

demonstrated that SV40 infectious particles delivering DNA encoding a toxin to tumors can be used as a novel cancer treatment.

This invention discloses a method for delivering a toxin such as *Pseudomonas* extotoxin (PE38) to tumor cells. Administration of the SV40 infectious particle can be by parenteral administration, which includes intraperitoneal, intravenous, intramuscular, subcutaneous, intraorbital, intracapsular, intraspinal, or intrasternal. This disclosure also provides a combined method of use of SV40 infectious particle/PE38 with a chemotherapeutic agent, such as doxorubicin. Interestingly, this combination is very effective at reducing tumor size while eliminating many of the side effects of conventional chemotherapy. This delivery system has a commercial advantage as a new method to increase efficacy and reduce side effects of standard chemotherapies.

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

Transcytosis of Adeno-Associated Viruses

John A. Chiorini and Giovanni Di Pasquale (NIDCR)
PCT Application No. PCT/US2005/03183 filed 08 Sep 2005 (HHS Reference No. E-298-2004/0-PCT-02)

Licensing Contact: Jesse Kindra; 301/435-5559; kindraj@mail.nih.gov.

The invention relates to a method for delivering nucleic acids to a variety of cells including those of the gut, kidney, lung and central nervous system. The underlying cells of such organs are covered by a barrier of endothelial or epithelial cells which can limit the transfer of nucleic acids, or other potentially therapeutic agents, to the underlying target cells. To overcome this limitation, the method employs certain members of the parvovirus family to transcytose the barrier cells. During transcytosis, the virus passes through these barrier cells and can infect cells of the underlying layer. Therefore, this method could facilitate the transfer of nucleic acids to cells that currently available viral vectors are unable to reach.

The method could be applied to the treatment of neurodegenerative diseases such as Parkinson's, Alzheimer's, Huntington's, lysosomal storage diseases, the dominant spinal cerebellar ataxias, and Krabbe's disease without the need for stereotactic injection. The method could potentially also be used

in the treatment of genetic muscle disorders such as muscular dystrophy. Several of the viruses described in the invention are serologically distinct and could be used in patients who have developed an immune response to other vectors. This work is part of an ongoing effort to development AAV vectors for gene transfer. Other key technology related to this invention, such as several vector platforms, production, purification methods, and target cell tropism is available for licensing.

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

Treatment of Hyperproliferative Epithelial Skin Diseases by Topical Application of Hydroxylated Aromatic Protein Cross-Linking Compounds

Caroline Stanwell et al. (NCI)
U.S. Patent No. 5,610,185 issued 11 Mar 1997 (HHS Reference No. E-067-1995/0-US-01)

Licensing Contact: George Pipia; 301/435-5560; [pipia@mail.nih.gov](mailto:pipiag@mail.nih.gov)

In recent years there has been a dramatic increase in the incidence of skin disease. Increase in exposure to UV light has contributed to the increase in premalignant skin lesions such as actinic keratoses. In the U.S. over 700,000 individuals suffer from superficial squamous and basal cell carcinoma. In addition, other skin diseases such as plantar and genital warts are extremely common. Currently, the treatment for these types of skin diseases include surgical resection or freezing the tissue to destroy the desired cells. Topical treatments, for example acidic compounds or cytotoxic agents, are also employed. However, none of the above treatments are without drawbacks. Surgical methods may be painful and the current topical treatments are not selective for hyperproliferative cells, not always curative, and may be toxic. This invention embodies a series of compounds, hydroxylated aromatic protein cross-linking agents, that can be applied topically and are useful for premalignant and malignant superficial neoplasias of the skin and for the treatment of basal and squamous cell carcinomas.

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

Pharmaceutical Compositions and Methods for Preventing Skin Tumor Formation and Causing Regression of Existing Tumors

Stuart R. Yuspa et al. (NCI)
U.S. Patent Application No. 10/445,251 filed 27 May 2003, claiming priority to 29 Mar 1991 (HHS Reference No. E-014-1991/0-US-08)

Licensing Contact: George Pipia; 301/435-5560; [pipia@mail.nih.gov](mailto:pipiag@mail.nih.gov).

