**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

Prospective Grant of an Exclusive Patent License: Methods and compositions for adoptive cell therapy

**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 Lyell Immunopharma, Inc. ("Lyell"), 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: Andrew Burke, Ph.D., 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)-276-5484; Facsimile: (240)-276-5504; E-mail: andy.burke@nih.gov.

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property**

GROUP A

E-022-2017: Methods for Selecting Therapy for a Cancer Patient

1. US Provisional Patent Application 62/418,461 filed November 7, 2016 (E-022-2017-0-US-01);
2. International Patent Application PCT/US2017/060304 filed November 7, 2017 (E-022-2017-0-PCT-02);
3. European Patent Application 17805342.7 filed May 6, 2019 (E-022-2017-0-EP-03); and
4. United States Patent Application 16/347,778 filed May 6, 2019 (E-022-2017-0-US-04).

GROUP B

E-250-2016: Methods of Preparing an Isolated or Purified Population of Thymic Emigrant Cells and Methods of Treatment Using the Same

1. US Provisional Patent Application 62/433,591 filed December 13, 2016 (E-250-2016-0-US-01);
2. International Patent Application PCT/US2017/065986 filed December 13, 2017 (E-250-2016-0-PCT-02);
3. European Patent Application 17825696.2 filed June 11, 2019 (E-250-2016-0-EP-03); and
4. United States Patent Application 16/468,890 filed June 12, 2019 (E-250-2016-0-US-04).

E-132-2017: Methods of Preparing Hematopoietic Progenitor Cells In Vitro

1. US Provisional Patent Application 62/583,240 filed November 8, 2017 (E-132-2017-0-US-01); and
2. International Patent Application PCT/US2018/059856 filed November 8, 2018 (E-132-2017-0-PCT-02).

E-133-2017: In Vitro Generation of Thymic Organoid from Human Pluripotent Stem Cells

1. US Provisional Patent Application 62/560,908 filed September 20, 2017 (E-133-2017-0-US-01); and
2. International Patent Application PCT/US2018/051625 filed September 19, 2018 (E-133-2017-0-PCT-02).

E-091-2019: Methods of Producing T Cell Populations using Induced Pluripotent Stem Cells

1. US Provisional Patent Application 62/957,939 filed January 7, 2020 (E-091-2019-0-US-01).

GROUP C

E-174-2012: Methods of Producing T Memory Stem Cell Populations

1. International Patent Application PCT/US2012/053947 filed September 6, 2012 (E-174-2012-0-PCT-01);
2. United States Patent 10,316,289 issued June 11, 2019 (E-174-2012-0-US-02.; and
3. United States Patent Application 16/410,327 filed May 13, 2019 (E-174-2012-

0-US-03).

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:

Field of Use Applying to Intellectual Property Group A

"Manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products."

Field of Use Applying to Intellectual Property Group B

"Manufacture and commercialization of adoptive T cell therapy products generated from autologously-derived, induced pluripotent stem cells for the treatment of cancer in humans."

Field of Use Applying to Intellectual Property Group C

"Manufacture and commercialization of adoptive T cell therapy products isolated from peripheral blood for the treatment of cancer in humans."

E-022-2017 generally discloses methods of using certain gene signature profiles to identify cancer patients likely to respond to T cell immunotherapy.

E-250-2016 generally discloses in vitro methodologies for generating induced pluripotent stem cell-based thymic emigrants and methods of using the same for the treatment of cancer.

E-132-2017 generally discloses methods of generating multi-potent hematopoietic progenitor cells from induced pluripotent stem cells and methods of using the same for the treatment of cancer.

E-133-2017 generally discloses methods of generating autologous thymic organoids from human pluripotent stem cells and methods of treating cancer using T cells produced by such organoids.

E-091-2019 generally discloses methods of reprogramming tumor infiltrating lymphocytes into induced pluripotent stem cells and methods of treating cancer using such cells.

E-174-2012 generally discloses a method of generating stem cell-like memory T cells by stimulating naive T cells in the presence of GSK-3beta inhibitors, and methods of treating cancer using cells conditioned in such a manner.

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 which 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: March 23, 2020. Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2020-06922 Filed: 4/1/2020 8:45 am; Publication Date: 4/2/2020]