DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 Child Health and Human Development Initial Review Group; Pediatrics Study Section.

Date: October 7, 2021.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Joanna Kubler-Kielb, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892, (301) 435–6916, *kielbj@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. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: October 1, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21855 Filed 10–5–21; 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: Development and Commercialization of T Cell Therapies for Mesothelin-Expressing 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 to Ares Immunotherapy, Inc. (''Ares''), a Delaware corporation.

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 applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276–5484; Email: *andy.burke@nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–078–2012: Anti-Mesothelin Chimeric Antigen Receptors

1. United States Provisional Patent Application No. 61/614,612 filed March 23, 2012 (NCI Reference E–078–2012–0–US–01);

2. PCT Patent Application No. PCT/US2013/028980 filed March 5, 2013 (NCI Reference E–078–2012–0–PCT–02);

3. Australian Patent No. 2013235726 issued August 3, 2017 (NCI Reference E–078–2012–0–AU–03);

4. Canadian Patent No. 2,868,121 issued June 1, 2021 (NCI Reference E–078–2012–0–CA–04);

5. European Patent No. 2828290 issued August 15, 2018 (NCI Reference E–078–2012–0–EP–05);

a. Validated in: FR, DE and UK

6. United States Patent No. 9,359,447 issued June 7, 2016 (NCI Reference E–078–2012–0–US–06);

7. European Patent No. 3421489 issued May 5, 2021 (NCI Reference E–078–2012–0–EP–07); and

a. Validated in: FR, DE and UK

8. Canadian Patent Application No. 3,116,051 filed April 23, 2021 (NCI Reference E–078–2012–0–CA–11).

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:

''Development, manufacture and commercialization of T cell therapy products engineered to express the chimeric antigen receptor(s) claimed in the Licensed Patent Rights for the treatment of mesothelin-expressing cancers in humans.''

The E–078–2012 invention family discloses certain chimeric antigen receptors (CARs) targeting mesothelin. CARs are synthetic proteins comprised of extracellular antigen binding domains and intracellular signaling domains designed to activate the cytolytic functions of CAR-expressing T cells upon antigen recognition.

Mesothelin is a cell surface protein. Its expression is primarily restricted to mesothelial cells of the pleura, peritoneum, and pericardium; however, research has demonstrated that several cancers, including malignant mesothelioma, pancreatic, ovarian and lung adenocarcinoma, also express mesothelin under certain circumstances. Due to its limited expression in normal tissues, CARs targeting mesothelin may be useful in the development of T cell therapy products for the treatment of select cancers.

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