Toxic drugs used to treat epithelial cancers often kill both normal and tumorous cells whereas retinoids used to prevent tumor formation appear to have a suppressive rather than a curative effect. The compositions and methods of administration described in this invention are based on indole carbazole, which causes terminal differentiation of tumor cells by exploiting a normal physiologic pathway. They can be used to regress as well as prevent skin tumors.

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

Dated: January 17, 2006.

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

[FR Doc. E6-877 Filed 1-24-06; 8:45 am]

BILLING CODE 4167-01-P

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.

Active MRI Compatible and Visible iMRI Catheter

Ozgur Kocaturk (NHLBI).
U.S. Provisional Application No. 60/716,503 filed 14 Sep 2005 (HHS Reference No. E-298-2005/0-US-01).
Licensing Contact: Chekesha Clingman; 301/435-5018; clingmac@mail.nih.gov.

Interventional magnetic resonance imaging (iMRI) has gained important popularity in many fields such as interventional cardiology and radiology, owing to the development of minimally invasive techniques and visible catheters under MRI for conducting MRI-guided procedures and therapies. This invention relates to a novel MRI compatible and active visible catheter for conducting interventional and intraoperative procedures under the guidance of MRI. The catheter features a non conductive transmission line and the use of ultrasonic transducers that transform RF signals to ultrasonic signals for transmitting RF signal to the MRI scanner. The unique design of this catheter overcomes the concern of patient/sample heating (due to the coupling between RF transmission energy and long conductors within catheter) associated with the design of conventional active MRI catheters.

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

Bioreactor Device and Method and System for Fabricating Tissue

Juan M. Taboas (NIAMS), Rocky S. Tuan (NIAMS), *et al.*
U.S. Patent Application No. 60/701,186 filed 20 Jul 2005 (HHS Reference No. E-042-2005/0-US-01).
Licensing Contact: Michael Shmilovich; 301/435-5019; shmilovm@mail.nih.gov.

Available for licensing and commercial development is a millifluidic bioreactor system for culturing, testing, and fabricating natural or engineered cells and tissues. The system consists of a millifluidic bioreactor device and methods for sample culture. Biologic samples that can be utilized include cells, scaffolds, tissue explants, and organoids. The system is microchip controlled and can be operated in closed-loop, providing

controlled delivery of medium and biofactors in a sterile temperature regulated environment under tabletop or incubator use. Sample perfusion can be applied periodically or continuously, in a bidirectional or unidirectional manner, and medium re-circulated.

An advantage of the millifluidic bioreactor: The device is small in size, and of conventional culture plate format. A second advantage: The millifluidic bioreactor provides the ability to grow larger biologic samples than microfluidic systems, while utilizing smaller medium volumes than conventional bioreactors. The bioreactor culture chamber is adapted to contain sample volumes on a milliliter scale (10 μ L to 1 mL, with a preferred size of 100 μ L), significantly larger than chamber volumes in microfluidic systems (on the order of 1 μ L). Typical microfluidic systems are designed to culture cells and not larger tissue samples. A third advantage: the integrated medium reservoirs and bioreactor chamber design provide for, (1) concentration of biofactors produced by the biologic sample, and (2) the use of smaller amounts of exogenous biofactor supplements in the culture medium. The local medium volume (within the vicinity of the sample) is less than twice the sample volume. The total medium volume utilized is small, preferably 2 ml, significantly smaller than conventional bioreactors (typically using 500-1000 mL). A fourth advantage: the bioreactor device provides for real-time monitoring of sample growth and function in response to stimuli via an optical port and embedded sensors. The optical port provides for microscopy and spectroscopy measurements using transmitted, reflected, or emitted (*e.g.* fluorescent, chemiluminescent) light. The embedded sensors provide for measurement of culture fluid pressure and sample pH, oxygen tension, and temperature. A fifth advantage: The bioreactor is capable of providing external stimulation to the biologic sample, including mechanical forces (*e.g.* fluid shear, hydrostatic pressure, matrix compression, microgravity via clinorotation), electrical fields (*e.g.* AC currents), and biofactors (*e.g.* growth factors, cytokines) while monitoring their effect in real-time via the embedded sensors, optical port, and medium sampling port. A sixth advantage: monitoring of biologic sample response to external stimulation can be performed non-invasively and non-destructively through the embedded sensors, optical port, and medium sampling port. Testing of tissue

mechanical and electrical properties (*e.g.* stiffness, permeability, loss modulus via stress or creep test, electrical impedance) can be performed over time without removing the sample from the bioreactor device. A seventh advantage: the bioreactor sample chamber can be constructed with multiple levels fed via separate perfusion circuits, facilitating the growth and production of multiphasic tissues.

