



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

### **National Institutes of Health**

#### **Prospective Grant of an Exclusive Patent License: Vaccine Augmented Adoptive Cell Therapy 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 Marble Therapeutics, Inc. (“Marble”), headquartered in Boston, MA.

**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](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]; and
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].

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 T cell product, where the T cells are tumor infiltrating lymphocytes (TIL) or chimeric antigen receptor-expressing T cells (CAR-T); 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 investigational 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. It is hoped that this two-part approach will enhance treatment efficacy. The exclusive field of use which may be granted to Marble applies to only certain autologous T cell products and vaccination strategies and does not include, for example, at least two broad classes of cell therapies: allogeneic T cell-based products and TCR-engineered T cell products (TCR-T). Accordingly, the proposed scope of rights which may be conveyed under the 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 U.S.C. 552.

Dated: February 2, 2024.

**Richard U. Rodriguez,**

*Associate Director,*

*Technology Transfer Center,*

*National Cancer Institute.*

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