

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

Date: March 18–19, 2021.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Krystyna H. Szymczyk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-4198, szymczyk@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: March 18–19, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887 hamelinc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; BRAIN Initiative: Targeted BRAIN Circuits Projects R01/R34.

Date: March 18–19, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301-435-1242, kgt@mail.nih.gov.

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

Date: March 18, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, 301-594-3292, niw@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biological Chemistry, Biophysics, and Assay Development.

Date: March 18, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John Harold Laity, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-402-8254, john.laity@nih.gov.