Date and Time: The meeting will be held on Tuesday, October 26, 1999, from 8 a.m. to 3:30 p.m.

Location: The meeting will be held at the Hilton-Houston Southwest, Regency Ballroom, 6780 Southwest Freeway, Houston, TX 77074, 713–977–7911, FAX 713–974–5808.

Contact: Sheryl Lunnon-Baylor, Dallas District Office (HFR–SW1580), Food and Drug Administration, 1445 North Loop West, suite 420, Houston, TX 77008, 713–802–9095, ext. 115, FAX 713–802–0906.

Registration: Send registration information (including name, title, organization title, mailing address, telephone number, and fax number) to the contact person by October 15, 1999.

If you need special accommodations due to a disability, please contact Sheryl Lunnon-Baylor (address above) at least 7 days in advance.

Executive Summary: An executive summary of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Room 12A–16, Rockville, MD 20852, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–25969 Filed 10–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J.R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056, ext. 206; fax 301/402–0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION:

Title: ''Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues.''

Inventors: Drs. Ira H. Pastan (NCI), Ulrich Brinkmann (NCI), George Vasmatzis (NCI) and Byungkook Lee (NCI).

DHHS Ref. No. E–028–99/0—Filed with the U.S.P.T.O. September 1, 1998.

Background

The basis of cancer immunotherapy as a viable option of treatment rests on the supposition that tumor-specific antigens are expressed by the tumor cells, and that immune effector mechanisms can be induced selectively to destroy these tumor cells. Although a variety of host immune effector cells have been shown to participate in the killing of tumor cells, tumor-specific CD8+ Cytotoxic T Lymphocytes (''CTL'') are highly specific and effective in mediating tumor cell killing. CTLs that recognize tumor cells have been isolated from melanoma, breast, ovarian, renal, lung, colorectal and prostrate cancer patients. Their existence suggests that there is an immune response to cancer in these patients and that its augmentation might be therapeutically beneficial. Thus, approaches based on induction of tumor-specific CTLs by therapeutic vaccines may provide an attractive alternative for treating cancer patients.

Technology

PAGE–4 is a human X-linked gene that is strongly expressed in prostate and prostate cancer, and is also expressed in other male and female reproductive tissue (*e.g.*, testis, fallopian tube, placenta, uterus, and uterine cancer). PAGE–4 shows similarity with the GAGE protein family, but it diverges significantly from members of the family so that it appears to belong to a separate family. This, and the existence of another gene, PAGE–2, that share more homology with PAGE–4 than with members of the GAGE family indicates that the PAGE–4 protein belongs to a separate protein family.

The specific detection of PAGE–4 might be valuable for the diagnosis of prostate and testicular tumors, as well as uterine tumors. There are sufficient differences between PAGE–4 and other members of the PAGE and MAGE proteins to produce specific antibodies. Analyses with such antibodies are needed to confirm by immunohistology the expression specificity that is seen in database and mRNA analyses, and to evaluate whether anti-PAGE–4 immunotherapy could be a promising therapeutic approach. One possibility of eliminating PAGE–4 expressing cells could be to use it as cancer vaccine. Among the many possible approaches to vaccination, one method is direct vaccination with plasmid DNA. In fact, Dr. Pastan's laboratory has been able to obtain good expression of the PAGE–4 protein with mammalian expression plasmids, and has demonstrated that DNA-immunization with such expression constructs leads to good immune responses. Hence, this method may generate anti-PAGE–4 responses, and allow us to analyze if ''PAGE–4-vaccination'' can eliminate PAGE–4 expressing cells, as a therapeutic approach towards neoplasms of the prostate, testis, and uterus.

Prostate Cancer

Prostate Cancer is a disease affecting approximately 1 million men in the U.S.A., with an annual incidence of around 300,000 and approximately 40,000 deaths per year. Control of primary tumor by surgical resection and/or radiation has proven effective in a number of cases, however, metastatic spread, primarily to the bone, especially at late hormone independent stages of the disease, has been more difficult to control and monitor.

The above mentioned invention is available, including any available foreign intellectual property rights, for licensing on an exclusive or non-exclusive basis.

Dated: September 28, 1999.

