

fields of use may be limited to the following:

Fields of Use Applying to Intellectual Property Group A

“Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by transposon-mediated gene transfer to express T cell receptors reactive to mutated KRAS, as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are, (a) retrovirally-engineered peripheral blood T cell therapy products for the treatment of human cancers, and (b) CRISPR-engineered peripheral blood T cell therapy products for the treatment of human cancers.

Development, manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.”

Intellectual Property Group A is primarily directed to isolated T cell receptors (TCRs) reactive to mutated Kirsten rat sarcoma viral oncogene homolog (KRAS), within the context of several human leukocyte antigens (HLAs). Mutated KRAS, which plays a well-defined driver role in oncogenesis, is expressed by a variety of human cancers, including: Pancreatic, lung, endometrial, ovarian and prostate. Due to its restricted expression in precancerous and cancerous cells, this antigen may be targeted on mutant KRAS-expressing tumors with minimal normal tissue toxicity.

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 from 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: April 13, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021-09333 Filed 5-3-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. Written comments will be accepted and registration is required to present oral comments. Information about the meeting and registration are available at <https://ntp.niehs.nih.gov/go/165>.

DATES: Meeting: Scheduled for June 8, 2021, 12:30 p.m.–5:00 p.m. Eastern Daylight Time (EDT). Written Public Comment Submissions: Deadline is June 1, 2021. Registration for Oral Comments: Deadline is June 1, 2021.

ADDRESSES: Meeting web page: The preliminary agenda, registration, and other meeting materials are available at <https://ntp.niehs.nih.gov/go/165>. Virtual Meeting: The URL for viewing the virtual meeting will be provided on the meeting web page.

FOR FURTHER INFORMATION CONTACT: Dr. Sheena Scruggs, Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-03, Research Triangle Park, NC 27709. Phone: 984-287-3355, Fax: 301-451-5759, Email: sheena.scruggs@nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include presentations from two of the Division of the National Toxicology Program

(DNTP)’s research program areas. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (<https://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting web page.

Meeting Attendance Registration: The meeting is open to the public with time scheduled for oral public comments. Registration is not required to view the virtual meeting; the URL for the virtual meeting is provided on the BSC meeting web page (<https://ntp.niehs.nih.gov/go/165>). TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: NTP invites written public comments. Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

The deadline for submission of written comments is June 1, 2021. Written public comments should be submitted through the meeting web page. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP web page, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Oral Public Comment Registration: The agenda allows for two formal public comment periods—one comment period for each program area (up to 3 commenters, up to 5 minutes per speaker, per topic). Persons wishing to make an oral comment are required to register online at <https://ntp.niehs.nih.gov/go/165> by June 1, 2021. Oral comments will be received only during the formal comment periods indicated on the preliminary agenda. Oral comments will only be by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Registration is on a first-come, first-served basis. Each organization is allowed one time slot per topic. After the maximum number of speakers per comment period is exceeded, individuals registered to provide oral comment will be placed on a wait list and notified should an opening become available. Commenters will be notified approximately one week

before the meeting about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to *NTP-Meetings@icf.com* by June 1, 2021.

Meeting Materials: The preliminary meeting agenda is available on the meeting web page (<https://ntp.niehs.nih.gov/go/165>) and will be updated one week before the meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Background Information on the BSC: The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, epidemiology, risk assessment, carcinogenesis, mutagenesis, cellular biology, computational toxicology, neurotoxicology, genetic toxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets periodically. The authority for the BSC is provided by 42 U.S.C. 217a, section 222 of the Public Health Service Act (PHS), as amended.

The BSC is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

Dated: April 15, 2021.

Brian R. Berridge,
Associate Director, National Toxicology Program.

[FR Doc. 2021-09331 Filed 5-3-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; PAR20-072, NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: May 27, 2021.

Time: 10:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G45, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Vanitha Sundaresa Raman, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G45, Rockville, MD 20852, 301-761-7949, vanitha.raman@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 28, 2021.

Tyeshia M. Roberson,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-09268 Filed 5-3-21; 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: Natural Product Based Nanoparticles as Dietary Management and/or Treatment of Inflammatory Related Diseases

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 to MaDu, LLC located at 2025 Broadway, Suite 23E, New York, NY 10023.

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 May 19, 2021 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: Michelle A. Favila, Ph.D., Technology Transfer Manager, National Institutes of Health, NCI Technology Transfer Center by email (michelle.favila@nih.gov).

SUPPLEMENTARY INFORMATION:

Intellectual Property

HHS Ref No. E-154-2018-0: Binary Lipid Bilayer-Containing Vesicles Comprising Embedded Cytotoxic Agents and Methods of Making and Using the Same

1. United States Provisional Patent Application No. No. 62/697,287 filed July 12, 2018. [HHS Ref No. E-154-2018-0-US-01]

2. International Patent Application No. PCT/US2019/041464 filed July 11, 2019. [HHS Ref. No. E-154-2018-0-PCT-02]

3. Canadian Patent Application No. 3106008 filed July 11, 2019. [HHS Ref No. E-154-2018-0-CA-03]

4. European Patent Application 19746275.7 filed July 11, 2019. [HHS Ref No. E-154-2018-0-EP-04]

5. Japanese Patent Application 2021-500734 filed July 11, 2019. [HHS Ref No. E-154-2018-0-JP-05] and

6. United States Patent Application 17/259,499 filed January 11, 2021 [HHS Ref No. E-154-2018-0-US-01]

The patent and patent application 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 will be less than the full patent term and the field of use may be limited to the following: Development and commercialization of the Binary Lipid Nanoparticle encapsulating known natural products curcumin, vitamin D, and/or L-serine that are Generally Recognized as Safe for use as medical foods, as defined by the FDA, or over-the-counter products for the management of pain and inflammatory-related diseases. The prospective licensee plans to develop Medical Foods, which is defined by the FDA as