

significantly to improving the clinical management of cancer and thus the quality of life for people suffering from the disease. Furthermore, the cancer diagnostic market is estimated to grow to almost \$10 billion dollars in the next 5 years, providing a significant financial opportunity.

Inventors: Yoon S. Cho-Chung (NCI).
U.S. Patent Status: U.S. Patent Application No. 10/592,040 (HHS Reference No. E-081-2004/2-US-02); Foreign Rights are also available.
Licensing Contact: David A. Lambertson, Ph.D.; Phone: (301) 435-4632; Fax: (301) 402-0220; E-mail: lambertson@mail.nih.gov.

A New Series of Thalidomide Analogs That Have Potent Anti-Angiogenic Properties

Description of Technology: This technology describes synthesis of several novel tetrahalogenated thalidomide derivatives that are potentially more anti-angiogenic than thalidomide. More specifically, two series of analogs based on two major common pharmacophores have been synthesized. One series preserves the thalidomide common structure, while the other series contains a different common structure (tetrafluorobenzamides). Several analogs from both series have shown significant anti-angiogenic properties, *in vitro*.

Applications: The novel thalidomide derivatives have therapeutic potential for a broad spectrum of cancer related diseases alone, or in combination with existing therapies. The compounds can also be useful for the treatment of autoimmune diseases.

Advantages: Superior anti-angiogenic and anti-cancer activity when compared with thalidomide; *In vitro* data supports use in multiple cancer types.

Benefits: Cancer is the second leading cause of death in the United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2007. Improving the quality of life and duration of life of cancer patients will depend a lot on chemotherapies with reduced toxicity and this technology can contribute significantly to that social cause. Furthermore, the technology involving novel anti-angiogenic small molecule cancer therapy technology has a potential market of more than \$2 billion.

Inventors: William D. Figg (NCI) *et al.*
U.S. Patent Status: Pending PCT Application PCT/US2007/008849 (HHS Reference No. E-080-2006/0-PCT-02).
Licensing Contact: David A. Lambertson, Ph.D.; Phone: (301) 435-4632; Fax: (301) 402-0220; E-mail: lambertson@mail.nih.gov.

Dated: July 30, 2007.

Steven M. Ferguson,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.
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BILLING CODE 4140-01-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.

Immortalized Cell Line for Retroviral Studies

Description of Technology: This technology describes immortalized human umbilical cord-blood T lymphocytes transformed with the retrovirus human T-cell leukemia-lymphoma virus (HTLV). These cells contain the HTLV genome and synthesize viral RNA but are restricted in their expression of viral structure proteins. This cell line should be useful in the study of retrovirus expression. Please visit the NIH AIDS Research and Reference Reagent Program Web site (<http://www.aidsreagent.org/catalog#404>) for additional information.

Applications: Viral expression studies; Study of viral proteins and nucleic acids involved in T-cell immortalization.

Inventors: Genoveffa Franchini (NCI).
Publications:

1. SZ Salahuddin *et al.* Restricted expression of human T-cell leukemia—lymphoma virus (HTLV) in transformed human umbilical cord blood lymphocytes. *Virology* 1983 Aug;129(1):51-64.

2. NIH AIDS Research and Reference Reagent Program Web site.

Patent Status: HHS Reference No. E-272-2007/0—Research Tool.

Licensing Status: Available for licensing.

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

Device and Method for Protecting Against Coronary Artery Compression During Transcatheter Mitral Valve Annuloplasty

Description of Technology: Catheter-based mitral valve regurgitation treatments that use a coronary sinus trajectory or coronary sinus implant can have unwanted effects because the coronary sinus and its branches have been found to cross the outer diameter of major coronary arteries in a majority of humans. As a result, pressure applied by any prosthetic device in the coronary sinus (such as tension on the annuloplasty device) can compress the underlying coronary artery and induce myocardial ischemia or infarction.

Available for licensing and commercial development are devices and methods that avoid constricting coronary artery branches during coronary sinus-based annuloplasty. These devices and methods protect coronary artery branches from constriction during trans-sinus mitral annuloplasty. The device protects a coronary vessel from compression during mitral annuloplasty in which an annuloplasty element, such as a tensioning device, extends at least partially through the coronary sinus over a coronary artery. The device is a surgically sterile bridge configured for placement within the coronary sinus at a location where the coronary sinus passes over a coronary artery, so that the protection device provides a support for a mitral annuloplasty element, such as a compressive prosthesis, including a tension element when it is placed under tension. The protection device has an arch of sufficient rigidity and dimensions to support the tensioning element over the coronary artery, redistribute tension away from an underlying coronary artery, and inhibit application of pressure to the underlying artery, for example when an annuloplasty tension element is placed under tension during mitral annuloplasty.

In particular, the protective device can be a support interposed in the

coronary sinus between the annuloplasty device and the coronary artery. The device may be substantially tubular so that the tensioning element is contained within the protective device and supported in spaced relationship to the coronary artery. An arch may be configured to extend between a proximal end and a distal end that are substantially collinear with one another so that the ends form stabilizing members such as feet that retain the bridge in position over the coronary artery.

