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 and applications claiming priority to these applications:

1. U.S. Provisional Patent Application No. 61/701,056 filed September 14, 2012 entitled ''T Cell Receptors Recognizing MCH Class II-Restricted Mage-A3'' (HHS Ref No. E–230–2012/0–US–01) and

2. PCT Application No. PCT/US13/059608 filed September 13, 2013 entitled ''T Cell Receptors Recognizing MCH Class II-Restricted Mage-A3'' (HHS Ref No. E–230–2012/0–PCT–02).

3. US Provisional Patent Application no. 61/535,086 filed September 15 2011, entitled ''T cell receptors recognizing HLA-A1 or HLA-Cw7 restricted MAGE'' (HHS Ref No. E–266–2011/0–US–01).

4. PCT Application No. PCT/US2012/054623 filed September 11 2012, entitled ''T cell receptors recognizing HLA-A1 or HLA-Cw7 restricted MAGE'' (HHS Ref No. E–266–2011).

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 and commercialization of melanoma antigen family (MAGE) A3 and A6-specific T cell receptor (TCR)-based autologous peripheral blood T cell therapy products as set forth in the Licensed Patent Rights for the treatment of MAGE A3 and A6 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 November 17, 2014 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; Email: *hastingw@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: There are twelve melanoma antigen family antigens (MAGE–A) designated A1–A12. Their normal function is not well defined, but in cancer cells they block the functions of tumor suppressor proteins to mediate tumor growth and spreading. The MAGE–A proteins are some of the most widely expressed cancer testis antigens expressed on human tumors. Other than non-MHC expressing germ cells of the testis, normal cells do not express these antigens, which make them ideal targets for cancer immunotherapies anticipated to generate less toxic side effects than conventional cancer treatments. These TCRs deliver a robust immune response against MAGE–A3 or A6 expressing cancerous cells and could prove to be a powerful approach for selectively attacking tumors without generating toxicity against healthy cells.

The instant technology describes T cell receptors (TCRs) against the MAGE–A3 and A6 tumor antigens in the context of major histocompatibility complex (MHC) class II molecule HLA-DP-beta1*04, and against MAGE–A3 antigen in context of the HLA-A*0101. They comprise the first HLA class II restricted MAGE–A3/A6-specific TCRs developed for use in adoptive immunotherapy. Since approximately 80% of patients express the HLA-DP-beta1*04 class II HLA allele, this TCR greatly expands the population pool treatable with MAGE–A3/A6 TCRs to include the majority of patients with an amenable target expression profile. Cancer immunotherapy with these new HLA class II TCRs could yield a robust and effective CD8+ and CD4+ T cell immune response and selectively target MAGE–A3/A6 expressing tumors without generating toxicity against healthy cells. Finally, they complement TCRs that are restricted to MHC class I molecules such as HLA-A*01, expanding the population of patients beyond HLA-DP-beta1*04 MHC class II positive.

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.

Complete 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 evaluation option 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: October 8, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–24502 Filed 10–15–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0018; OMB No. 1660–0039]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; National Fire Academy Long-Term Evaluation Form for Supervisors and National Fire Academy Long-Term Evaluation for Students/Trainees

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (i.e., the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 17, 2014.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or