

Closed: June 8, 1999, 4:15 p.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.

Place: Building 31, C Wing, 6 Floor, Conference Room 10, National Institutes of Health, 3100 Center Drive, Bethesda, MD 20892.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Executive Plaza North, Suite 600, 6130 Executive Boulevard, Rockville, MD 20892, (301) 496-5147.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 1, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-14374 Filed 6-4-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel.

Date: June 21-22, 1999.

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Madison Hotel, Fifteenth & M Streets NW, Washington, DC 20005.

Contact Person: Alan Willard, PHD, PHD, Scientific Review Administrator, Scientific

Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 1, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-14373 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 Lymphomas and Leukemias

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 USPA SN: 60/041,437, entitled: "Recombinant Antibodies and Immunoconjugates Targeted to CD-22 Bearing Cells and Tumors"; USPN 4,892,827, entitled, "Recombinant *Pseudomonas* Exotoxin: Construction of an Active Immunotoxin with Low Side Effects"—excluding any foreign equivalents corresponding to 4,892,927 (= 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: 06/005,388, 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. having an address in 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 RFB4 (dsFv)—PE38 [also known as BL22] immunotoxin and relevant patents and patent applications for the therapeutic treatment of Lymphomas and Leukemias which express the CD22 surface antigen.

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 this contemplated exclusive license 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 patent applications.

SUPPLEMENTARY INFORMATION: The technology is directed to a RFB4 (dsFv)—PE38 (also known as: BL22) immunotoxin and to methods and DNA sequences to produce disulfide-stabilized (ds) recombinant polypeptide fragments to construct the aforementioned immunotoxin. RFB4 is a disulfide-linked recombinant immunotoxin fused to PE38, a mutant form of *Pseudomonas* Exotoxin, that binds to CD22—a 135kDa phosphoglycoprotein adhesion molecule present on the surface of B-cells. RFB4 is a mouse monoclonal antibody that recognizes an external epitope on the CD22 cell surface antigen and has no detectable cross-reactivity with any other normal cell types. CD22 is a lineage-restricted B-cell antigen that belongs to the Ig superfamily and is displayed on chronic B-Lymphocytic Leukemia cells and B-cell Non-Hodgkins Lymphoma cells. To kill CD22-positive cells, the RFB4 antibody was used to make a recombinant immunotoxin. To construct the recombinant PE immunotoxin, the variable portions of the heavy and light chains of RFB4 were 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 RFB4 (dsFv)—PE38, or BL22.

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 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.