Methods for Assessing the Ability of HIV Patients To Restrict HIV Replication

Mark Connors, Stephen Migueles (NIAID)

U.S. Provisional Application No. 60/412,020 filed 20 Sep 2002 (DHHS Reference No. E–260–2002/0–US–01); PCT Application No. PCT/US03/29549 filed 22 Sep 2003 (DHHS Reference No. E–260–2002/0–PCT–02)

Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov.*

One of the current obstacles for the design and testing of effective vaccines and immunotherapies of HIV is the lack of in vitro correlates that will predict the ability to restrict virus replication. This invention relates to methods for evaluating the effectiveness of HIV therapies and vaccines and methods for assessing the ability of HIV patients to restrict virus replication. Upon restimulation of CD8+ T cells, the expression of perforin in these cells, and the cell cycle stage of these cells may be measured and used as in vitro markers for monitoring the patient's ability to restrict HIV replication and the effectiveness of the therapies and vaccines applied. Significant proliferation of CD8+ T cells, the presence of perforin in these cells, and the ability of these cells to progress beyond the G1 stage signify the patient's ability to restrict HIV replication and a favorable effect of the therapies or vaccines. These methods may be advantageously applied in conjunction with other measurements of HIV specific immune response such as HLA tetramers.

gp64 Pseudotyped Vectors and Uses Thereof

Mukesh Kumar, Joshua Zimmerberg (NICHD,

U.S. Provisional Application No. 60/425,853 filed 12 Nov 2002 (DHHS Reference No. E–191–2001/0–US–01); PCT Application filed 10 Nov 2003 (DHHS Reference No. E–191–2001/0–PCT–02)

Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov.*

This invention relates to a general gene therapy technology which uses an HIV–1 based vector containing a baculovirus gp64 protein. HIV–1 based gene therapy vectors hold great promise due to their ability to deliver genes to non-dividing cells including hematopoietic stem cells. However native HIV only binds to cells with a CD4 receptor, while gene therapy vectors would need to be delivered to a variety of cells. Various different envelope proteins have been tried to replace the native envelope protein of HIV with a new envelope protein whose origin is another enveloped virus (pseudotyping) that has more general binding capabilities. However, to date, no one has been successful for practical purposes, due to either low titers or cytotoxic effects of the expressed proteins. The inventors have developed a family of nontoxic vectors using baculovirus gp64 protein (which binds to a variety of cells) and HIV proteins that efficiently deliver genes of interest to target cells. Furthermore, since gp64 expression in producer cells is not accompanied by cytotoxic side effects, this protein is an ideal candidate for the development of cell lines for constitutive expression of gp64 for the process of construction of the hybrid HIV (packaging cell lines).

Dated: December 11, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–31329 Filed 12–18–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Prospective Investigation of Pulmonary Embolism Diagnosis III.

Date: February 11, 2004.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Arthur N. Freed, PhD, Review Branch, Room 7186, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892. (301) 435–0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS.)

Dated: December 12, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–31318 Filed 12–18–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Aldosterone Antagonists for the Treatment of Heart Failure with Preserved Sytolic Function.

Date: January 28, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Patricia A Haggerty, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7188, MSC 7924, Bethesda, MD 20892. 301/435–0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS.)

Dated: December 12, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–31319 Filed 12–18–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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 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: Center for Inherited Disease Research Access Committee.

Date: January 8, 2004.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, Washington, DC 20015.

Contact Person: Jerry Roberts, PhD, Scientific Review Administrator, Office of Scientific Review, National Institutes of Health, Building 38A, Bethesda, MD 20892, 301 402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: December 12, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–31320 Filed 12–18–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of 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 a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council on Aging.

Date: February 3–4, 2004.

Closed: February 3, 2004, 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Open: February 4, 2004, 8 a.m. to 2 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Closed: February 4, 2004, 2 p.m. to 2:30 p.m.

Agenda: To review and evaluate program documents.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Miriam F. Kelty, PhD, Director, Office of Extramural Affairs, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, MD 20892. 301–496–9322.

In the interest of security, NIH has instituted stringent procedures for entrance 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: *http://www.nih.gov/nia/naca/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS.)

Dated: December 12, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–31317 Filed 12–18–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of 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 an exclusive license to practice the inventions embodied in U.S. provisional patent application 60/393,021 (DHHS ref. no. E–143–2002/0–US–01) filed June 28, 2002, international PCT application PCT/US02/38290 (DHHS ref. no. E–143–2002/0–PCT–02), international PCT application PCT/US03/20428 (DHHS ref. no. E–143–2002/0–PCT–04), and United States Patent Application Serial No. 10/607,598 (DHHS ref. no. E–143–2002/0–US–03), all entitled, ''Zenapax (Humanized Antibody Against the IL–2 Receptor Alpha Chain) As A Novel Treatment for Multiple Sclerosis,'' and all corresponding foreign patent applications to Protein Design Laboratories, of Fremont, California. The patent rights in these inventions have been assigned to the United States of America.

The prospective 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.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before February 17, 2004 will be considered.

ADDRESSES: Requests for copies of the patent(s)/patent application(s), inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Catherine M. Joyce, Intellectual Property Management Specialist, Office of Technology Transfer, National Institutes