BILLING CODE 4167-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered Cell Therapies for the Treatment of HPV 16 E6-Expressing Cancers

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 MedGene Therapeutics, Inc. ("MedGene"), a company located in Silver Spring, Maryland, the United States of America.

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: 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: *burkear@mail.nih.gov*

SUPPLEMENTARY INFORMATION:

Intellectual Property

Reference Number (with Country Code)	Application Number	File Date	Patent Number	Issue Date
E-495-2013-0-US-01	61/846,167	7/15/2013		
E-495-2013-0-PCT-02	PCT/US2014/046480	7/14/2014		
E-495-2013-0-JP-07	2016-527006	1/15/2016	6628719	12/13/2019
E-495-2013-0-US-08	14/905,108	1/14/2016	9,822,162	11/21/2017
E-495-2013-0-US-09	15/786,966	10/18/2017	10,329,339	6/25/2019
E-495-2013-0-US-11	16/408,939	5/10/2019	10,913,785	2/9/2021
E-495-2013-0-JP-19	2019-219105	12/3/2019	6959970	10/12/2021

E-495-2013-0-US-22	17/142,486	1/6/2021	11,697,676	7/11/2023
E-495-2013-0-JP-23	2021-166407	10/8/2021	7223822	2/8/2023
E-495-2013-0-US-02	18/323,493	5/25/2023	12,187,779	1/7/2025

The prospective exclusive license territory may be "Japan, Republic of Korea and the United States of America", and the field of use may be limited to the following:

"Ex vivo generated T cell therapy products comprising autologous or allogeneic T cells genetically engineered to express exogenous T-cell receptors reactive to the HPV-16 E6 oncoprotein for the treatment of HPV-associated cervical cancer, head and neck cancer (including oropharyngeal cancer), and anogenital cancer in humans."

The E-495-2013 patent family is primarily directed to an isolated T cell receptor (TCR) reactive to HPV 16 E6 antigen in the context of HLA-A*02. Among other applications, the claimed TCR may be useful in the development of engineered adoptive cell therapy products for the treatment of HPV-16 E6-positive cancers in patients who also express HLA-A*02.

Human papillomaviruses (HPV) are a diverse group of viral pathogens which commonly infect humans. While most infections are rapidly cleared by the host, certain HPV (e.g., HPV 16 and 18) may establish chronic infections and are highly associated with the development of cancer. In such cases, cancer formation is facilitated by the sustained activity of certain oncoproteins, chiefly E5, E6 and E7.

E6 is a small (~150 amino acid) protein that promotes malignant transformation primarily through its ability to bind the tumor suppressor p53 in complex with the cellular ubiquitin ligase E6-AP (UBE3A), thereby targeting p53 for proteasomal degradation. Together with the E7 oncoprotein (which inactivates the tumor suppressor pRb), E6 cooperatively drives carcinogenesis in infected cells, and its continued expression is required for maintenance of the transformed phenotype. By virtue of this essential role and its restricted expression to diseased cells, E6 is a recognized therapeutic target.

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. Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. 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 in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

"This Notice is made in accordance with 35 U.S.C. 209(e) and 37 CFR §404 Authority to grant exclusive licenses."

Dated: September 11, 2026.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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