Jack Spiegel, Ph.D.,

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

[FR Doc. 99–25950 Filed 10–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage

for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Adenoviral Vector Expressing a SV4OT Antigen Antisense RNA

David S. Schrump, Z. Sheng Guo, Ishrat Wahseed (NCI)
Serial No. 60/124,776 filed 17 Mar 1999
Licensing Contact: Richard U. Rodriguez; 301/496–7056 ext. 287; e-mail: rr154z@nih.gov

Desired nucleic acid sequences with therapeutic potential may be introduced into mammalian cells using appropriate vectors. Antisense technology is well known in the art and describes a mechanism whereby a nucleic acid comprising a nucleotide sequences, which is in a complementary, ''antisense'' orientation with respect to a coding or ''sense'' sequence of an endogenous gene, is introduced into a cell, whereby a duplex forms between the antisense sequence and its complementary sense sequence. The formation of this duplex results in inactivation of the endogenous gene.

The present invention describes a method of treatment of cancer by administering a replication-deficient recombinant adenovirus comprising a nucleic acid that encodes an antisense rebonucleic acid to the SV40 T antigene. In addition, it provides methods for reducing the level of expression of SV40 T antigen, induction of apoptosis, effecting cell growth arrest, reducing the levels of proto-oncogene expression, unregulating pro-apoptotic proteins, maintaining normal levels of functional p53, and maintaining normal levels of functional Rb, p107, and p130. The types of cancers contemplated by this invention include all cancers that express SV40 T antigen.

Aspartic Protease Inhibitors, Compositions, and Associated Therapeutic methods

Ramnarayan S. Randad, John W. Erickson, Michael A. Eissenstat, Lucyna Lubkowska (NCI)
Serial No. 60/114,868 filed 06 Jan 1999
Licensing Contact: John Peter Kim; 301/496–7056 ext. 264; e-mail: jk141n@nih.gov

The human immunodeficiency virus (HIV) is the causative agent of acquired immunodeficiency syndrome (AIDS). Drug-resistance is a critical factor contributing to the gradual loss of clinical benefit to treatments for HIV infection. Accordingly, combination therapies have further evolved to address the mutating resistance of HIV. However, there has been great concern regarding the apparent growing resistance of HIV strains to current therapies.

The subject invention provides compounds which may serve as therapeutic candidates for inhibition of HIV–1 PR (protease) and thus serve in controlling AIDS, as well as having anti-malarial properties. These compounds may be used in combination with other protease inhibitors or inhibitors of HIV–1 reverse transcriptase, especially in patients who have developed resistance to other HIV protease inhibitors. These inhibitors have high potency, lower molecular weight, and lower lipophilicity than previous compounds, as well as a better profile towards drug resistant mutant strains of HIV.

2,5-Diamino-3,4-Disubstituted-1,6-Diphenylhexane Isosteres Comprising Benzamide, Sulfonamide and Anthranilamide Subunits and Methods of Using

Ramnarayan S. Randad and John W. Erickson (NCI)
Serial Nos. 09/039,669 and 09/039,670 filed 16 Mar 1998; Serial No. 08/359,612 filed 20 Dec 1994
Licensing Contact: John Peter Kim; 301/496–7056, ext. 264; e-mail: jk141n@nih.gov

The human immunodeficiency virus (HIV) is the causative agent of acquired immunodeficiency syndrome (AIDS). Drug-resistance is a critical factor contributing to the gradual loss of clinical benefit to treatments for HIV infection. Accordingly, combination therapies have further evolved to address the mutating resistance of HIV. However, there has been great concern regarding the apparent growing resistance of HIV strains to current therapies.

The subject invention provides for treatment and prevention of HIV infection and/or AIDS. The invention provides for 2,5-diamino-3,4-disubstituted-1,6-diphenylhexane (DAD) isosteres comprising benzamide, sulfonamide, and anthranilamide subunits; a pharmaceutical composition comprising such compounds; a method of using such compounds to treat retroviral, specifically HIV and more specifically HIV–1 and HIV–2, infections in mammals, particularly humans; a method of synthesizing asymmetric DAD isosteres comprising benzamide, sulfonamide, and anthranilamide subunits; and a method of using such compounds to assay new compounds; for antiretroviral activity.

