



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Chimeric Antigen Receptor (CAR) Therapies for the Treatment of FMS-like tyrosine kinase 3 (FLT3) Expressing Malignancies Using Natural Killer Cells (NK Cells) Transduced With Retroviral or Lentiviral Vectors.

**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 15 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: at E-mail: [jim.knabb@nih.gov](mailto:jim.knabb@nih.gov).

### SUPPLEMENTARY INFORMATION:

#### Intellectual Property

E-133-2016-0: FLT3-Specific Chimeric Antigen Receptors and Methods Using Same

1. US Provisional Patent Application 62/342,394, filed May 27, 2016 (E-133-2016-0-US-01);
2. International Patent Application PCT/US2017/034,691, filed May 26, 2017 (E-133-2016-0-PCT-02)
3. EP Patent Application No.:17729627.4, filed December 11, 2018 (E-133-2016/0-EP-03)
4. US Patent Application No.: 16/304,552, filed November 26, 2018 (E-133-2016/0-US-05)
5. Australia Patent Application No.: 2017271606, filed November 13, 2018 (E-133-2016/0-AU-06)
6. Canadian Patent Application No.: 3025516, filed November 23, 2018 (E-133-2016/0-CA-07)
7. Japan Patent Application No.: 2018-561669, filed November 22, 2018 (E-133-2016/0-JP-08)

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 and commercialization of a universal or split chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic T cells transduced with lentiviral vectors, or autologous or allogeneic NK cells transduced with retroviral vectors, including but not limited to lentiviral vectors, for the prophylaxis or treatment of cancers expressing FMS-

like tyrosine kinase 3 (FLT3; also known as CD135), wherein the CAR construct binds to the FLT3-binding domain referenced as NC7 in the invention, but NC7 is not included in the CAR construct. Specifically excluded from the field of use for this exclusive license are FLT3-specific CAR-based immunotherapies wherein the CAR construct comprises the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain.” For clarity, “universal/split CAR-based immunotherapy” in the context of this license means CAR therapies wherein the FLT3-binder is soluble and infused into the patient independent from the modified lymphocytes. The patient is then infused with lymphocytes expressing a CAR construct that recognizes the FLT3-binder (an exogenous protein tag like FITC or the heavy chain of an scFv for example).

A co-exclusive license to: “the development and commercialization of a multi-specific FLT3 CAR-based immunotherapy using autologous or allogeneic T cells transduced with lentiviral vectors, or autologous or allogeneic NK cells transduced with retroviral vectors, including but not limited to lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.” For clarity, “multi-specific FLT3 CAR-based immunotherapy” in the context of this license means therapies wherein the CAR-expressing lymphocytes recognize FLT3 and additional antigens.

A co-exclusive license to: “the development of a FLT3-specific Regulated or Switch or Logic-Gated CAR-based immunotherapy using autologous or allogeneic T cells transduced with lentiviral vectors, or autologous or allogeneic NK cells transduced with retroviral vectors, including but not limited to lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets

FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.” For clarity, FLT3-specific Regulated or Switch or Logic-Gated CAR-based immunotherapy in the context of this license means therapies wherein the CAR-expressing lymphocytes recognize FLT3 and are engineered to respond to one or more signals, such as recognizing one or more additional antigens, responding to an exogenous small molecule, or responding to a biological signal (but not necessarily all of the signals).

These technologies disclose therapies to treat AML by utilizing CARs that recognize AML cells through a binder for FLT3, specifically through the FLT3 binder known as NC7. FLT3 is a validated immunotherapeutic target that is expressed on the surface of cancerous cells, its expression is amplified on the surface 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 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 Freedom of Information Act, 5 USC 552.

Dated: December 17, 2020.

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