

prospective licensee, or for vaccine development against malaria.

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. The prospective exclusive license may be granted unless, within 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.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: January 14, 2002.

**Jack Spiegel,**

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

[FR Doc. 02-1438 Filed 1-18-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: Specific Killing of HIV Infected Lymphocytes by a Recombinant Immunotoxin Directed Against the HIV-1 GP 120 Envelope Glycoprotein**

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

**ACTION:** Notice.

**SUMMARY:** This 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 an exclusive patent license to practice the inventions embodied in U.S. Patent Application, 60/088,860 (refiled): "Specific Killing of HIV Infected Lymphocytes by a Recombinant Immunotoxin Directed Against the HIV-1 GP 120 Envelope Glycoprotein" (DHHS Ref. E-201-98/0); PCT Patent Application, PCT/US99/12909 (refiled): "Specific Killing of HIV Infected Lymphocytes by a Recombinant Immunotoxin Directed Against the HIV-1 GP 120 Envelope Glycoprotein" (DHHS Ref. E-201-98/1); Related Foreign Filed National Stage Applications claiming priority to 60/088,860, (pending) in Europe, Canada,

Japan, Australia and the National Stage United States Application [S/N 09/673,707 (DHHS Ref. E-201-98/2)]: "Specific Killing of HIV Infected Lymphocytes by a Recombinant Immunotoxin Directed Against the HIV-1 GP 120 Envelope Glycoprotein;" US Patent 4,892,827, S/N 06/911,227: "Recombinant Pseudomonas Exotoxin: Construction of an Active Immunotoxin with Low Side Effects,"—excluding any foreign equivalents corresponding to 4,892,827 (DHHS Ref. E-385-86/0); US Patent 5,747,654, S/N 08/077,252: "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity." PHS is an owner of corresponding foreign rights in national phase prosecution in Canada, Australia, Japan, and the European Patent Office. (DHHS Ref. E-163-93/0); US Patent 6,147,203, S/N 09/002,753: "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity," (DHHS Ref. E-163-93/4); US Patent 6,051,435, S/N 07/865,722: "Recombinant Antibody-Toxin Fusion Protein," (DHHS Ref. E-135-89/1) US Patent 5,863,745, S/N 08/461,825: "Recombinant Antibody-Toxin Fusion Protein," (DHHS Ref. E-135-89/2); and US Patent 5,696,237, S/N 08/463,163: "Recombinant Antibody-Toxin Fusion Protein," (DHHS Ref. E-135-89/3) to IVAX Corporation which is located in Miami, Florida. 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 human therapeutics for the treatment of HIV-associated diseases using 3B3(scFv)-PE38 or 3B3(dsFv)-PE38 immunotoxin constructs.

**DATES:** Only written comments and/or license applications which are received by the National Institutes of Health on or before March 25, 2002 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: Richard U. Rodriguez, M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD. 20852-3804; Telephone: (301) 496-7056, x287; Facsimile: (301) 402-0220; and E-mail: [rodrigur@od.nih.gov](mailto:rodrigur@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The primary technology is directed to an immunotoxin that specifically binds to and kills cells expressing an HIV gp-120 coat protein. The immunotoxin comprises an anti-gp-120 antibody

directed to the conserved CD4 binding site of gp 120 attached to a cytotoxin (e.g., a Pseudomonas exotoxin). In one preferred embodiment, the immunotoxin is a recombinantly expressed fusion protein comprising a disulfide linked Fv region attached to a modified Pseudomonas exotoxin [i.e., 3B3 (Fv)-PE38]. The technology is also directed to: a pharmaceutical composition; a composition of the immunotoxin; methods for killing HIV infected cells; and to a kit for killing cells that display a gp-120 protein.

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. 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: January 14, 2002.

**Jack Spiegel,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### **Substance Abuse and Mental Health Services Administration**

#### **Notice of a Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council in February 2002.

The SAMHSA National Advisory Council meeting will be open and will include a presentation by the New SAMHSA Administrator on his Vision and Priorities for the Agency, discussions on the Agency's restructuring and delayering plans, on the National Summit on Terrorism/BioTerrorism Response Activities, on the President's new Mental Health Commission, on FY 2002 appropriation