

Dated: May 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10336 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters: Establishment

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services (HHS) Office of the Secretary announces establishment of the National Advisory Committee on Children and Disasters (NACCD). The Advisory Committee will provide advice and consultation to the HHS Secretary on pediatric medical disaster planning, preparedness, response, and recovery with respect to the medical and public health needs of children in relation to disasters. The Office of the Assistant Secretary for Preparedness and Response (ASPR) shall provide management and administrative oversight to support the activities of the Advisory Committee. The Office of the Secretary is accepting application submissions from qualified individuals who wish to be considered for membership on the NACCD. Up to 13 new voting members with expertise in pediatric medical disaster planning, preparedness, response, or recovery will be selected for the Committee. Please visit the NACCD website at www.phe.gov/naccd for all application submission information and instructions. Application submissions will be accepted for 30 calendar days from the date this posting is published in the **Federal Register**.

Application Period: The application period is from midnight (Eastern Time) May 27th–June 27th.

FOR FURTHER INFORMATION CONTACT: Maxine Kellman, DVM, Ph.D., PMP, Alternate Designated Federal Official for National Advisory Committees, Washington, DC, Office (202) 260–0447 or email maxine.kellman@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) of 1972, the HHS Secretary, in consultation with the Secretary of the U.S. Department of Homeland Security, established the National Advisory Committee on Children and Disasters

(NACCD). Section 2811A of the Public Health Service Act, as amended by Pandemic and All Hazard Preparedness and Advancing Innovation Act of 2019 (42 U.S.C. 300hh–10b) requires that the Secretary for Health and Human Services (HHS) establish the National Advisory Committee on Children and Disasters (NACCD) to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters. The purpose of the NACCD is to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters. The Office of the Assistant Secretary for Preparedness and Response provides management and administrative oversight to support the activities of the NACCD.

Description of Duties: The NACCD: (1) Provides advice and consultation with respect to the activities addressing at-risk individuals carried out as applicable and appropriate (2) evaluates and provides input with respect to the medical and public health needs of children as they relate to preparation for, response to, and recovery from all-hazards emergencies; (3) provides advice and consultation with respect to state emergency preparedness and response activities and children, including related drills and exercises pursuant to the preparedness goals under the National Health Security Strategy; and (4) provides advice and recommendations to the HHS Secretary with respect to children and the medical and public health grants and cooperative agreements implementing the Public Health Emergency Preparedness and Hospital Preparedness Programs and other activities, as applicable to preparedness and response activities.

Structure: The Advisory Committee consists of not more than 13 voting members, including the Chairperson. Members will be appointed by the HHS Secretary, in consultation with such other Secretaries as may be appropriate, from among the nation's preeminent scientific, public health, and medical experts in areas consistent with the purpose and functions of the NACCD. Section 2811A(d)(2) of the Public Health Services (PHS) Act States:

(2) REQUIRED NON-FEDERAL MEMBERS.—The Secretary, in consultation with such other heads of Federal agencies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including—

(A) at least 2 non-Federal professionals with expertise in pediatric

medical disaster planning, preparedness, response, or recovery;

(B) at least 2 representatives from State, local, Tribal, or territorial agencies with expertise in pediatric disaster planning, preparedness, response, or recovery;

(C) at least 4 members representing health care professionals, which may include members with expertise in pediatric emergency medicine; pediatric trauma, critical care, or surgery; the treatment of pediatric patients affected by chemical, biological, radiological, or nuclear agents, including emerging infectious diseases; pediatric mental or behavioral health related to children affected by a public health emergency; or pediatric primary care; and

(D) other members as the Secretary determines appropriate, of whom—

(i) at least one such member shall represent a children's hospital;

(ii) at least one such member shall be an individual with expertise in schools or child care settings;

(iii) at least one such member shall be an individual with expertise in children and youth with special health care needs; and

(iv) at least one such member shall be an individual with expertise in the needs of parents or family caregivers, including the parents or caregivers of children with disabilities in the following categories: Non-federal health care professionals and representatives from state, local, territorial, or tribal agencies.

The NACCD shall also have up to 12 federal, non-voting members (*ex officio*), including the following officials or their designees:

A. The Assistant Secretary for Preparedness and Response;

B. The Director of the Biomedical Advanced Research and Development Authority;

C. The Director of the Centers for Disease Control and Prevention;

D. The Commissioner of Food and Drugs;

E. The Director of the National Institutes of Health;

F. The Assistant Secretary of the Administration for Children and Families;

G. The Administrator of the Health Resources and Services Administration;

H. The Administrator of the Federal Emergency Management Agency;

I. The Administrator of the Administration for Community Living;

J. The Secretary of Education;

K. The Assistant Secretary for Mental Health and Substance Use; and

L. The Administrator of the Environmental Protection Agency.

A voting member of the NACCD shall serve for a term of three years, except

that the Secretary may adjust the terms of appointees who are initially appointed after the date of enacted of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (June 24, 2019) in order to provide for a staggered term of appointment for all members. A voting member may serve not more than three terms on the NACCD, and not more than two of such terms may be served consecutively. Voting members shall not be full-time or permanent part-time federal employees but shall be appointed by the Secretary as Special Government Employees (5 U.S.C. 3109). A member may serve after the expiration of his/her term until a successor has been appointed. Members whose term expires after this charter's renewal date will have a term length contingent upon renewal of the advisory committee. Vacancies will be filled as members rotate out or resign using the same procedures as the initial selection process.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2020-10323 Filed 5-13-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Mono-Specific Chimeric Antigen Receptor (CAR) Therapies for the Treatment of Cluster of Differentiation 33 (CD33) Expressing Malignancies

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 Vor Biopharma Inc. ("Vor"), located in Cambridge, MA.

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 June 15, 2020 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: Jim Knabb, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240)-276-7856; Facsimile: (240)-276-5504; Email: jim.knabb@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-097-2018-0: Anti-CD33 Chimeric Antigen Receptors for Treatment of Human Acute Myeloid Leukemia

1. U.S. Provisional Patent Application 62/643,015, filed March 14, 2018 (E-097-2018-0-US-01);
2. International Patent Application PCT/US2019/022,309, filed March 14, 2019 (E-097-2018-0-PCT-02)

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 fields of use may be limited to the following:

An exclusive license to:

The development of a chimeric antigen receptor (CAR) therapy monospecific for CD33 for the prophylaxis or treatment of CD33-expressing hematological malignancies wherein the CAR is comprised of the CD33-binding domain referenced as Hu195 or hP67.6, is delivered via lentiviral transduction, and the T cells are:

1. Derived autologously (meaning cells derived from one individual who is both the donor and the recipient) in the first-line or relapsed/refractory setting, or

2. derived allogeneically (meaning cells derived from a matched healthy donor), in the post-transplant setting.

This technology discloses a CAR therapy that targets CD33 by utilizing the anti-CD33 binder known as Hu195 or hP67.6 for the treatment of hematological malignancies. CD33 is a validated immunotherapeutic target that is expressed on the surface of the vast majority of acute myelogenous leukemia (AML) blasts and cells in chronic myeloid leukemia-blast crisis (CML-BC).

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 thirty (30) 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: May 7, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020-10304 Filed 5-13-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Logic-Gated Chimeric Antigen Receptor (CAR) Therapies for the Treatment of Cluster of Differentiation 33 (CD33) 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 Senti Bio ("Senti"), located in South San Francisco, CA.

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 June 15, 2020 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: Jim Knabb, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609