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 **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER]** 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; E-mail: 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. US 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 USC 552.

Dated: May 7, 2020.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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