

SNH and taxol are synergistic at inhibiting breast cell cancer growth and can potentiate the cytotoxicity of taxol in an *in vivo* human xenograft breast cancer mouse model.

Combination therapy using these agents may therefore greatly enhance the response rate of different cancers to these drugs and may significantly reduce side effects by permitting a lower therapeutic dose to be administered. Available for licensing are compositions of matter and methods of use of VIP receptor antagonists.

Dated: September 15, 2005.

**Steven M. Ferguson,**

*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, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency 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.

#### HIV-Encoded siRNA, microRNA and Suppressor of RNA Silencing

Yamina Bennasser *et al.* (NIAID)

U.S. Provisional Application No. 60/677,839 filed 05 May 2005 (HHS Reference No. E-203-2005/0-US-01).

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

The present invention relates to virus-encoded siRNA and miRNA species and the use of such RNAs in the diagnosis, prevention and/or treatment of retroviral infection, especially HIV or SIV infection. This invention conveys the first evidence that HIV-1 encodes viral siRNA precursors in its genome and that natural HIV-1 infection provokes nucleic acid-based immunity in human cells. To overcome this cellular defense, the HIV-1 Tat protein has evolved to include a suppressor of RNA silencing (SRS) function. Additionally, this invention identifies five microRNA (miRNA) precursor candidates that regulate cellular gene expression at a post-transcriptional level. The five miRNA precursors (21-25 nucleotides in length) are encoded in highly conserved regions of HIV such as TAR sequence, gag, pol and nef genes. These findings indicate that viruses utilize RNA interference as a mechanism to regulate cellular gene expression.

This technology is further described in: Bennasser *et al.*, "HIV-1 encoded candidate micro-RNAs and their cellular targets," *Retrovirology* 2004 Dec 15, 1(1):43, doi:10.1186/1742-4690-1-43; and Bennasser *et al.*, "Evidence that HIV-1 encodes an siRNA and a suppressor of RNA silencing," *Immunity* 2005 May, 22(5):607-619, doi:10.1016/j.immuni.2005.03.010.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### Miniature Laser-Induced Fluorescence Detector

Paul Smith, Nicole Morgan, Edward Wellner, Terry Phillips (ORS)  
U.S. Provisional Application No. 60/682,847 filed 20 May 2005 (HHS Reference No. E-129-2005/0-US-01).  
*Licensing Contact:* Michael Shmilovich; 301/435-5019; shmilovm@mail.nih.gov.

Available for licensing and commercial development is a miniature laser-induced fluorescence detector having an in-line microfluidic detection cell. The detection cell finds application in High Performance Liquid Chromatography (HPLC), Capillary Electrophoresis (CE) and Mass Spectroscopy (MS) applications, among others. The cell for fluorescence measurements can have a measurement volume of 1 nL or less and a sample can be excited using two excitation wavelengths. The detection cell can include a 5 mm to 5 cm long capillary tube and an excitation fiber proximate to the capillary tube. A detection fiber

is also proximate to the capillary tube, and the detection fiber has a diameter the same size or larger than the external diameter of the capillary tube. A plurality of both excitation and detection fibers can be used.

In addition to licensing, the technology may be available for further development through collaborative research opportunities with the inventors.

#### Cellular Receptor for Varicella-Zoster Virus and Cell-to-Cell Spread of Virus

Jeffery Cohen *et al.* (NIAID)

U.S. Provisional Application No. 60/684,526 filed 26 May 2005 (HHS Reference No. E-289-2004/0-US-01).

*Licensing Contact:* Chekeshia S.

Clingman; 301/435-5018;

clingmac@mail.nih.gov.

This technology relates to identification of insulin degrading enzyme (IDE) as a cellular receptor for Varicella-Zoster-Virus (VZV), the etiologic agent of varicella (chickenpox) and zoster (shingles). Acute infection of VZV is followed by cell-associated viremia and the development of varicella rash. The virus establishes life-long latency in the nervous system and can reactivate to cause zoster. The mechanism of VZV entry into target cells and spread from cell-to-cell is not well understood. The inventors have shown that antibodies to IDE and recombinant IDE partially inhibit infection with the virus in cell culture. Reducing the level of IDE in the cell (with siRNA), or blocking the ability of IDE to bind with a VZV glycoprotein, markedly diminishes cell-to-cell spread of the virus in cell culture and partially inhibits infection of cells with cell-free virus. This invention further describes molecules that may have a role in the treatment or prevention of VZV infections, including antibodies to IDE, peptides that block IDE-VZV interactions, and other molecules that block binding activity of IDE.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### A Novel Amplification Method Permits Pathogens To Be Detected With Microarrays

Michael J. Brownstein, Charles Xiang, and Zhi-Qing Qi (NIMH)

U.S. Provisional Application No. 60/635,239 filed 09 Dec 2004 (DHHS Reference No. E-184-2004/0-US-01).

