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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of T Cell Receptors (TCRs) Targeting the KRAS G12D Mutation for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Kite Pharma, Inc. ("Kite") located in Santa Monica, CA to practice the inventions embodied in the following patent applications:

Intellectual Property

United States Provisional Patent Application No. 62/084,654, filed November 26, 2014, entitled "Anti-mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015/0-US-01]; and

PCT Application No. PCT/US2015/062269 filed November 24, 2015 entitled "Anti-mutated KRAS T Cell Receptors" [HHS Reference No. E-028-2015/1-PCT-01].

The patent rights in these inventions have been assigned 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 development, manufacture and commercialization of retrovirally-engineered mutated KRAS TCR-based autologous peripheral blood T cell therapy products as set forth in the Licensed Patent Rights for the treatment of human cancers.

DATED: Only written comments and/or applications for a license which are received by the National Cancer Institute 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 application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Andrew Burke, Ph.D., Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, MSC 9702, Rockville, MD 20852; Telephone: (240) 276-5484; E-mail andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION: The present invention describes an isolated T cell receptor (TCR) which recognizes the G12D mutation of the Kristen rat sarcoma viral oncogene homolog (KRAS) protein within the context of major histocompatibility complex HLA-A11 presentation.

KRAS is an oncogene with a well-characterized role in the formation of several human cancers, including: pancreatic, colorectal and lung. Certain mutations, such as the substitution of aspartic acid or valine for glycine at codon 12 (termed G12D and G12V, respectively), occur at relatively high frequency and may represent amenable targets for immunotherapies. Due to the restricted expression of KRAS G12D in pre-cancerous and malignant cells, engineered T cell therapies based on the present invention may be useful for the treatment of select cancers.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NCI 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.

Complete applications for a license in an appropriate field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 8, 2016 _____

Richard U. Rodriguez,

Associate Director

Technology Transfer Center

National Cancer Institute

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