[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Kite Pharma, Inc., which is located in Los Angeles, California to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Patent Application No. 61/650,020 filed May 22, 2012 entitled "Murine anti-NY-ESO-1 T cell receptors" (HHS Ref No. E-105-2012/0-US-01) and
2. PCT Application No. PCT/US13/042162 filed May 22, 2013 entitled "Murine anti-NY-ESO-1 T cell receptors" (HHS Ref No. E-105-2012/0-PCT-02)

The patent rights in these inventions have been assigned to 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, distribution, sale, and use of the compositions and methods set forth in the Licensed Patent Rights using genetically engineered autologous T lymphocytes derived from the peripheral blood of humans for the treatment of NY-ESO-1-expressing cancers.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: hastingw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The instant technology describes a T cell receptor (TCR) derived from mouse T cells (i.e. murine TCR) that can be expressed in human T cells to recognize the cancer testis antigen (CTA), NY-ESO-1, with high specificity. This anti-NY-ESO-1 TCR has murine variable regions that recognize the NY-ESO-1 epitope and murine constant regions. The inventors performed in vitro studies comparing this murine NY-ESO-1 TCR with a previously developed human NY-ESO-1 TCR counterpart, which yielded promising clinical outcomes in patients with a variety of cancers. The murine TCR functioned similarly to the human counterpart in their ability to recognize and react to NY-ESO-1 tumor targets.

NY-ESO-1 is a CTA, which is expressed only on tumor cells and germline cells of the testis and placenta. CTAs are ideal targets for developing cancer immunotherapeutics, such as anti-CTA TCRs, because these TCRs are expected to target cancer cells without harming normal tissues and thereby minimize the harsh side effects associated with other types of cancer treatment. NY-ESO-1 is expressed on a wide variety of cancers, including but not limited to breast, lung, prostate, thyroid, and ovarian cancers, melanoma, and synovial sarcomas. Thus, this technology should be applicable in adoptive cell transfer therapies for many types of cancer.

The prospective exclusive license, subject to current non-exclusive license applications under consideration and any further license applications received as objections to this Notice of Intent to Grant an 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 thirty (30) days from the date of this published notice, the NIH 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.

Any additional applications for a license in the field of use 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: March 20, 2014.

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Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health.

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