



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Prospective Grant of an Exclusive Patent License: Vaccine Augmented Tumor Infiltrating Lymphocytes for the Treatment of Cancer**

**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 AFTER DATE OF PUBLICATION 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](mailto:andy.burke@nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Intellectual Property**

1. United States Provisional Patent Application No. 63/295,762 filed December 31, 2021, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-US-01];
2. International Patent Application No. PCT/US2022/082579 filed December 29, 2022, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-PCT-02];

3. Australian Patent Application No. 2022425620 filed June 25, 2024, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-AU-01];
4. Canadian Patent Application No. 3241588 filed June 18, 2024, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-CA-01];
5. Chinese Patent Application No. 202280092973.5 filed August 30, 2024, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-CN-01];
6. European Patent Application No. 22854399.7 filed June 25, 2024, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-EP-01];
7. Japanese Patent Application No. 2024-539628 filed June 28, 2024, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-JP-01]; and
8. United States Patent Application No. 18/720,347 filed June 14, 2024, entitled “T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer” [HHS Reference No. E-046-2022-0-US-02].

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:

“Development, manufacture and commercialization of combination immunotherapies for the treatment of cancer in humans, comprising at least the following elements:

1. An autologous tumor infiltrating lymphocyte (TIL) T cell product; and
2. A neoantigen cancer vaccine.”

The E-046-2022 patent family is primarily directed to a combination immunotherapy comprising a population of antigen-specific immune cells (*e.g.*, T cells) and a vaccine targeting

the same antigen(s). In oncology, many adoptive cell therapies rely on antigen-specific T cells isolated from the patient in need of treatment. However, these cells often exist in a terminally differentiated and exhausted state and are unable to mount a robust immune response following reinfusion. Recent evidence suggests that administration of a vaccine in parallel with the T cell product can ameliorate this performance defect when the vaccine targets antigen(s) recognized by the T cells. This two-part approach may enhance treatment efficacy.

It is noted that the exclusive field of use which may be granted to Iovance applies to only certain autologous T cell products and vaccination strategies and does not include, for example, any non-TIL-based applications. Accordingly, the scope of rights which may be conveyed under the proposed license covers a portion of the possible applications of E-046-2022.

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 Freedom of Information Act, 5 USC 552.

Dated: November 25, 2024.

**Richard U. Rodriguez,**

*Associate Director,*

*Technology Transfer Center,*

*National Cancer Institute.*

