[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Chitosan/IL-12 Conjugate as Immunotherapeutic Products for Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209and 37 CFR Part 404, 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 Scion Cardio-vascular ("Scion") located in Miami, FL, USA.

Intellectual Property:

1. U.S. Provisional Patent Application No. 60/846,481; filed September 22, 2006 entitled "Methods and Compositions for the Treatment of Cancer" [HHS Ref. No. E-311-2006/0-US-01],;
2. International Patent Application No. PCT/US2007/020540 filed September 21, 2007 entitled "Compositions And Methods For Chitosan Enhanced Immune Response [HHS Ref. No. E-311-2006/1-PCT-01];
3. European Patent Application No. 07838692.7 filed September 21, 2007 entitled "Compositions And Methods For Chitosan Enhanced Immune Response [HHS Ref. No. E-311-2006/1-EP-02]; and

4. U.S. Patent Application No. 12/442,483 filed March 23, 2009 entitled "Compositions And Methods For Chitosan Enhanced Immune Response [HHS Ref. No. E-311-2006/1-US-03]

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 Chitosan/IL-12 conjugates as immunotherapeutic products for human cancers. Please note that the Field of Use is limited to the use of Chitosan with IL-12 only and does not include the use of the Chitosan with any other antigen. Additionally, the Field of Use may be limited to certain cancer indications.

DATES: 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.

ADDRESSES: 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:

The technology describes the use of chitosan depots with appropriate antigens and/or cytokines for generating an immune response in a subject. Such depots are made by mixing one or more antigens and/or cytokines with chitosan or a chitosan derivative. Similar compositions are described wherein chitosan or a derivative forms a micro- or nanoparticle, which have resulted in a more immunogenic presentation of antigen compared to antigen in solution. Using a representative antigen, the inventors showed that mice vaccinated with the subject depots had increased humoral and cellular immune responses compared to mice vaccinated with antigen alone. Furthermore, comparative mouse studies showed the antigen-specific immune response generated with chitosan depots of this invention to be equipotent to incomplete Freund's adjuvant (IFA) and superior to aluminum hydroxide, a widely used adjuvant for licensed and routinely administered vaccines. Thus, this technology improves upon commonly used adjuvant technology and is widely applicable.

This technology is the first to show that subcutaneous administrations of chitosan and an appropriate antigen, with no other component, can be used for enhancing immune responses. In additional studies, the inventors showed that chitosan is able to maintain a depot of recombinant cytokine. A single subcutaneous injection of chitosan-cytokine outperforms daily injections of recombinant cytokine in both the expansion of draining lymph nodes and in the antigen presenting ability of lymph node cells. This technology is the first to show that chitosan can maintain a depot of cytokine which results in a significant enhancement of the functional effects of a cytokine. This technology can be used for vaccines and immunotherapies against various infectious agents and cancer.

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.

Dated: November 18, 2013. _____

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

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