

Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 02, 2021, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594-4757, malikk@nidk.nih.gov.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: September 1-2, 2021.

Open: September 02, 2021, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 02, 2021, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594-4757, malikk@nidk.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 18, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-28523 Filed 12-23-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

A portion of 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 Advisory Council on Minority Health and Health Disparities.

Date: February 1, 2021.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 2, 2021.

Open: 11:00 a.m. to 4:00 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council.

Place: National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas M. Vollberg, Sr., Ph.D., National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, Maryland 20892-5465, 301-402-1366, Thomas.Vollberg@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: NIMHD: <https://www.nimhd.nih.gov/about/advisory->

council/, where an agenda and any additional information for the meeting will be posted when available.

Dated: December 18, 2020.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-28528 Filed 12-23-20; 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 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 January 12, 2021 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 Email: 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

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.

[FR Doc. 2020-28526 Filed 12-23-20; 8:45 am]

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