This document is scheduled to be published in the
Federal Register on 03/26/2013 and available online at
http://federalregister.gov/a/2013-06837, and on FDsys.gov

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Papilloma Pseudovirus and Virus-like Particles as a Delivery System for Human Cancer Therapeutics and Diagnostics

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 license to Aura BioSciences to practice the inventions embodied in U.S. Provisional Patent Application No. 60/928,495 entitled, "Papillomavirus Pseudoviruses for Detection and Therapy of Tumors" filed May 8, 2007 [HHS Ref. No. E-186-2007/0-US-01], U.S. Provisional Patent Application No. 61/065,897 entitled "Papillomavirus Pseudoviruses for Detection and Therapy of Tumors" filed February 14, 2008 [HHS Ref. No. E-186-2007/1-US-01], PCT Application No. PCT/US2008/062296 "Papillomavirus Pseudoviruses for Detection and Therapy of Tumors" filed May 1, 2008 [HHS Ref. No. E-186-2007/2-PCT-01], Australian Patent Application No. 2008251615 entitled "Papillomavirus Pseudoviruses for Detection and Therapy of Tumors" filed May 1, 2008 [HHS Ref. No. E-186-2007/2-AU-02], Canadian

Patent Application No. 2,686,990 entitled "Papillomavirus Pseudoviruses for Detection and Therapy of Tumors" filed May 1, 2008 [HHS Ref. No. E-186-2007/2-CA-03], European Patent Application No. 08747407.8 entitled "Papillomavirus Pseudoviruses for Detection and Therapy of Tumors" filed May 1, 2008 [HHS Ref. No. E-186-2007/2-EP-04], U.S. Patent Application No. 12/598,684 entitled, "Papillomavirus Pseudoviruses for Detection and Therapy of Tumors" filed February 8, 2010 [HHS Ref. No. E-186-2007/2-US-05], and US Patent Application No. 13/763,365 entitled, "Papilloma Pseudovirus for Detection and Therapy of Tumors" filed February 8, 2013 [HHS Ref. No. E-186-2007/2-US-06] and all continuing applications and foreign counterparts. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the development and use of the Licensed Patent Rights in combination with Licensee's proprietary nanosphere encapsulation technology for the treatment, diagnosis and imaging of cancer tumors and metastases as well as their respective pre-cursor dysplasia states. Licensee's proprietary nanosphere encapsulation technology is understood to consist of: 1) methods for manipulating the outer proteins of human papillomavirus-derived nanoparticles to create particles targeted to solid tumors and distant metastases; and 2) enhancements for the delivery of particles created by Licensee's proprietary technology.

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, comments, and other materials relating to the contemplated exclusive license should be directed to: Jennifer Wong, M.S., Senior 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) 435-4633; Facsimile: (301) 402-0220; E-mail: wongje@mail.nih.gov.

SUPPLEMENTARY INFORMATION: There is extensive literature on the use of viral vectors, particularly those based on the adenovirus, to increase the potency of anti-tumor gene therapy. However, these approaches have had limited success because of limited anti-tumor effects and unacceptable toxicity. This invention describes the use of human papillomavirus pseudoviruses (PsV) as a cancer diagnostic and therapeutic. Preliminary studies showed that PsVs bind to ovarian tumor cells while normal tissues were not affected. PsVs does not infect several other normal intact tissues but continues to selectively infect additional cancer cells. This technology could be an effective anti-tumor therapy because it has shown increased infection of cancer cells with an inability to infect normal cells thereby reducing potential toxicity to patients. In addition to a potential anti-cancer therapeutic, this technology could also be used as a diagnostic tool in the detection of tumor masses. Detection can be achieved through the use of fluorescent dye coupled particles of PsVs that have preferential binding to tumor tissues and not normal tissues.

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.

March 18, 2013
Date

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

[FR Doc. 2013-06837 Filed 03/25/2013 at 8:45 am; Publication Date: 03/26/2013]