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

Universally Applicable Technology for Inactivation of Enveloped Viruses and Other Pathogenic Microorganisms for Vaccine Development

Yossef Raviv *et al.* (NCI).
U.S. Provisional Application filed 22 Mar 2004 (HHS Reference No. E-303-2003/0-US-01);
PCT Application filed 22 Mar 2005 (HHS Reference No. E-303-2003/0-PCT-02).
Licensing Contact: Susan Ano; 301/435-5515; anos@mail.nih.gov.

The current technology describes the inactivation of viruses, parasites, and tumor cells by the hydrophobic photoactivatable compound, 1,5-iodoanphtylazide (INA). This non-toxic compound will diffuse into the lipid bilayer of biological membranes and upon irradiation with light will bind to proteins and lipids in this domain thereby inactivating fusion of enveloped viruses with their corresponding target cells. Furthermore, the selective binding of INA to protein domains in the lipid bilayer preserves the structural integrity and therefore immunogenicity of proteins on the exterior of the inactivated virus. This technology is universally applicable to other microorganisms that are surrounded by biological membranes like parasites and tumor cells. The broad utility of the subject technology has been demonstrated using influenza virus, HIV, SIV and Ebola virus as representative examples. The inactivation approach for vaccine development presented in this technology provides for a safe, non-infectious formulation for vaccination against the corresponding agent. Vaccination studies demonstrated that mice immunized with INA inactivated influenza virus mounted a heterologous protective immune response against lethal doses of influenza virus. This technology and its application to HIV are further described in the Journal of

Virology 2005, volume 29, pp 12394–12400.

In addition to licensing, the technology is available for further studies in application to vaccine development in animal models through collaborative research opportunities with the inventors. Please contact Dr. Yossef Raviv at yrviv@ncifcrf.gov.

Dated: January 18, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–909 Filed 1–24–06; 8:45 am]

BILLING CODE 4167–01–P

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 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 Human Genome Research Institute Initial Review Group; Genome Research Review Committee.

Date: March 8–10, 2006.

Time: March 8, 2006, 7 p.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Time: March 9, 2006, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Time: March 10, 2006, 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Rudy O. Pozzatti, PhD, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892. 301–402–0838. (Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 17, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–691 Filed 1–24–06; 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 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 for Human Genome Research.

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 for Human Genome Research.

Date: February 13–14, 2006.

Open: February 13, 2006, 8:30 a.m. to 2 p.m.

Agenda: To discuss matters of program relevance.

Place: National Institutes of Health, 5635 Fisher Lane, Terrace Level Conference Room, Rockville, MD 20892.

Closed: February 13, 2006, 2 p.m. to 5 p.m.

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

Place: National Institutes of Health, 5635 Fisher Lane, Terrace Level Conference Room, Rockville, MD 20892.

Closed: February 14, 2006, 8:30 a.m. to 5 p.m.

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

Place: National Institutes of Health, 5635 Fisher Lane, Terrace Level Conference Room, Rockville, MD 20892.

Contact Person: Mark S. Guyer, PhD, Director for Extramural Research, National Human Genome Research Institute, 5635 Fisher Lane, Suite 4076, MSC 9305,

Bethesda, MD 20892, 301–496–7531, guyerm@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement 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: <http://www.genome.gov/11509849>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 17, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–692 Filed 1–24–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 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 Mental Health Special Emphasis Panel; ITV Related Child Disorders.

Date: February 8–9, 2006.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA 22202. 703–386–1111.

Contact Person: Christopher S. Sarampote, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9608, Bethesda, MD 20892–9608. 301–443–1959. csarampo@mail.nih.gov.

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.