DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Monospecific CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell 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 Syncopation Life Sciences Inc. (“Syncopation”), located in Palo Alto, California.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before July 9, 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: Jim Knabb, Senior Technology Transfer Manager, at Telephone: (240)–276–7856; or at Email: jim.knabb@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–080–2012–0: Human Monoclonal Antibodies Specific for CD22

5. U.S. Patent Application 15/012,023, filed February 1, 2016 (E–080–2008–0–US–05);

E–291–2012–0: M971 Chimeric Antigen Receptors

5. Canada Application No: 2889055, filed September 18, 2013 (E–291–2012–0–CA–05);
6. China Application No: 201380061387.5, filed May 25, 2015 (E–291–2012–0–CN–06);

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:

“Development, manufacture and commercialization of chimeric antigen receptor T cell (CAR–T) immunotherapies (both autologous and allogeneically derived) for the treatment of B cell malignancies that express CD22 wherein:

1. The T cells are engineered to be monospecific for CD22; and
2. The chimeric antigen receptor is specific for CD22 via the m971 scFv”.

This technology discloses CAR–T therapies that target CD22 by utilizing the anti-CD22 binder known as m971. CD22 is expressed on the surface of B cells in B cell malignancies and CD22–targeting CAR–T has shown early promise in clinical trials for ALL and NHL.

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
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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

The meetings will be closed to the public in accordance with the provisions set forth in sections 552(b)(c)(4) and 552(b)(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: Center for Scientific Review Special Emphasis Panel; PAR Panel: The Role of Social Connectedness and Isolation on Health Outcomes.

Date: July 12, 2021.

Time: 1:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Steven Michael Frenk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, (301) 480–4198, szymczykk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psychopathology, Substance Abuse and Community-Based Interventions Across the Lifespan.

Date: July 13–14, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Radiation Therapy and Biology SBR/STTR.

Date: July 13–14, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psychopathology, Substance Abuse and Community-Based Interventions Across the Lifespan.

Date: July 13–14, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psychopathology, Substance Abuse and Community-Based Interventions Across the Lifespan.

Date: July 13–14, 2021.

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Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4198, szymczykk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Radiation Therapy and Biology.

Date: July 13, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Animal and Biological Resource Centers and Resource-Related Research.

Date: July 13, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psychopathology, Substance Abuse and Community-Based Interventions Across the Lifespan.

Date: July 13–14, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–2902, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Nutrition for Precision Health, powered by the All of Us Research Program: Metabolomics and Clinical Assays Center and Dietary Assessment Center.

Date: July 13, 2021.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Latha Meenalochna Malaiyandi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812Q, Bethesda, MD 20892, (301) 435–1999, malaiyandil@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Alzheimer’s Disease Clinical Trials.

Date: July 13, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1767, guoqin.yu@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biology of Vision.

Date: July 13, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Steven Michael Frenk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, hargravesl@mail.nih.gov.