[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of MUC-1 Tumor Associated Antigens as cancer vaccines for bladder cancer, breast cancer, colorectal cancer, gastric cancer, kidney cancer, liver cancer, lung cancer, ovarian cancer, prostate cancer and pancreatic cancer.

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that 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 following U.S. Patents and Patent Applications to Bavarian Nordic Immunotherapeutics ("BNIT") located in Mountain View, CA, USA:

> Intellectual Property: U.S. provisional patent application no. 61/582, 723 filed January 3, 2012 entitled "Native and Agonist CTL Epitopes of the MUC-1 Tumor Antigen" [HHS Ref. No. E-001-2012/0-US-01] as well as all international applications, continuation applications and divisional applications.

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 will be limited to the use of Licensed Patent Rights for development of Pox-virus based vaccines for bladder cancer, breast cancer, colorectal cancer, gastric cancer, kidney cancer, liver cancer, lung cancer, ovarian cancer, prostate cancer and pancreatic cancer."

DATE: 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.

ADDRESS: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; E-mail: chatterjeesa@od.nih.gov.

SUPPLEMENTARY INFORMATION: Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells, and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that results in tumor destruction. The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen-specific via the peptide/ major histocompatibility complex and the

second or ‘‘co-stimulatory’’ signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

Dr. Jeffrey Schlom et al. at NCI have identified 7 new agonist epitopes of the MUC-1 tumor associated antigen. Compared to their native epitope counterparts, peptides reflecting these agonist epitopes have enhanced ability to generate cytotoxic T-lymphocytes (CTL), which in turn have a greater ability to kill MUC-1 expressing human tumor cells. The agonist epitopes span both the VNTR region of MUC-1 and the C-terminus region. The epitopes encompass two major MHC alleles reflecting the majority of the population.

Along with the method of use, the technology encompasses the use of these agonist epitopes in peptide- and protein-based vaccines, with dendritic cells or other antigen presenting cells, or encoding sequences in DNA, viral, bacterial, yeast, or other types of vectors, or to stimulate T-cells in vitro for adoptive immunotherapy protocols.

The MUC-1 tumor associated antigen has been shown to be overexpressed and/or underglycosylated in a wide range of human cancers. The C-terminus region of MUC-1 (MUC-1C) has been shown to be an oncogene and has been associated with a more aggressive phenotype in several different 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 404.7. 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 404.7.

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.

February 13, 2013
Date

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

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