Novel Tumor Necrosis Factor Family Member, DRL, and Related Compositions and Methods

MJ Lenardo, J Wang, Di Jiang (NIAID)
Serial No. 60/106,976 filed 04 Nov 1998
Licsening Contact: Susan S. Rucker; 301/496–7056 ext. 245; e-mail: sr156v@nih.gov

The invention described and claimed in this patent application relates the isolation, cloning and characterization of a ligand which belongs to the TNF family of cytokines. This ligand, named DRL (also known as APRIL and TNFSF13), is a type II membrane protein of 250 amino acids. The gene encoding DRL is found on the short arm of chromosome 17 at 17 p11.2–12. Soluble DRL can be obtained by preparing a DRL–IgG fusion protein utilizing the extracellular domain of DRL. DRL has been demonstrated to play a significant role in T cell activation and is able to induce crosslinking of the T cell receptor. It is also capable of inducing T cell proliferation. These results suggest that DRL may be a target to be exploited in the treatment of conditions related to inappropriate T cell activation such as autoimmune diseases, tissue rejection and graft vs. host disease.

Methods and Compositions of Chemokine-Tumor Antigen Fusion Proteins as Cancer Vaccines

Larry W. Kwak, Arya Biragyn (NCI)
U.S. Provisional Patent Application 60/077,745 filed 12 Mar 1998 (corresponding to PCT/US99/05345 filed 12 Mar 1999)
Licensing Contact: Elaine Gese; 301/496–7056 ext. 282; e-mail: 3g46t@nih.gov

The current invention embodies a broad range of fusion proteins, each of which consists of a chemokine and a tumor or viral antigen. Administration of these fusion proteins, or a nucleic acid encoding the fusion protein, elicits a specific and potent *in vivo* immune response directed against the antigen, thereby effectively inhibiting the growth of cells expressing that antigen. The fusion proteins or DNA vaccines therefore represent potential vaccines for use against cancer and also against human immunodeficiency virus (HIV) infection.

Dated: September 27, 1999.

Jack Spiegel,

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

[FR Doc. 99–25952 Filed 10–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, 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.

Name of Committee: Director's Council of Public Representatives.

Date: October 21, 1999.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: Among topics proposed for discussion are: (1) NCI research program relating to health disparities; (2) PubMed Central (repository for electronic dissemination of life sciences research); (3) NIH international research program; (4) privacy of research information; and (5) public involvement in programs of the NEI, NICHD, NIGMS, and NIAAA.

Place: National Institutes of Health, Building 31, C Wing, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Anne Thomas, Director, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892, (301) 496–4461.

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. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program, National Institutes of Health, HHS)

Dated September 29, 1999.

Nancy Middendorf,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–25946 Filed 10–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meeting

Notice is hereby given of a meeting of an *ad hoc* National Gene Vector Laboratories Panel. The meeting will be held October 26, 1999, from 10:30 a.m. until 5 p.m. at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland. The meeting is open to the public, and will be limited to space available. The purpose of the meeting is to discuss the scope of future National Gene Vector Laboratory activities.

For detailed information on the meeting, an agenda, or a list of panel members, contact Dr. Richard Knazek, Clinical Research, National Center for Research Resources, 6705 Rockledge Drive, Suite 6030, MSC 7965, Bethesda, MD 20892–7965, 301–435–0790.

Any person wishing to provide information to the panel may do so in writing. Written comments should be sent to Dr. Knazek at the above address, and must be received by close of business October 19, 1999.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Knazek in advance of the meeting.

Dated: September 23, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–25954 Filed 10–5–99; 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 Meetings

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 meetings.

The meetings 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/or contract proposals 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 and/or contract proposals, 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, WISE Extension Review.

Date: October 25, 1999.

Time: 3 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: David T. George, PhD, NIH, NHLBI, DEA, Review Branch, Rockledge Building II, Room 7188, 6701 Rockledge Drive, Bethesda, MD 20892–7924, 301/435–0288.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, ''Iron Overload and Hereditary Hemochromatosis Study—Coordinating Center''.

Date: October 26–27, 1999.

Time: October 26, 1999, 7 p.m. to 9 p.m.

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Time: October 27, 1999, 8:30 a.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Diane M. Reid, MD, Scientific Review Administrator, NIH, NHLBI, DEA, Two Rockledge Center, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, (301) 435–0277.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Minority Training Grant Applications.

Date: December 9–10, 1999.

Time: December 9, 1999, 7:30 p.m. to 9 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Time: December 10, 1999, 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Terry Bishop, PhD, Scientific Review Administrator, Review Branch, NIH, NHLBI, DEA, Rockledge Center II, 6701 Rockledge Drive, Suite 7210, Bethesda, MD 20892–7924, (301) 435–0303.

(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