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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

PROSPECTIVE GRANT OF EXCLUSIVE LICENSE: Development of oncolytic viral cancer therapies

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 patent license to practice the inventions embodied in the following U.S. Patents to Jennerex Biotherapeutics ("Jennerex") located in San Francisco, CA, USA.

Intellectual Property:

1. U.S. Patent No. 7,045,313 issued May 16, 2006 entitled, "Recombinant Vaccinia Virus Containing a Chimeric Gene Having Foreign DNA Flanked by Vaccinia Regulatory DNA" [HHS Ref. No. E-552-1982/2-US-03];

2. U.S. Patent No. 7,015,024 issued March 21, 2006 entitled, "Compositions Containing Recombinant Poxviruses Having Foreign DNA Expressed under the Control of Poxvirus Regulatory Sequence" [HHS Ref. No. E-552-1982/2-US-04];

3. U.S. Patent No. 7,045,136 issued May 16, 2006 entitled, "Methods of Immunization Using Recombinant Poxviruses Having Foreign DNA Expressed under the Control of Poxvirus Regulatory Sequence" [HHS Ref. No. E-552-1982/2-US-05]; and

4. U.S. Patent No. 6,998,252 issued February 14, 2006 entitled, “Recombinant Poxviruses Having Foreign DNA Expressed under the Control of Poxvirus Regulatory Sequence” [HHS Ref. No. E-552-1982/2-US-06].

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be the U.S. and the field of use may be the “development and use of Licensed Patent Rights in combination with Licensee’s proprietary or in-licensed technologies for the treatment of human cancers”.

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, 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) 301-402-0220; E-mail: wongje@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The instant technology relates to recombinant poxviruses, and in particular the vaccinia virus, as a backbone that carries a foreign DNA. The virus has been modified by inserting a chimeric gene containing foreign DNA adjacent to poxvirus transcriptional regulatory sequence. The recombinant virus is subsequently transfected into a host and the foreign gene is expressed. For example, the foreign DNA can be related to a viral pathogen, tumor-associated antigen, or

therapeutic transgenes. Upon administration of the recombinant virus to a human or animal subject, the foreign gene is expressed *in vivo* to elicit an immune response or express the therapeutic genes. The technology takes advantage of the unique properties of poxviruses as a delivering vehicle and of the ease of preparation of such constructs.

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.

April 10, 2012
Date

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

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