



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Engineered tumor infiltrating 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 Iovance Biotherapeutics, Inc. (“Iovance”), headquartered in San Carlos, 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, Telephone: (240)-276-5484; E-mail: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-068-2018: Tethered Interleukin-15 and Interleukin-21

1. US Provisional Patent Application 62/628,454, filed February 9, 2018 (E-068-2018-0-US-01);

2. International Patent Application PCT/US2019/016975, filed February 7, 2019 (E-068-2018-0-PCT-02);
3. Australian Patent Application 2019218785, filed August 7, 2020 (E-068-2018-0-AU-03);
4. Chinese Patent Application 201980012443.3, filed August 7, 2020 (E-068-2018-0-CN-04);
5. European Patent Application 19709154.9, filed August 18, 2020 (E-068-2018-0-EP-05);
6. United States Patent Application 16/964,796, filed July 24, 2020 (E-068-2018-0-US-06); and
7. Canadian Patent Application 3,090,512, filed August 5, 2020 (E-068-2018-0-CA-07).

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 field of use may be limited to the following:

“The use of the Licensed Patent Rights to develop, manufacture, distribute, sell, and use unselected whole autologous tumor infiltrating lymphocyte (TIL) adoptive cell therapy products for the treatment of metastatic melanoma, lung, breast, bladder, and HPV-positive cancers. Specifically excluded from this Agreement are methods of generating or using selected subpopulations of TIL and the use of T cell receptors isolated from TIL.”

E-068-2018 is primarily directed to recombinant constructs for the co-expression of Interleukins-15 and 21 (IL-15 and 21). IL-15 and IL-21 have been reported to support the function of anti-tumor T cells; however, their clinical utility has been constrained, in

part, by dose-limiting toxicity following systemic administration and the need for repeated dosing. The subject invention addresses these limitations through synthetic IL-15/21 sequences which incorporate flexible linker regions and cell membrane anchors. T cells engineered to express these constructs experience autocrine IL-15/21 signaling leading to enhanced anti-tumor function in vivo.

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 establishing 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: February 12, 2021.

Richard U. Rodriguez,
Associate Director,
Technology Transfer Center,
National Cancer Institute.

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