*Licensing Contact:* Cristina

Thalhammer-Reyero; 301/435-4507; thalhamc@mail.nih.gov.

Available for licensing and commercial development is a high throughput, microarray-based multiplex method of detecting target nucleic acids in a sample. In particular, PCR is coupled with microarrays for the qualitative identification of multiple target nucleic acids, with primers specific for a target sequence, and used to detect genomic nucleic acids of pathogens of interest, or transcripts derived therefrom. Also claimed are oligonucleotide microarrays for use in such methods.

The present method is distinguished from other multiplex PCR assays by the additional steps to ensure specificity and sensitivity, so that a larger number of probes can be detected simultaneously in each single reaction. An important application of this method, for which it was developed, is the detection of multiple "Category A List" agents for the purpose of differential diagnosis in case of bioterrorism attacks. The method comprises: (a) screening the genomes of the desired infectious agents to find sequences specific for each of them and distinct from human sequences; (b) designing 60 base long oligonucleotide targets, to print on microarrays; and (c) including in the microarrays both sense and antisense versions of each, as well multiple targets per virus, to increase reliability.

Other methods, such as PCR amplification followed by separation and characterization of DNA products by gel electrophoresis, are simple and sensitive, but they have a number of inherent shortcomings. Highly sensitive PCR amplification tends to generate nonspecific DNA products, which complicate interpretation of the results. Additionally, in a typical method for detecting pathogens in a sample, PCR reactions for each pathogen must be run separately from one another due to differences in amplification conditions. Furthermore, in cases where multiplex PCR coupled with a microarray is used for the qualitative detection of several pathogens, the generation of nonspecific DNA products can be a significant problem. The current method is a rapid, high-throughput method for qualitative identification of multiple target nucleic acids that is sensitive, highly discriminating and robust.

#### Methods for Treating Viral-Associated Tumors With LFA-1 Inhibiting Statins

Jeffrey Cohen *et al.* (NIAID)

U.S. Provisional Application No. 60/515,013 filed 28 Oct 2003 (HHS Reference No. E-312-2003/0-US-01); PCT Application No. PCT/US2004/035829 (publication WO2005/042710)

filed 28 Oct 2004 (HHS Reference No. E-312-2003/0-PCT-02).

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

This technology describes the use of certain natural and synthetic statins, including simvastatin, other leukocyte function antigen-1 (LFA-1) inhibiting statins, and compounds derived from LFA-1 inhibiting statins and statin-like compounds, for treatment or prevention of Epstein-Barr Virus (EBV) associated tumors, including lymphomas that express LFA-1 and transforming proteins. Such compounds could also be used to treat tumors associated with other viruses that express LFA-1. Cancers associated with EBV that could be treated with the statins by methods described herein include gastric carcinoma (the second leading cause of cancer deaths worldwide), nasopharyngeal carcinoma, Hodgkin's disease, lymphoproliferative disease, T-cell lymphoma, and non-Hodgkin's lymphoma. These compounds could potentially be used as chemotherapeutics with possibly less severe side effects than currently employed chemotherapies.

This technology is further described in: Katano *et al.*, "Simvastatin induces apoptosis of Epstein-Barr virus (EBV)-transformed lymphoblastoid cell lines and delays development of EBV lymphomas," PNAS, 2004 Apr 6, 101(14):4966-4971, doi 10.1073/pnas.0401064101.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### Attenuated Human Parainfluenza Virus (PIV) for Use as Live, Attenuated Vaccines and as Vector Vaccines

U.S. Provisional Application No. 60/643,310 filed 12 Jan 2005 (HHS Reference No. E-295-2004/0-US-01) Sheila M. Nolan *et al.* (NIAID) and

U.S. Provisional Application No. 60/412,053 filed 18 Sep 2002 (HHS Reference No. E-092-2002/0-US-01); U.S. Patent Application No. 10/667,141 filed 18 Sep 2003 (HHS Reference No. E-092-2002/0-US-02; PCT Application No. PCT/US03/29685 filed 18 Sep 2003, which published as WO2004/027037 on 01 Apr 2004 (HHS Reference No. E-092-2002/0-PCT-03), and National Stage filed in Canada, Europe, Japan, Australia, and India

Mario H. Skiadopoulos *et al.* (NIAID) *Licensing Contact:* Susan Ano; 301/435-5515; *anos@mail.nih.gov.*

The identified technologies describe self-replicating infectious recombinant paramyxoviruses with one or more attenuating mutations, such as a separate variant polynucleotide encoding a P protein and a separate monocistronic polynucleotide encoding a V protein, or at least one temperature sensitive mutation and one non-temperature sensitive mutation. Compositions and methods for recovering, making and using the infectious, recombinant paramyxoviruses as described are also included (*e.g.* recombinant human parainfluenza virus type 2 (HPIV2)). In addition, these inventions provide novel tools and methods for introducing defined, predetermined structural and phenotypic changes into an infectious HPIV2 candidate for use in immunogenic compositions, including live attenuated virus vaccines. Furthermore, these inventions describe the recombinant HPIV2 P+V can be used to introduce attenuating mutations to develop live attenuated virus vaccines. The paramyxoviruses of the invention are also useful as vectors for expressing heterologous antigens (*e.g.* RSV, HMPV, measles or mumps viruses) in an immunogenic composition. As members of the paramyxoviruses, HPIVs are important pathogens causing severe lower respiratory tract infections in infants and young children. Despite considerable efforts, there are currently no parainfluenza virus vaccines available.

