

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 U.S.C. 552.

Dated: December 17, 2020.

Richard U. Rodriguez,
Associate Director, Technology Transfer
Center, National Cancer Institute.

[FR Doc. 2020-28569 Filed 12-23-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Special Emphasis Panel; NTU Bench/Clinical Testing for COVID-19.

Date: February 3, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jing Chen, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892-4874, chenjing@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 18, 2020.

David W. Freeman,
Program Analyst, Office of Federal Advisory
Committee Policy.

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