[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: Human Papillomavirus 16 E2 and E6 Peptides for Cervical Cancer Vaccine Development

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 Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive worldwide license to practice the inventions embodied in:

NIH REF NO.	PATENT APPLICATION NO.	FILING DATE	ISSUED PATENT NO. (*if any*)
NIH Ref. E-126-2001/0-AU-06	2002258614	March 22, 2002	2002258614
NIH Ref. E-126-2001/0-CA-04	2441947	March 22, 2002	
NIH Ref. E-126-2001/0-EP-05	2728570.9	March 22, 2002	
NIH Ref. E-126-2001/0-PCT-02	PCT/US02/09261	March 22, 2002	(Expired)
NIH Ref. E-126-2001/0-US-01	60/278,520	March 23, 2001	(Expired)
NIH Ref. E-126-2001/0-US-03	10/472,661	September 23, 2003	7,189,513
NIH Ref. E-126-2001/0-US-07	11/685,632	March 13, 2007	7,507,538
NIH Ref. E-155-2005/0-US-01	60/671,463	April 15, 2005	(Expired)
NIH Ref. E-155-2005/1-US-01	60/680,000	May 12, 2005	(Expired)

NIH Ref. E-155-2005/2-US-01	60/724,783	October 11, 2005	(Expired)
NIH Ref. E-155-2005/3-AU-04	2006236905	April 11, 2006	
NIH Ref. E-155-2005/3-CA-05	2604909	April 11, 2006	
NIH Ref. E-155-2005/3-EP-03 (CH, DE, FR, GB, and IE)	6749659.6	April 11, 2007	1877087
NIH Ref. E-155-2005/3-PCT-01	PCT/US2006/1331	April 11, 2006	(Expired)
NIH Ref. E-155-2005/3-US-02	11/918,557	October 11, 2006	7,691,579

to Georgia Health Sciences University Research Institute, Inc. having a principal place of business in Augusta, Georgia.

The United States of America is an assignee to the patent rights of these inventions.

The contemplated exclusive license may be in a field of use directed to cervical cancer vaccines.

DATE: Only written comments and/or applications for a license that 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 a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq, CLP , Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; E-mail: shmilovm@od.nih.gov. A signed confidential disclosure agreement may be required to receive copies of patent applications assuming it has not already issued or been published under either the publication rules of either the US Patent and Trademark Office or World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

NIH Ref. No. E-155-2005/0-3 (as above)

The invention pertains primarily to CD8+ T cell epitopes from HPV16 E2. These epitopes generated from amino acid positions 69-77 (ALQAIELQL) and 138-147 (YICEEASVTV) bind to HLA.A2 and elicit CD8+ cytotoxic T cell responses that lyse tumor cells of low-grade cervical neoplasia (wart).

NIH Ref. No. E-126-2001/0 (as above)

Immunogenic peptides from the HPV-18E6 (X_1KLPDLCTELX$_{2;}$, wherein X_2 and X_1 are peptides of 0-11 amino acids in length comprising contiguous HPV 18 E6 amino acid sequences) protein that comprise class I restricted T cell epitopes and methods of administering the same. The HPV-18E6 peptide cross-reacts immunologically with both HPV type 16 and HPV type 18 with higher affinity than most common human lymphocyte antigen (HLA), HLA-A2 than the homologous peptide from HPV 16. E6 peptide vaccines are potentially prophylactic or therapeutic for cervical cancer, other genital cancers, head and neck cancers, and upper digestive tract cancers. It could also be potentially used in the treatment of patients presenting with pre-malignant cervical disease, especially in underdeveloped countries with no access to surgical treatment or to completely avoid surgical treatment.

The prospective exclusive license will be royalty-bearing and 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, 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.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: July 9, 2013.

Richard Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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