[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of a Start-up Exclusive Commercial License Agreement: Development of MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1, for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404.7, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an start-up exclusive commercial license to Immunova Therapeutics, Inc., which is located in Houston, Texas, to practice the inventions embodied in the following patent applications and applications claiming priority to these applications:

E-090-2000

1. U.S. Provisional Patent Application No. 61/179,004 filed January 28, 2000 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/0-US-01);
2. U.S. Provisional Patent Application No. 60/237,107 filed September 29, 2000 entitled "HLA-DP Restricted CD4+ T Cell Epitopes from the Cancer

Antigen, NY ESO-1" (HHS Ref No. E-227-2000/0-US-01 was combined with E-090-2000/0-US-01 at the PCT stage, creating the E-090-2000/1 technology family and associated applications);

3. PCT Application No. PCT/US01/02765 filed January 26, 2001 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-PCT-01);
4. Canadian Patent No. 2398743 issued June 23, 2015 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-CA-02);
5. Australian Patent No. 785151 issued January 18, 2007 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-AU-03);
6. Japanese Patent No. 5588363issued August 1, 2014 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-JP-12);
7. U.S. Patent No. 7,619,057 issued November 17, 2009 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-US-06);
8. U.S. Patent No. 8,754,046 issued June 17, 2014 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-US-07);
9. U.S. Patent Application No. 12/568,134 filed September 28, 2009 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-US-013);
10. European Patent Application No. 10010354.8 filed January 26, 2001 entitled "MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO-1" (HHS Ref No. E-090-2000/1-EP-10);

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective start-up exclusive commercial license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to develop, manufacture, distribute, sell and use NY-ESO-1 based vaccines and cell therapy products for the treatment of NY-ESO-1-positive 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 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240) 276-5530; Facsimile: (240) 276-5504; E-mail: chatterjeesa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: NY-ESO-1 is a known tumor antigen which is expressed on a broad range of tumor types, including melanoma, breast, bladder, ovarian, prostate, head and neck cancers, neuroblastoma, and small cell lung cancer. The above-referenced inventions embody the identification of a number of novel immunogenic peptide epitopes, and analogs thereof, which are derived from the NY-ESO-1 tumor antigen. Specifically, this technology describes novel MHC Class II restricted epitopes of NY-ESO-1 which are recognized by CD4+ T cells. It also embodies the identification of two additional immunogenic peptide epitopes of NY-ESO-1. The latter two epitopes are presented by HLA-DP4, a prevalent MHC Class II allele present in 43-70% of Caucasians. The inventors also determined that the DP allele is highly associated with the NY-ESO-1 antibody production. In addition, one of these epitopes has dual HLA A2 and DP4 specificity, thereby it has the potential to generate both CD4+ and CD8+ tumor specific T cells. These epitopes may be of great value as

prophylactic and/or therapeutic cancer vaccines or cell therapy products for use against a number of common cancers.

The prospective start-up exclusive commercial license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective start-up exclusive commercial license may be granted unless within fifteen (15) 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 404.7.

Any additional, properly filed, and 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 commercial 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: September 28, 2015

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Richard U. Rodriguez, M.B.A.
Acting Director
Office of Technology Transfer
National Institutes of Health

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