

affinity and biological activity toward  $\delta$ -opioid and  $\mu$ -opioid receptors. These compounds therefore, have the potential to treat opiate and alcohol abuse, neurological diseases, neuropeptide or neurotransmitter imbalances, neurological and immune dysfunction, graft rejections through immunosuppression with antagonists, pain control through short half-life agonists, and shock and brain injuries.

#### Scratch Wound Assay Device

Katherine Malinda et al. (NINR), Serial No. 09/496,134 filed 01 Feb 2000; Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov.

Tissue wounds undergo a complex and ordered series of events to repair tissue. These events may include infiltration of inflammatory immune cells as part of the process to remove and destroy necrotic tissue, increased vascularization by angiogenic factors, and increased cell proliferation and extracellular matrix deposition. Although the basic process of tissue repair has been characterized, the individual steps and factors necessary to carry out this complex series of events are not yet well understood or fully identified. Accordingly, there is a need to develop a way of reproducibly injuring a layer of cells to study the effects of different compounds of treatments on the ability of the remaining cells to repair the damaged area.

The present invention provides a device that reproducibly makes a wound of a desired size in a cell layer grown on a cell culture material. The device allows researchers to use small volumes of cells and test materials suggesting its use as a tool in high throughput screening of compounds. This provides researchers with a faster, more accurate way of screening large numbers of factors and determining the effects of cell growth and migration agents in model wounds produced in the cell, organ, or tissue layer.

#### Method of in vitro T cell Differentiation of CD34+ Progenitor Cells

Ruiz et al. (NIAID), DHHS Reference No. E-206-98/0 filed 29 Oct 1999; Licensing Contact: J. P. Kim; 301/496-7056 ext. 264; e-mail: kimj@od.nih.gov.

The present invention relates to a human in vitro system for inducing the growth and de novo differentiation of T cells from CD34+ progenitor cells in the presence of various cytokine cocktails and lymph node stroma. The mature T cells which are generated may be used to treat individuals with primary or

acquired T cell immunodeficiencies, including HIV infection.

Dated: October 13, 2000.

#### Jack Spiegel,

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

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## 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 Institutes 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.

#### A Plasmid for Expression of a Soluble Form of HIV-1 Integrase Protein

Robert Craigie et al. (NIDDK), NIH Reference No. E-108-00/0; Licensing Contact: J.P. Kim; 301/496-7056 ext. 264; e-mail: kimj@od.nih.gov.

Integrase is an essential HIV enzyme and a promising target for antiviral therapy. Integrase protein is required to assay for inhibitors of this enzyme and for mechanistic studies on HIV DNA integration. Further, drugs targeted to integrase would provide a new therapeutic approach to the treatment of AIDS and could be used in combination therapy with drugs that target RT and protease. The subject plasmid can be used to produce large quantities of a

soluble form of HIV-1 integrase protein for such work.

#### TTP as a Regulator of GM-CSF mRNA Deadenylation and Stability

Ester Carballo-Jane, Wi S. Lai, Perry J. Blackshear (NIEHS), NIH Reference No. E-204-99/0 filed 13 Aug 1999; Licensing Contact: Vasant Gandhi; 301/496-7056 ext. 244; e-mail: gandhiv@od.nih.gov.

The disclosed invention provides materials and methods to treat granulocytopenia (low white cell count in the blood) which is characterized by a reduced number of granulocytes (relative) or an absence of granulocytes (absolute). This condition is commonly associated with cancer chemotherapy, but is seen less frequently in a number of conditions including the use of propylthiouracil, radiotherapy for marrow ablation for bone marrow transplantation, aplastic anemia, systemic lupus erythematosus, AIDS and a variety of other situations. The invention proposes a method to increase GM-CSF levels in a treated subject, and this increase is achieved by inhibiting the degradation of GM-CSF messenger RNA (mRNA). Tristetraprolin (TTP) is one member of a family of cys-cys-cys-his (CCCH) zinc finger proteins, and it is a factor that binds to and causes the instability of GM-CSF mRNA. Methods are provided for the development of screening assays for molecules that inhibit the binding of TTP and its related proteins to GM-CSF mRNA, or otherwise inhibit the effect of TTP to promote breakdown of the mRNA, leading in turn to increased mRNA stability and enhanced production of GM-CSF. Compounds identified by such screens, and their derivatives, could be useful in treating granulocytopenia from whatever cause.

#### Novel Post-Transcriptional Regulatory Elements and Uses Thereof

George N. Pavlakis and Filomena Nappi (NCI), NIH Reference Nos. E-143-98/0 filed 22 May 1998 and E-143-98/1 filed 22 May 1999; Licensing Contact: Carol Salata; 301/496-7735 ext. 232; e-mail: salatac@od.nih.gov.

