



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of an Exclusive Patent License: Manufacture, Distribution, Sale and Use of T-Cell-Based Immunotherapies for Solid Tumors**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Cancer Institute, both institutes of the National Institutes of Health, Department of Health and Human Services, are 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 EnZeta Immunotherapies, Inc. of the State of Delaware.

**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: Richard T. Girards, Jr., Esq., MBA, Senior Technology Transfer Manager, National Institutes of Health, NCI Technology Transfer Center by email ([richard.girards@nih.gov](mailto:richard.girards@nih.gov)) or phone (240-276-6825).

#### **SUPPLEMENTARY INFORMATION:**

##### **Intellectual Property**

E-010-2021: ENHANCED ANTIGEN REACTIVITY OF IMMUNE CELLS EXPRESSING A MUTANT NON-SIGNALING CD3 ZETA CHAIN

1. United States Provisional Patent Application No. 63/113,428, filed 13 November 2020 (HHS Reference No. E-010-2021-0-US-01);
2. International Patent Application No. PCT/US2021/059109, filed 12 November 2021 (HHS Reference No. E-010-2021-0-PCT-02);
3. United States Patent Application No. 18/036,112, filed 09 May 2023 (HHS Reference No. E-010-2021-0-US-02);
4. European Patent Application No. 21824143.8, filed 30 March 2023 (HHS Reference No. E-010-2021-0-EP-01); and
5. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future

The patent and patent application 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: manufacture, distribution, sale and use of T-cell-based immunotherapies for solid tumors.

These technologies disclose, e.g., cells expressing a modified CD3 subunit chain comprising at least one ITAM deletion. The inventive cells and populations thereof can be formulated into a composition, such as a pharmaceutical composition. Such cells and compositions thereof can be utilized to treat a wide variety of conditions, including but not limited to the indications within the scope of the contemplated exclusive license.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR 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 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:** August 8, 2023.

**Richard U. Rodriguez,**

*Associate Director,*

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*National Cancer Institute.*

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