

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]

BILLING CODE 4150-37-P

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]

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 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

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:

1. The development of a CD33-specific logic-gated CAR-based immunotherapy using autologous human T cells transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets CD33 (comprised of the CD33-binding domain referenced as Hu195 or hP67.6 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of CD33-expressing cancers. For clarity, "CD33-specific logic-gated CAR-based immunotherapy" means therapies where the CAR-expressing T cells recognize CD33 and are engineered to respond to one or more additional antigens (but not necessarily all of the signals).

2. The development of a CD33-specific logic-gated CAR-based immunotherapy using allogeneic human NK cells transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets CD33 (comprised of the CD33-binding domain referenced as Hu195 or hP67.6 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of CD33-expressing cancers. For clarity, "CD33-specific logic-gated CAR-based immunotherapy" means therapies where the CAR-expressing NK cells recognize CD33 and are engineered to respond to one or more additional antigens (but not necessarily all of the signals).

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. 2020-10303 Filed 5-13-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act. To request a copy of these documents, call or email the SAMHSA Reports Clearance Officer on (240) 276-0361 or carlos.graham@samhsa.hhs.gov.

Project: Projects for Assistance in Transition from Homelessness (PATH) Program Annual Report (OMB No. 0930-0205)—Revision

The Center for Mental Health Services awards grants each fiscal year to each of the states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101-645, 42 U.S.C. 290cc-21 *et seq.*, the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 *et seq.* of the Public Health Service (PHS) Act) and the 21st Century Cures Act (114-255 Pub. L). Section 522 of the PHS Act and the 21st Century Cures Act requires that the grantee states and territories must expend their payments under the Act solely for making grants to political subdivisions of the state, and to nonprofit private entities (including community-based veterans' organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act and the 21st Century Cures Act specify that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The proposed changes to the PATH 2020 Annual Report are as follows:

1. HMIS Data Standards updates

When needed, field response options and questions have been updated to align with the most recent version of the HMIS Data Standards.

Effective October 1, 2019, the HMIS Data Standards have been further updated. The changes in the HMIS Data Standards are reflected in this version of the PATH Annual Report Manual, and include:

- Updates to response categories for Living Situation
- Addition of an "Unable to Locate Client" response option to PATH Status