DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Chimeric L1/L2 Protein and Virus-Like Particles Based Human Papillomavirus Vaccines

AGENCY: National Institutes of Health, Department of Health and Human Services.

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 U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to PathoVax, LLC located in Baltimore, MD.

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 June 5, 2017 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 Email: *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 Application No. 2,596,698 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–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: ''Use of Human Papillomavirus Virus (HPV) L1/L2 chimeric proteins and Virus Like Particles (VLPs) for the prevention and/or treatment of cutaneous, mucosal HPV infections and diseases.''

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.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. 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: May 11, 2017.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2017–10153 Filed 5–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Fellowship Review.

Date: July 21, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Room, 5635 Fishers Lane, Bethesda, M.D 20892

Contact Person: Richard A. Rippe, Ph.D., Scientific Review Officer , Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Room 2109, Rockville, MD 20852, 301–443–8599, *rippera@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: May 15, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–10113 Filed 5–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: The Development of Monospecific and Bispecific Antibodies to GPC3 for the Treatment of Human Liver Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to AbPro, located in Woburn, Massachusetts, to practice the inventions embodied in the patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before June 5, 2017 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., 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)–276–6467; Email: *david.lambertson@nih.gov*.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement: U.S. Provisional Patent Application 61/654,232 entitled ''High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof'' [HHS Ref. E–136–2012/0–US–01], PCT Patent Application PCT/US2013/043633 entitled ''High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof'' [HHS Ref. E–136–2012/0–PCT–02], Chinese Patent Application 201380039993.7 entitled ''High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof'' [HHS Ref. E–136–2012/0–CN–03], Japanese Patent Application 2015–515243 entitled ''High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof'' [HHS Ref. E–136–2012/0–JP–04], South Korean Patent Application 10–2014–7037046 entitled ''High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof'' [HHS Ref. E–136–2012/0–KR–05], Singapore Patent Application 11201407972R entitled ''High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof'' [HHS Ref. E–136–2012/0–SG–06], and United States Patent 9,409,994 entitled ''High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof'' [HHS Ref. E–136–2012/0–US–07], and all continuing U.S. and foreign patents/patent applications for the technology family, to AbPro. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective Exclusive Patent License territory may be worldwide for the following field of use:

The use of the YP7, YP8 and YP9.1 anti-GPC3 monoclonal antibodies as monospecific or bispecific antibodies for the treatment of liver cancer. The licensed field of use excludes any non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, Immunotoxins, and antibody-drug conjugates (ADCs).

The present inventions to be licensed concern monoclonal antibodies that are specific for the cell surface domain of GPC3: YP6, YP7, YP8, YP9 and YP9.1. These antibodies can potentially be used for the treatment of GPC3-expressing cancers such as HCC. By binding to and blocking GPC3 function, these antibodies can inhibit the growth of HCC cells, thereby decreasing the ability of tumors to grow and metastasize. Alternatively, the antibodies can be used to induce antibody-dependent anti-tumor activity by selectively killing cells which overexpress GPC3 while leaving healthy, normal cells unscathed. Finally, a secondary antibody capable of recruiting T cells to the tumor can be attached to the antibodies, thereby allowing for the localization of T cells or NK cells only to those cells which express GPC3, similarly leading to the selective killing of the cancer cells.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and 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.