Advantages of the subject technologies to generate live attenuated viruses or vectored vaccine candidates via multiple mutations are the design of safe and stable viral vaccine candidates. Since two common vaccine development approaches (viral subunit vaccines and inactivated whole virus preparations) elicited either short-lived, inadequate immunity or unfavorable immune responses, the identified technologies provide a promising means to develop vaccines against HPIVs and other human pathogens. In addition, live attenuated viruses are the most promising candidate vaccines because they induce both local and systemic immunity and are efficacious even in the presence of passively transferred serum antibodies, the very situation found in the target population of infants with maternally derived antibodies.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

### Imaging With Positron-Emitting Taxanes as a Guide to Antitumor Therapy

Jerry M. Collins, Raymond W. Klecker, Lawrence Anderson (FDA)  
U.S. Provisional Application No. 60/155,061 filed 21 Sep 1999 (HHS Reference No. E-263-1998/0-US-01); U.S. Patent Application Nos. 10/088,561 filed 19 Mar 2002 (HHS Reference No. E-263-1998/0-US-03) and 10/319,812 filed 16 Dec 2002 (HHS Reference No. E-263-1998/1-US-01) are pending.

**Licensing Contact:** Michael Shmilovich; (301) 435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing and commercial development is a method for using positron-emitting compounds to label taxane type drugs. This invention also describes methods of synthesizing these taxane type compounds. Further, methods to guide treatment of solid tumors, with labeled taxanes, are also disclosed in the present application. Advantages of using this technology include: (1) Avoidance of exposing patients to toxic drugs that have no potential for benefit; (2) ability to rapidly determine whether a given tumor will be likely to respond to a particular drug; and (3) the ability to monitor the impact of various dosages, schedules, and modulators for delivery, in situ, at the actual tumor under treatment conditions.

Additional information may be found in: Ravert *et al.*, "Radiosynthesis of [<sup>11</sup>C]paclitaxel," J Label Compd and Radiopharm, 2002, 45(6):471-477.

Dated: September 15, 2005.

**Steven M. Ferguson,**

*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

#### National Cancer 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 Cancer Institute Special Emphasis Panel, Small Grants Program for Cancer Epidemiology and Cancer Research Small Grant Program.

**Date:** November 8-10, 2005.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Doubletree Hotel & Executive Meeting Center, 1750 Rockville Pike, Regency Meeting Room, Rockville, MD 20852.

**Contact Person:** Mary Jane Slesinski, PhD, Scientific Review Administrator, Special Review and Resources Branch, DEA/NCI/NIH, 6116 Executive Boulevard, Room 8045, Bethesda, MD 20892, 301/594-1566, [slesinsm@mail.nih.gov](mailto:slesinsm@mail.nih.gov)

(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: September 16, 2005.

**Anthony M. Coelho, Jr.,**

*Acting Director, Office of Federal Advisory Committee Policy.*

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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 President's Cancer Panel.

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.

**Name of Committee:** President's Cancer Panel.

**Date:** October 24, 2005.

**Open:** October 24, 2005, 8 a.m. to 5 p.m.

**Agenda:** Strategic Planning-Translating Research Team Science/Clinical Research/Infrastructure Needs.

**Place:** Hotel Washington, 15th and Pennsylvania Ave., NW., Washington, DC 20004.

**Contact Person:** Abby Sandler, PhD, Executive Secretary, National Cancer Institute, National Institutes of Health, Building 6116, Room 212, 6116 Executive Boulevard, Bethesda, MD 20892, 301-451-9399.

Any interested person may file written comments with the committee by forwarding the comments to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person. Information is also available on the Institute's/Center's home page: [deainfo.nci.nih.gov/advisory/pcp/pcp.htm](http://deainfo.nci.nih.gov/advisory/pcp/pcp.htm), where an agenda and any additional information for the meeting will be posted when available.

(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: September 16, 2005.

**Anthony M. Coelho, Jr.,**

*Acting Director, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND SERVICES

### National Institutes of Health

#### National Cancer 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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Cancer Institute Special Emphasis Panel, Clinical Trial Data Collection Using Handheld Technology.

**Date:** October 12, 2005.