

have been approved under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 29, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-21687 Filed 10-5-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy

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 (U.S.) Patents and Patent Applications listed in the Supplementary Information section of this notice to NE1 Inc, located at 515 Madison Avenue, 8th Fl. Suite 8096, New York, NY 10022.

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 October 21, 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: Dr. Berna Uygun, Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5530; Email: berna.uygun@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

(United States Provisional) Patent Application No. 62/946,934, filed on December 11, 2019 and entitled "Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy"

[HHS Reference No. E-003-2020/0-US-01]. (PCT) Patent Application No. PCT/US2020/064412, filed on December 11, 2020 and entitled "Personalized Tumor Vaccine and Use Thereof for Cancer Immunotherapy" [HHS Reference No. E-003-2020/0-PCT-02].

The patent rights in this invention are co-owned by (a) the United States of America, as represented by the Secretary, Department of Health and Human Services, (b) University of South Bohemia, and (c) NE1 Inc. The prospective exclusive license territory may be worldwide, and the field of use may be limited to: Development, manufacture, and commercialization of the MBTA Therapy Products, as claimed in the Licensed Patent Rights, for the treatment of cancer in humans.

This technology discloses "MBTA Therapy Product(s)" which are vaccine products comprising irradiated tumor cells pulsed with phagocytic agonists (Mannan-BAM, a polysaccharide derivative of mannan), TLR (Toll-like receptor) ligands, and Anti-CD40-monoclonal antibody. The MBTA Therapy Products may be used as personalized tumor vaccines to treat cancer.

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: October 1, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021-21845 Filed 10-5-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health 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: National Institute of Environmental Health Sciences Special Emphasis Panel; Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences.

Date: October 12, 2021.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27713 (Virtual Meeting).

Contact Person: Quentin Li, M.D., Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MSC K3-05, Research Triangle Park, NC 27709, 240-858-3914, quentin.li@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. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: September 30, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-21793 Filed 10-5-21; 8:45 am]

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