

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Use of IL13-PE38 for the Treatment of Asthma and Pulmonary Fibrosis

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 (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent Application No. 60/337,179 filed December 4, 2001, entitled "IL-13 Receptor-Targeted Immunotoxins Ameliorates Symptoms of Asthma and of Allergy" [HHS Reference No. E-296-2001/0-US-01], PCT Application No. PCT/US02/00616 filed February 28, 2002, entitled "Alleviating Symptoms of TH2-Like Cytokine Mediated Disorders by Reducing IL-13 Receptor-Expressing Cells in the Respiratory Tract" [HHS Reference No. E-296-2001/0-PCT-02], U.S. Patent Application No. 10/497,804 filed June 4, 2004, entitled "Alleviating Symptoms of TH2-Like Cytokine Mediated Disorders by Reducing IL-13 Receptor-Expressing Cells in the Respiratory Tract" [HHS Reference No. E-296-2001/0-US-03], Australian Patent Application No. 2002258011 filed June 8, 2004, entitled "Alleviating Symptoms of TH2-Like Cytokine Mediated Disorders by Reducing IL-13 Receptor-Expressing Cells in the Respiratory Tract" [HHS Reference No. E-296-2001/0-AU-04], Canadian Patent Application No. 2469082 filed February 28, 2002, entitled "Chimeric Molecule for the Treatment of TH2-Like Cytokine Mediated Disorders" [HHS Reference No. E-296-2001/0-CA-05], and European Patent Application No. 02727815.9 filed June 29, 2004 entitled "Alleviating Symptoms of TH2-Like Cytokine Mediated Disorders by Reducing IL-13 Receptor-Expressing Cells in the Respiratory Tract" [HHS Reference No. E-296-2001/0-EP-06], including background patent rights to U.S. Patent No. 4,892,827, issued on January 9, 1990, entitled "Recombinant Pseudomonas Exotoxins: Construction of an Active Immunotoxin with Low Side Effects" [HHS Reference No. E-385-1986/0-US-01], U.S. Patent No. 5,919,456, issued on July 6, 1999, entitled "IL-13 Receptor Specific

Chimeric Proteins" [HHS Reference No. E-266-1994/0-US-07], U.S. Patent 6,518,061, issued on February 11, 2003, entitled "IL-13 Receptor Specific Chimeric Proteins and Uses Thereof" [HHS Reference No. E-266-1994/0-US-08], to NeoPharm, Inc., which has offices in Waukegan, Illinois. 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 treatment of asthma and pulmonary fibrosis with IL13-PE38.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., 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; E-mail: lambertsond@od.nih.gov.

SUPPLEMENTARY INFORMATION: The technology relates to the treatment of asthma and pulmonary fibrosis. When airway inflammation occurs (e.g., during an asthmatic attack or a response to an allergen), the number of cells that produce the receptor for IL-13 increases in the lungs. When IL-13 interacts with the receptor, an inflammatory response is induced; when this occurs in the lungs, it leads to the symptom of constricted breathing. Blocking the interaction between IL-13 and its receptors on the cells has been shown to reduce the inflammatory response.

A chimeric molecule was developed that comprised both an IL-13 domain (capable of interacting with its cognate receptor) and a toxin domain. This molecule has the capacity to interact with and kill IL-13 receptor expressing cells. The invention relates to a method of treating asthma or pulmonary fibrosis by administering a chimeric molecule comprising a toxin linked to an IL-13 targeting moiety (e.g., IL13-PE38). By administering the toxin in this form, cells involved in airway inflammation can be selectively targeted and killed, thereby alleviating the symptom of constricted breathing.

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 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: February 27, 2006.

Steven M. Ferguson,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Method for Determining Redox Status of a Tissue

James B. Mitchell et al. (NCI). U.S. Provisional Application No. 60/707,518 filed August 11, 2005 (HHS Reference No. E-258-2005/0-US-01). *Licensing Contact:* Chekesha Clingman; 301/435-5018; clingmac@mail.nih.gov.