

into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: [www.nlm.nih.gov/od/bor/bor.html](http://www.nlm.nih.gov/od/bor/bor.html), where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: August 19, 2004.

**LaVerne Y. Stringfield,**  
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-19535 Filed 8-25-04; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: "BL22, an Immunotoxin That Shows Efficacy in Clinical Trials in Treating Patients With Chemotherapy-Resistant Hairy Cell Leukemia, and HA22, a Newly Engineered Immunotoxin, Which Shows Improved Cytotoxic Activity Over BL22"**

**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: E-146-1999/0, entitled Reduction of Nonspecific Animal Toxicity of Immunotoxin by Mutating Framework Regions of Fv To Lower Isoelectric Point, which includes: Pending U.S. Patent Application 10/416,129, based on PCT application PCT/US01/43602; E-216-2000/2, entitled Pegylation of Linkers Improves Antitumor Activity and Reduces Toxicity of Immunoconjugates, which includes: Pending U.S. Patent Application 10/297,337, based on PCT application PCT/US01/18503; E-129-2001/0, entitled Mutated Anti-CD22 Antibodies With Increased Affinity to CD22 Expressing Leukemia Cells, which includes: PCT application PCT/US02/30316; and E-046-2004/0, entitled Mutated Anti-CD22 Antibodies and Immunoconjugates, which includes: U.S. Patent Application number 60/525,371; to Genencor International, Inc.,

which is located in Palo Alto, California. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to the use of the BL22 and HA22 immunoconjugates for the treatment of hematologic malignancies.

**DATES:** Only written comments and/or license applications which are received by the National Institutes of Health on or before October 25, 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](mailto:heftib@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** This technology is a family of two immunoconjugates, each consisting of an anti-CD22 antibody coupled to a killing moiety, specifically pseudomonas exotoxin (PE38). The immunotoxins are both targeted towards CD22, and might be useful as therapeutics for the treatment of leukemias, lymphomas, and autoimmune diseases. The BL22 immunoconjugate has shown success in early clinical trials, and it is believed by the investigators that the HA22 immunoconjugate will be superior to the BL22 because of its increased affinity for CD22.

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 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: August 18, 2004.

**Steven M. Ferguson,**

Director, Division of Technology Development and Transfer, Office of Technology Transfer.  
[FR Doc. 04-19537 Filed 8-25-04; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: Development of Antibody-Based Therapeutics That Specifically Bind the Platelet-Derived Growth Factor Receptor Alpha (CD140A/PDGFR2/PDGFRα)**

**AGENCY:** National Institutes of Health, Public Health Service, 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 (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in any or all of (a) U.S. patents 5,468,468 (11/21/1995); 5,833,986 (11/10/1998); 5,863,739 (01/26/1999); 5,965,359 (10/12/1999); 6,228,600 (05/08/2001) and 6,660,488 (12/09/2003), (b) U.S. patent applications 07/308,282 (02/09/1989, now abandoned), 07/915,884 (7/20/1992, now abandoned), 08/439,095 (05/11/1995, pending), 10/700,249 (11/03/2003, pending) and (c) foreign applications corresponding to PCT Patent Application PCT/US90/00617 entitled "Type Alpha Platelet Derived Growth Factor Receptor Gene", published as WO 90/10013 (9/7/1990) to ImClone Systems Incorporated of New York, New York.

The prospective exclusive license may be limited to the development of compositions and methods of utilizing antibody-based products that specifically bind the alpha platelet-derived growth factor receptor ( $\alpha$ -PDGFR/CD140a/PDGFRα/PDGFR2/PDGFR- $\alpha$ ), for the treatment of cancer.

**DATES:** Only written comments and/or applications for a license which are received by NIH on or before October 25, 2004 will be considered.

**ADDRESSES:** Requests for a copy of these patent applications, inquiries, comment and other materials relating to the contemplated license should be directed to Susan S. Rucker, Esq., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard,

Suite 325, Rockville, Maryland 20852–3804; telephone: 301/435–4478; fax: 301/402–0220. A signed Confidentiality Agreement (CDA) will be required to receive copies of the patent applications.

**SUPPLEMENTARY INFORMATION:** The patents and patent applications describe and claim compositions and methods that incorporate or are derived from the molecule known as alpha platelet derived growth factor receptor ( $\alpha$ -PDGFR).  $\alpha$ -PDGFR is also known as CD140a/PDGFRα/PDGFR2/PDGFR- $\alpha$ . PDGFR- $\alpha$  is a type III receptor tyrosine kinase characterized by an extracellular domain having five IgG-like domains, a transmembrane domain and a catalytic intracellular domain. Research suggests it has autocrine and paracrine signaling capability. PDGFRA expression and signaling have been linked to tumorigenesis and its activity, although not always coupled with over-expression, has been implicated in a number of cancers including lung cancer, ovarian cancer, prostate cancer, glioblastoma and melanoma.

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 404.7. This prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, 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 404.7.

Applications for a license (*i.e.*, a completed “Application for License to Public Health Service Inventions”) in the indicated exclusive field of use filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and/or objections filed in response to the notices of January 27, 1993 [58 FR 6287] and February 15, 1994 [59 FR 7259] are not considered responsive to this notice and will not be treated as objections thereto. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act 5 U.S.C. 552.

Dated: August 18, 2004.

**Steven M. Ferguson,**

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 04–19538 Filed 8–25–04; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Co-Exclusive License: Zenapax (Humanized Antibody 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. US 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 modification of a notice published in the **Federal Register** in 68 FR 70826–70827, Dec. 19, 2003.

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](mailto: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 receptor antagonist to a patient is effective in the treatment of autoimmune disorders. Examples in the patent applications show that a humanized antibody to the interleukin-2 receptor alpha chain (IL-2R $\alpha$ ) (humanized anti-Tac antibody), daclizumab, is effective in treating MS. In particular, it has been discovered that patients who failed to respond to therapy with interferon-beta showed dramatic improvement when treated with daclizumab, with patients showing both a reduction in the total number of lesions and cessation of appearance of new lesions during the treatment period. Pending claims in the above-referenced patent applications are directed to methods of treating a patient with multiple sclerosis (MS) by administering a therapeutically effective amount of an IL-2 receptor antagonist. IL-2 receptor antagonists can be antibodies, peptides, chemical compounds, and small molecules.

The prospective co-exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective co-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 co-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.