

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 exclusive 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., completed "Application for License to Public Health Service Inventions"] in the field of use of the RFB4 (dsFv)-PE38 immunotoxin and the relevant Patents and Patent Applications for the therapeutic treatment of Lymphomas and Leukemias which express the CD22 surface antigen filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. 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: May 26, 1999.

Jack Spiegel,

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

[FR Doc. 99-14242 Filed 6-4-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Drug and Method for the Therapeutic Treatment of Leukemia, Lymphoma, Hair Cell Leukemia, Hodgkin's Disease and Other Hematologic Malignancies Plus to Prevent and Treat Graft-versus-Host Disease and Allograft Rejection

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 404.7(a)(1)(I) that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to U.S. Patents and Patent Applications USPN 4,892,827, entitled, "Recombinant *Pseudomonas* Exotoxin: Construction of an Active Immunotoxin with Low Side Effects"—excluding any foreign equivalents corresponding to 4,892,827 (= USSN 06/911,227); USPN 5,747,654, entitled, "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity"; USPA SN: 09/002,753, entitled: "Recombinant Disulfide-Stabilized

Polypeptide Fragments Having Binding Specificity"; USPA SN: 07/865,722, entitled: "Recombinant Antibody-Toxin Fusion Protein"; USPN 5,863,745, entitled: "Recombinant Antibody-Toxin Fusion Protein"; USPN 5,696,237, entitled: "Recombinant Antibody-Toxin Fusion Protein"; and USPA SN: 60/005,388, entitled: "Immunotoxin Containing a Disulfide-Stabilized Antibody Fragment Joined to a *Pseudomonas* Exotoxin that does not Require Proteolytic Activation" and corresponding foreign patent applications to AlbaPharm, Inc. of Ann Arbor, Michigan. The United States of America is an assignee of the patent rights in these inventions and the contemplated exclusive license may be limited to the use of an anti-Tac(dsFv)-PE38 based immunotoxin and/or anti-Tac(Fc)-PE38 immunotoxin and relevant patents and patent applications for the therapeutic treatment of refractory Leukemia, Lymphoma, Hairy Cell Leukemia, Hodgkin's disease and other hematologic malignancies and for the treatment of Graft-versus-Host Disease and Allograft Rejection.

DATES: Only written comments and/or applications for a license which are received by NIH on or before August 6, 1999, will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: J.R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804. Telephone: (301) 496-7735, ext. 206; Facsimile: (301) 402-0220, E-Mail: DixonJ@OD.NIH.GOV. A signed Confidentiality Agreement will be required to receive copies of any of the patent applications.

SUPPLEMENTARY INFORMATION: The technology is directed to an anti-Tac(dsFv)-PE38 and/or anti-Tac(Fv)-PE38 immunotoxin for the therapeutic treatment of refractory Leukemia, Lymphoma, Hairy Cell Leukemia, Hodgkin's disease and other hematologic malignancies. Anti-Tac(dsFv)-PE38 and anti-Tac(scFv)-PE38 are recombinant immunotoxins composed of a disulfide-stabilized (ds) or a single chain Fv form of the anti-Tac (anti-CD25) monoclonal antibody which binds to the α subunit of the IL2 receptor (also called P55, Tac, or CD25), fused to PE38, a mutant form of *Pseudomonas* Exotoxin A which has ADP ribosylating activity and the ability to translocate across a cell membrane.

Anti-Tac-(dsFv)PE38 or anti-Tac(scFv)-PE38 immunotoxins are very cytotoxic to normal or malignant cells expressing this IL2 receptor. The technology is also directed to methods and DNA sequences to produce disulfide-stabilized (ds) or single-chain (sc) recombinant polypeptide fragments to construct the aforementioned immunotoxins. Anti-Tac is a monoclonal antibody fused to PE38, a mutant form of *Pseudomonas* Exotoxin, that binds to the CD25 surface antigen. To kill CD25-positive cells, the anti-Tac antibody was used to make a recombinant immunotoxin. To construct the recombinant PE immunotoxin, the variable portions of the heavy and light chains of anti-Tac could be cloned and the Fv fragments linked together by a disulfide bond to form a disulfide stabilized (ds) construct. The construct was combined by gene fusion with PE38, a truncated version of PE, to form an anti-Tac(dsFv)-PE38 or anti-Tac(scFv)-PE38 immunotoxin.

The technology is also directed to an anti-Tac(dsFv)-PE38 and anti-Tac(scFv)-PE38 immunotoxin for: (1) the prevention of Graft-versus Host Disease ("GVHD") by purging bone marrow of potentially recipient-reactive donor T-cells, (2) the treatment of Graft-versus Host Disease by i.v. administration, and (3) the treatment or prevention of allograft rejection.

