[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Concatenated L2 Peptide Based Human Papillomavirus Vaccines

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of 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 Patents and Patent Applications listed in the Supplementary Information section of this notice to BravoVax Co., Ltd located in Wuhan, China**.**

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center 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 application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Kevin W. Chang, Ph.D., Senior Technology Transfer 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)-276-6910; Facsimile: (240)-276-5504 E-mail: changke@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 60/649,249 filed February 1, 2005 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Reference No. E-103-2005/0-US-01]; United States Provisional Patent Application No. 60/697,655 filed July 7, 2005 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Reference No. E-103-2005/1-US-01]; United States Provisional Patent Application No. 60/752,268 filed December 21, 2005 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Reference No. E-103-2005/2-US-01]; International PCT Application No. PCT/US2006/003601 filed February 1, 2006, and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Reference No. E-103-2005/3-PCT-01]; United States Patent No. 8,404,244, issued March 26, 2013 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-US-02]; United States Patent No. 9,388,221 issued July 12, 2016 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-US-10]; Canadian Patent No. 2,596,698 issued May 16, 2017 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-CA-03]; Australian Patent No. 2006210792 issued November 8, 2012 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-

neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-AU-04]; Japanese Patent No. 5224821 issued March 22, 2013 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-JP-05]; Brazilian Patent Application No. PI0607097-3 filed February 1, 2006 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-BR-06]; Chinese Patent No. 200680011079.1 issued March 27, 2013 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-CN-07]; Indian Patent No. 263255 issued October 16, 2014 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-IN-08]; European Patent No. 1853307 issued December 14, 2016 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-EP-09]; German Patent No. 1853307 issued December 14, 2016 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-DE-11]; French Patent No. 1853307 issued December 14, 2016 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-FR-12]; and United Kingdom Patent No. 1853307 issued December 14, 2016 and entitled, "Papillomavirus L2 N-terminal Peptides For The Induction Of Broadly Cross-neutralizing Antibodies" [HHS Ref. No. E-103-2005/3-GB-13]. The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: "Development and use of concatenated L2 peptides for the prevention of Human Papillomavirus (HPV) infection and associated diseases. Specifically excluded from the field of use are L2 based virus-like particles (VLPs), L1/L2 chimeric peptides, and L1/L2 chimeric peptide/protein based VLPs."

The subject technologies are papillomavirus L2 capsid protein based vaccines against HPV. The L2 protein is the minor papillomavirus capsid protein for papillomaviruses. It is known that antibodies to this protein can neutralize homologous infection. Furthermore, L2 proteins can induce cross-neutralizing antibodies. Specifically, epitopes at the N-terminus of L2 shared by cutaneous and mucosal types of papillomavirus types and by types that infect divergent species are broadly cross-neutralizing. These epitopes at the N-terminus of L2 can be used to elicit cross-neutralizing antibodies against different types of HPV.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: November 14, 2017

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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