[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer 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 Intima Bioscience, Inc. ("Intima"), headquartered in New York, NY.

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

Intracellular Genomic Transplant and Methods of Therapy

1. International Patent Application PCT/US2016/044856, filed July 29, 2016 (E-171-2018-6-PCT-01).

GROUP B

Modified Cells and Methods of Therapy

1. International Patent Application PCT/US2016/044858, filed July 29, 2016 (E-171-2018-7-PCT-01);
2. Canadian Patent Application 2993431, priority to July 31, 2015 (E-171-2018-7-CA-02);
3. European Patent Application 16833645.1, priority to July 31, 2015 (E-171-2018-7-EP-03);
4. Israeli Patent Application 257105, priority to July 31, 2015 (E-171-2018-7-IL-04);
5. Chinese Patent Application 201680059180.8, priority to July 31, 2015 (E-171-2018-7-CN-05);
6. United Kingdom Patent Application 1803280.5, priority to July 31, 2015 (E-171-2018-7-GB-06);
7. Japanese Patent Application 2018-525531, priority to July 31, 2015 (E-171-2018-7-JP-07);
8. Hong Kong Patent Application 18115478.9, priority to July 31, 2015 (E-171-2018-7-HK-08);
9. United States Patent 10,166,255, issued January 1, 2019 (E-171-2018-8-US-01);
10. United States Patent Application 16/180,867, filed July 29, 2016 (E-171-2018-8-US-02);
11. United States Patent Application 16/182,146, filed November 3, 2018 (E-171-2018-8-US-03);
12. United States Patent Application 16/182,189, filed November 6, 2018 (E-171-2018-8-US-04);
13. United States Patent Application 15/224,159, filed July 29, 2016 (E-171-2018-9-US-01);

14. United States Patent Application 15/250,514, filed August 29, 2016 (E-171-2018-9-US-02);
15. United States Patent Application 15/256,086, filed September 2, 2016 (E-171-2018-9-US-03); and
16. United States Patent Application 16/513,933, filed July 17, 2019 (E-171-2018-9-US-04).

GROUP C

Viral Methods of T Cell Therapy

1. International Patent Application PCT/US2017/058615, filed October 26, 2017 (E-173-2018-2-PCT-01);
2. United States Patent Application 16/389,586, filed April 19, 2019 (E-173-2018-2-US-02);
3. Australian Patent Application 2017347854, priority to October 26, 2016 (E-173-2018-2-AU-03);
4. Canadian Patent Application 3,041,835, priority to October 26, 2016 (E-173-2018-2-CA-04);
5. European Patent Application 17865054.5, priority to October 26, 2016 (E-173-2018-2-EP-05);
6. Japanese Patent Application 2019-522944, priority to October 26, 2016 (E-173-2018-2-JP-06);
7. Chinese Patent Application [awaiting application number], priority to October 26, 2016 (E-173-2018-2-CN-07); and
8. United Kingdom Patent Application 1906850.1, priority to October 26, 2016 (E-173-2018-2-GB-08).

GROUP D

CAS9 Modified TIL for Treatment of Gastrointestinal Cancer

1. International Patent Application PCT/US2017/057228, filed October 18, 2017 (E-174-2018-2-PCT-01);
2. United States Patent Application 15/947,688, filed April 6, 2018 (E-174-2018-2-US-02);
3. United Kingdom Patent Application 1906855.0, priority to October 18, 2016 (E-174-2018-2-GB-03).
4. Australian Patent Application 2017346885, priority to October 18, 2016 (E-174-2018-2-AU-04);
5. Canadian Patent Application 3,041,068, priority to October 18, 2016 (E-174-2018-2-CA-05);
6. Chinese Patent Application, 2017800784716, priority to October 18, 2016 (E-174-2018-2-CN-06);
7. Japanese Patent Application, 2019-520738, priority to October 18, 2016 (E-174-2018-2-JP-08); and
8. European Patent Application, 17861792.4, priority to October 18, 2016 (E-174-2018-2-EP-09).

The patent rights in these inventions are co-owned by a) the United States of America, as represented by the Secretary, Department of Health and Human Services, b) Regents of the University of Minnesota, and c) Intima Bioscience, Inc.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

"Autologous T cell therapy products genetically engineered by CRISPR to specifically reduce expression or activity of a checkpoint gene (e.g. CISH, PD-1 or CTLA-4) for the treatment of gastrointestinal (GI) epithelial cancer, lung cancer, breast cancer and/or B cell lymphoma (BCL) in humans.

Autologous T cell therapy products (excluding tumor infiltrating lymphocytes) genetically engineered by CRISPR or adeno-associated viral vectors to express exogenous, tumor-reactive T cell receptors for the treatment of gastrointestinal (GI) epithelial cancer, lung cancer, breast cancer and/or B cell lymphoma (BCL) in humans.

Allogeneic T cell therapy products genetically engineered by CRISPR/CAS9 to specifically reduce expression or activity of a checkpoint gene for the treatment of gastrointestinal (GI) epithelial cancer, lung cancer, breast cancer and/or B cell lymphoma (BCL) in humans.

Allogeneic T cell therapy products genetically engineered by CRISPR/CAS9 or adeno-associated viral vectors to express exogenous, tumor-reactive T cell receptors for the treatment of gastrointestinal (GI) epithelial cancer, lung cancer, breast cancer and/or B cell lymphoma (BCL) in humans."

Intellectual Property Group A is primarily directed to methods and compositions relating to the generation of T cells engineered to contain multiple genomic disruptions and methods of treating cancer using the same.

Intellectual Property Group B is primarily directed to methods and compositions relating to the generation of T cells genetically engineered to express an exogenous T cell receptor and a genomic disruption in a checkpoint gene and methods of treating cancer using the same.

Intellectual Property Group C is primarily directed to methods and compositions relating to the generation of T cells genetically engineered by CRISPR and adeno-associated viral vectors to coordinately introduce a genomic disruption in a checkpoint gene and an exogenous T cell receptor, and methods of treating cancer using the same.

Intellectual Property Group D is primarily directed to methods and compositions relating to the generation of tumor infiltrating lymphocytes comprising a genomic disruption in the checkpoint gene *CISH* and methods of treating cancer using the same.

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: August 22, 2019.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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