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, NIH receives written evidence and argument that establishes that the grant of the exclusive 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., completed Application for License to Public Health Service Inventions] in the field of use of the anti-Tac(dsFv)-PE38 and/or anti-Tac(scFv)-PE38 immunotoxin and the relevant Patent Applications for the therapeutic treatment of refractory Leukemia, Lymphoma, Hairy Cell Leukemia, Hodgkin's disease and other hematologic malignancies and for the treatment of Graft-versus-Host Disease and Allograft Rejection filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. 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: May 26, 1999.

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

**Center for Mental Health Services;
Center for Substance Abuse Treatment; Fiscal Year 1999 Funding Opportunity**

AGENCIES: Department of Health and Human Services, Substance Abuse and

Mental Health Services Administration, Center for Mental Health Services (CMHS), Center for Substance Abuse Treatment (CSAT).

ACTION: Notice of Availability of Funds for Cooperative Agreements for CMHS/CSAT Collaborative Program on Homeless Families: Women with Psychiatric, Substance Use, or Co-occurring Disorders and Their Dependent Children.

SUMMARY: The U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) and Center for Substance Abuse Treatment (CSAT), announce the availability of FY 1999 funds for cooperative agreements

for the following activity. This activity is discussed in more detail under section 4 of this notice. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA) before preparing an application. Note: SAMHSA also published notices of available funding opportunities for FY 1999 in previous issues of the **Federal Register**.

Activity	Application deadline	Estimated funds available	Estimated number of awards	Project period
Homeless Families Program (Study Sites)	08/11/99	\$3.8 Million	16	Up to 2 yrs.
Homeless Families Program (Coordinating Center)	08/11/99	\$1 Million	1	Up to 5 yrs.

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the number and quality of applications received. FY 1999 funds for the activity discussed in this announcement were appropriated by the Congress under Pub. L. 105-277. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The SAMHSA Centers' substance abuse and mental health services activities address issues related to Healthy People 2000 objectives of Mental Health and Mental Disorders; Alcohol and Other Drugs; Clinical Preventive Services; HIV Infection; and Surveillance and Data Systems. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0) or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-512-1800).

General Instructions: Applicants must use application form PHS 5161-1 (Rev. 5/96; OMB No. 0937-0189). The application kit contains the GFA (complete programmatic guidance and

instructions for preparing and submitting applications), the PHS 5161-1 which includes Standard Form 424 (Face Page), and other documentation and forms. Application kits may be obtained from the organization specified for the activity covered by this notice (see Section 4).

When requesting an application kit, the applicant must specify the particular activity for which detailed information is desired. This is to ensure receipt of all necessary forms and information, including any specific program review and award criteria.

The PHS 5161-1 application form and the full text of the activity (i.e., the GFA) described in section 4 are available electronically via SAMHSA's World Wide Web Home Page (address: <http://www.samhsa.gov>).

Application Submission: Applications must be submitted to: SAMHSA Programs, Center for Scientific Review, National Institutes of Health, Suite 1040, 6701 Rockledge Drive MSC-7710, Bethesda, Maryland 20892-7710.* (*Applicants who wish to use express mail or courier service should change the zip code to 20817.)

Application Deadlines: The deadline for receipt of applications is listed in the table above.

Competing applications must be received by the indicated receipt date to be accepted for review. An application received after the deadline may only be accepted if it carries a legible proof-of-mailing date assigned by the carrier and that date is not later than one week prior

to the deadline date. Private metered postmarks are not acceptable as proof of timely mailing.

Applications received after the deadline date and those sent to an address other than the address specified above will be returned to the applicant without review.

For Further Information Contact: Requests for activity-specific technical information should be directed to the program contact person identified for the activity covered by this notice (see section 4).

Requests for information concerning business management issues should be directed to the grants management contact person identified for the activity covered by this notice (see Section 4).

1. Program Background and Objectives

SAMHSA's mission within the Nation's health system is to improve the quality and availability of prevention, early intervention, treatment, and rehabilitation services for substance abuse and mental illnesses, including co-occurring disorders, in order to improve health and reduce illness, death, disability, and cost to society.

Reinventing government, with its emphases on redefining the role of Federal agencies and on improving customer service, has provided SAMHSA with a welcome opportunity to examine carefully its programs and activities. As a result of that process, SAMHSA moved assertively to create a renewed and strategic emphasis on using its resources to generate