Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06549 Filed 4–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Frederick National Laboratory Advisory Committee to the National Cancer Institute was renewed for an additional two-year period on March 30, 2019.

It is determined that the Frederick National Laboratory Advisory Committee to the National Cancer Institute is in the public interest in connection with the performance of duties imposed on the National Cancer Institute and National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Acting Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *harriscl@nih.gov*.

Dated: April 1, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–06569 Filed 4–3–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive/Co-Exclusive Patent License: Development and Commercialization of Next Generation Chimeric Antigen Receptor (CAR) Therapies for the Treatment of FMS-Like tyrosine kinase 3 (FLT3) 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/Co-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 April 19, 2019 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive/Co-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; Email: *jim.knabb@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–133–2016: 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/co-exclusive license territory may be worldwide, and the fields of use may be limited to the following:

An exclusive license to: ''the development of a universal/split chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with 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.'' The proposed territory is worldwide.

A co-exclusive license to: ''the development of a multi-specific FLT3 CAR-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with 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.'' The proposed territory is worldwide.

A co-exclusive license to: ''the development of a FLT3-specific Regulated/Switch/Logic-Gated CAR-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with 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.'' The proposed territory is worldwide.

This technology discloses a CAR therapy that targets FLT3 by utilizing the anti-FLT3 binder known as NC7. FLT3 (CD135) is a cytokine receptor expressed on hematopoietic progenitor cells and is one of the most frequently mutated genes in acute myeloid leukemia (AML) and infant acute lymphoblastic leukemia (ALL). FLT3 mutation leads to increased cell surface expression and therefore on leukemic cells, which makes it an attractive candidate for cellular therapies such as CAR–T.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive/co-exclusive license will be royalty bearing, and the prospective exclusive/co-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: March 28, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–06575 Filed 4–3–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Scientific Information Reporting System (SIRS) (National Institute of General Medical Sciences)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of General Medical Sciences (NIGMS), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Ming Lei, Director, Division for Research Capacity Building NIGMS, NIH, 45 Center Drive, Room 2AS44C, MSC–6200, Bethesda, Maryland 20892 or call non-toll-free number (301) 827–5323 or Email your request, including your address to: *leim@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Scientific Information Reporting System (SIRS), 0925–0735, Expiration Date 3/31/2019, REINSTATEMENT WITHOUT CHANGE, National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

Need and Use of Information Collection: The SIRS is an online data collection system whose purpose is to obtain supplemental information to the annual Research Performance Progress Report (RPPR) submitted by grantees of the Institutional Development Award (IDeA) Program and the Native American Research Centers for Health (NARCH) Program. The SIRS will collect program-specific data not requested in the RPPR data collection system. The IDeA Program is a congressionally mandated, long-term interventional program administered by NIGMS aimed at developing and/or enhancing the biomedical research competitiveness of States and Jurisdictions that lag in NIH funding. The NARCH Program is an interagency initiative that provides support to American Indian and Alaska Native (AI/AN) tribes and organizations for conducting research in their communities in order to address health disparities, and to develop a cadre of competitive AI/AN scientists and health professionals. The data collected by SIRS will provide valuable information for the following purposes: (1) Evaluation of progress by individual grantees towards achieving grantee-designated and program-specified goals and objectives, (2) evaluation of the overall program for effectiveness, efficiency, and impact in building biomedical research capacity and capability, and (3) analysis of outcome measures to determine need for refinements and/or adjustments of different program features including but not limited to initiatives and eligibility criteria. Data collected from SIRS will be used for various regular or *ad hoc* reporting requests from interested stakeholders that include members of Congress, state and local officials, other federal agencies, professional societies, media, and other parties.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 744.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
SIRS	Principal Investigators, COBRE Phase I	54	1	3.5	189
SIRS	Principal Investigators, COBRE Phase II	34	1	3.5	119
SIRS	Principal Investigators, COBRE Phase III	54	1	3.5	189
SIRS	Principal Investigators, INBRE	24	1	5.5	132
SIRS	Principal Investigators, IDeA–CTR	11	1	3.5	38.5
SIRS	Principal Investigators, NARCH	17	1	4.5	76.5
Total		194	194		744