This invention concerns a novel post-transcriptional regulatory element that can function as an RNA nucleocytoplasmic transport element (NCTE) and its use to make recombinant attenuated HIV strains useful as vaccines. HIV regulates its expression by controlling the nuclear transport of unspliced mRNA encoding structural proteins. HIV utilizes the Rev/RRE system. RRE (Rev responsible element) is an HIV encoded NCTE, which is part of every HIV RNA encoding the

structural genes (Gag/Pol and Env). Rev is an HIV encoded protein which binds to RRE. This interaction is essential for nucleo-cytoplasmic transport of the RRE containing viral mRNAs and the expression of Gag/Pol and Env proteins. The inventors have produced an attenuated HIV by disabling Rev/RRE, by point mutations, and inserting in its place the novel murine NCTE of the invention. The resultant HIV is attenuated between 50 and 200 fold compared to wild type HIV. Claimed at the novel NCTE, recombinant retroviruses comprising the NCTE and vaccines.

Dated: October 6, 2000.

**Jack Spiegel,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Consensus Development Conference on Adjuvant Therapy for Breast Cancer**

Notice is hereby given of the National Institutes of Health (NIH) Consensus Development Conference on "Adjuvant Therapy for Breast Cancer," which will be held November 1-3, 2000, in the NIH's Natcher Conference Center, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:00 am on November 1 and 2, and at 9:00 am on November 3 and is open to the public.

Each year, more than 180,000 women in the United States are diagnosed with breast cancer, the most common type of non-skin cancer among women in this country. Through continuing research into new treatment methods, women with breast cancer now have more effective treatment options than ever before. Studies have shown that adjuvant therapy—treatment to kill cancer cells that may have begun to spread, or metastasize, from the breast tumor—given in addition to surgery or other primary therapies increases a woman's chance of long-term survival.

Two types of systemic adjuvant therapy, either alone or in combination, are used for breast cancer. Adjuvant chemotherapy involves a combination of anticancer drugs. Adjuvant hormone therapy deprives cancer cells of the female hormone estrogen, which some breast cancer cells need to grow. In addition to these systemic therapies,

radiation therapy is sometimes used as a local adjuvant treatment to help destroy breast cancer cells that have spread to nearby tissues.

The rapid pace of discovery in this area continues to broaden the knowledge base from which informed treatment decisions can be made. The purpose of this conference is to clarify, for clinicians, patients, and the general public, various issues regarding the use of adjuvant therapy for breast cancer. After 1½ days of presentations and audience discussion of the latest adjuvant therapy research, an independent, non-Federal consensus development panel will weigh the scientific evidence and draft a statement that will be presented to the conference audience on the third day. The consensus development panel's statement will address the following key questions:

*Which factors should be used to select systemic adjuvant therapy?*

*For which patients should adjuvant hormonal therapy be recommended?*

*For which patients should adjuvant chemotherapy be recommended?*

*Which agents should be used and at what dose or schedule?*

*For which patients should postmastectomy radiotherapy be recommended?*

*How do side effects and quality-of-life issues factor into individual decision-making about adjuvant therapy?*

*What are promising new research directions for adjuvant therapy?*

On the final day of the conference, the panel's draft statement will be read in public, at which time members of the public are invited to offer comments on the draft.

The primary sponsors of this meeting are the National Cancer Institute and the NIH Office of Medical Applications of Research. Cosponsors include the National Institute of Nursing Research and the NIH Office of Research on Women's Health.

This is the 114th Consensus Development Conference held by the NIH in the 23-year history of the Consensus Development Program. Advance information about the conference and conference registration materials may be obtained from Prospect Associates of Silver Spring, Maryland, by calling (301) 592-3320 or by sending e-mail to [breastcancer@prospectassoc.com](mailto:breastcancer@prospectassoc.com). Prospect Associates' address is 10720 Columbia Pike, Suite 500, Silver Spring, Maryland 20901-4437. A conference agenda and registration information is also available on the NIH Consensus Program Web site at <http://consensus.nih.gov>.

Dated: October 13, 2000.

**Ruth L. Kirschstein,**

Principal Deputy Director, National Institutes of Health.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; 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 the meeting of the National Cancer Institute Board of Scientific Advisors.

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)(6) and 552b(c)(9)(B), Title 5 U.S.C. The discussions could reveal information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy and the premature disclosure of discussions related to personnel and confidential administrative information would be likely to significantly frustrate the subsequent implementation of recommendations.

*Name of Committee:* National Cancer Institute Board of Scientific Advisors.

*Date:* November 16-17, 2000.

*Open:* November 16, 8:30 am to 5 pm; November 17, 8:30 am to 2 pm.

*Agenda:* Report of the Director, NCI; Ongoing and New Business, Status Reports, Budget Presentation, Reports of Special Initiatives, and RFA/RFP Concept Reviews.

*Closed:* November 16, 5 pm to 6 pm.

*Agenda:* To review and evaluate personnel and programmatic issues.

*Place:* National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6 Floor, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Paulette S. Gray, Ph.D., Executive Secretary, Deputy Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8141, Bethesda, MD 20892, (301) 496-4218. (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