DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Anthrax Toxin Fusion Proteins and Uses Thereof,'' ''Anthrax Toxin Fusion Proteins and Related Methods,'' and ''Targeting Agents to the MHC Class I Processing Pathway with an Anthrax Toxin Fusion Protein''

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the Food and Drug Administration and the Department of Health and Human Services is contemplating the grant of an exclusive license to practice the inventions embodied in ''Anthrax toxin fusion proteins and uses thereof'', by Leppla *et al.*, issued as U.S. patent 5,591,631 on January 7, 1997; ''Anthrax toxin fusion proteins and related methods'' by Leppla *et al.*, issued as U.S. patent 5,677,274 on October 14, 1997; and ''Targeting agents to the MHC class I processing pathway with an anthrax toxin fusion protein'' by Klimpel *et al.* filed internationally as PCT/US97/16452, and claiming priority to U.S. provisional patent application 60/025,270, filed September 17, 1996 to Avant Immunotherapeutics, Inc., which is located in Needham, MA. The patent rights in these inventions have been assigned to the United States of America. This technology is currently licensed to Avant Immunotherapeutics, Inc. on a non-exclusive basis in the area of immune diseases.

The prospective exclusive license territory will be worldwide and the field of use may be limited to vaccines and immunotherapeutics for the prevention or treatment of the following human and animal diseases: Human immunodeficiency, hepatitis B virus and hepatitis C virus.

DATES: Only written comments and/or license applications that are received by the National Institutes of Health on or before November 30, 2004 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Brenda J. Hefti, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 435–4632; Facsimile: (301) 402–0220; and e-mail: *heftib@od.nih.gov.*

SUPPLEMENTARY INFORMATION: In this technology, an anthrax binary toxin system provides antigen access to MHC Class I processing pathway. The *Bacillus antracis* binary toxin consists of two proteins, a protective antigen (PA) combines with lethal factor (LF) to make anthrax toxin. In this system PA binds to the protein receptor on the target cell, is cleaved to produce the PA63 fragment, PA63 binds to LF and the binary anthrax toxin is endocytosed and transported into the cell to be processed by the MHC Class I processing pathway. Advantages of this system include its ability to accommodate large fusion proteins and the fact that anthrax toxin is not widely used for immunization.

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 sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 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: September 27, 2004.

Steven M. Ferguson,

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

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Monoclonal Antibodies Against the IL–2 Receptor Alpha Chain as a Novel Treatment for Multiple Sclerosis

AGENCY: National Institutes of Health, Public Health Services, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a co-exclusive license to practice the inventions embodied in U.S. Provisional Patent Application No. 60/393,021, filed June 28, 2002, ''Method of Treating Autoimmune Diseases with Interferon-Beta and IL–2R Antagonist'' (DHHS ref. no. E–143–2002/0–US–01), International Patent Application No. PCT/US2002/038290, filed November 27, 2002, International Publication No. WO 2004/002500 A1, published January 8, 2004, ''Method of Treating Autoimmune Diseases with Interferon-Beta and IL–2R Antagonist'' (DHHS ref. no. E–143–2002/0–PCT–02), International Application No. PCT/US2003/020428, filed June 27, 2003, International Publication No. WO 2004/002421 A2, published January 8, 2004, ''Method For the Treatment of Multiple Sclerosis'' (DHHS ref. no. E–143–2002/0–PCT–04), and U.S. Patent Application No. 10/607,598, filed June 27, 2003, Publication No. U.S. 2004/0109859 A1, published June 10, 2004, ''Method For the Treatment of Multiple Sclerosis'' (DHHS ref. no. E–143–2002/0–US–03), and all corresponding foreign patent applications to Serono S.A., of Geneva, Switzerland. The patent rights in these inventions have been assigned to the United States of America. This notice is a correction of a notice published in the **Federal Register** in 69 FR 52515–52516, Aug. 26, 2004.

The prospective co-exclusive license territory will be worldwide. The field of use may be limited to the treatment of multiple sclerosis using monoclonal antibodies against the interleukin-2 receptor. Two co-exclusive licenses may be granted.

DATES: Only license applications which are received by the National Institutes of Health on or before October 25, 2004 will be considered.

ADDRESSES: Requests for information, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: Thomas P. Clouse, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301–435–4076; Facsimile: 301–402–0220; E-mail: *clouset@mail.nih.gov.* Copies of the international publications can be obtained from *http://ep.espacenet.com.* Copies of the U.S. publication can be obtained from *http://www.uspto.gov.*

SUPPLEMENTARY INFORMATION: The above-identified patent applications relate to the discovery that administration of an interleukin-2