The device may be used in methods of improving the function of a mitral valve in a subject in which an annuloplasty element, for example an element that exerts compressive remodeling forces on the mitral valve (such as a tensioning element), is introduced at least partially around the mitral valve, for example at least partially through the coronary sinus and over a coronary artery. The protective device is placed between the annuloplasty element and the coronary artery, with the annuloplasty element supported by the bridge of the device. Compressive remodeling forces are exerted by the annuloplasty device (for example by applying tension to alter the shape or configuration of the mitral valve annulus to reduce its circumference) while supporting the annuloplasty element on the bridge to inhibit application of pressure to the coronary artery. The function of the mitral valve in the patient is thereby improved without impairing coronary blood flow.

The annuloplasty element can be introduced at least partially around the mitral valve by advancing the annuloplasty element in an endovascular catheter through the vascular system to the heart and introducing the annuloplasty element and the protective device from the catheter into the coronary sinus through a coronary sinus ostium. In those embodiments in which the protective device includes an internal lumen, the annuloplasty element extends through the lumen of the protective device over the coronary artery so that the annuloplasty element is supported by the protective device. The protective device can be integrated directly into the annuloplasty element, such as a resilient or expandable device, or a tensioning element or tensioning material.

In other embodiments, this disclosure provides a method of improving function of a mitral valve in a subject who has mitral regurgitation by performing a mitral valve cerclage annuloplasty. In a particular disclosed

example of the procedure, a guiding catheter is percutaneously inserted through the vasculature of a subject. The guiding catheter is introduced through the coronary sinus into the great cardiac vein, and a steerable microcatheter or other coaxial guiding catheter or steering device introduces a guidewire into a basal blood vessel such as the first septal coronary vein. From there the guidewire traverses under imaging guidance the septal myocardium or annulus fibrosis and reenters the right ventricle or right atrium. The guidewire is then retrieved using a vascular snare and the guiding catheter and guidewire are replaced with a tensioning system. The protective device is then introduced through the guiding catheter over or in tandem with the tensioning system so as to protect an underlying coronary artery when tension is introduced to perform the annuloplasty.

Applications: Cardiac valve repair; Interventional Cardiology; Cardiac Surgery.

Development Status: Early-stage; Pre-clinical data available; Prototype.

Inventors: June-Hong Kim, Robert J. Lederman, Ozgur Kocaturk (NHLBI).

Patent Status: U.S. Provisional Application No. 60/858,716 filed 14 Nov 2006. (HHS Reference No. E-249-2006/0-US-01); U.S. Provisional Application No. 60/932,611 filed 31 May 2007 (HHS Reference No. E-249-2006/1-US-01); The issued and pending patent rights are solely owned by the United States Government.

Licensing Status: Available for licensing on an exclusive or non-exclusive basis.

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The NHLBI Cardiovascular Branch is seeking statements of capability or interest from parties interested in collaborative research to further development, evaluate, or commercialize catheter-based cardiovascular devices. Please contact Peg Koelble, NHLBI Office of Technology Transfer and Development, at 301-594-4095 or koelblep@nhlbi.nih.gov.

A Shuttle Plasmid, Recombinant MVA/HIV1 Clinical Vaccine Constructs and a Mechanism for Enhanced Stability of Foreign Gene Inserts by Codon Alternation and for Insertion of the Foreign Gene Between Two Vaccinia Virus Essential Genes

Description of Technology: Since the onset of the AIDS epidemic more than two decades ago, enormous efforts have been directed to making a vaccine that

will protect against human immunodeficiency virus-1 (HIV); an effective vaccine is thought to require the induction of cellular and humoral responses. Vaccine candidates have included a variety of HIV immunogens delivered as DNA, attenuated poxviruses, adenoviruses, vesicular stomatitis virus, proteins, and various combinations thereof. The inventors' efforts to design an HIV vaccine have focused on modified vaccinia virus Ankara (MVA) as a vector.

The patent application describes (1) The shuttle plasmid, pLW73, used for insertion of a foreign gene between two essential vaccinia virus genes (in this case, I8R, G1L), (2) an MVA/Ugandan Clade D (UGD) construct, and (3) an MVA/HIV 75 AG construct using pLW73 as a vector. Additionally, the invention provides two methods: (1) A method useful for large-scale production of recombinant vaccinia viruses, and (2) a method for stabilizing foreign gene inserts that undergo mutation after repeated passages, again useful in large-scale production of recombinant vaccinia viruses.

Application: Immunization against HIV.

Developmental Status: Vaccine candidates have been synthesized and preclinical studies have been performed. The vaccine candidates of this invention are slated to enter Phase I clinical trials in the next year.

Inventors: Bernard Moss, Patricia Earl, Linda Wyatt (NIAID).

Patent Status: U.S. Patent Application No. 60/840,093 filed 25 Aug 2006 (HHS Reference No. E-248-2006/0-US-01); U.S. Patent Application No. 60/840,755 filed 28 Aug 2006 (HHS Reference No. E-248-2006/1-US-01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter J. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Molecular Probes for Identification or Isolation of Membrane Proteins

Description of Technology: This technology describes a new class of molecular probes designed around an iodonaphthyl succinate antigen that can be used to label and tag proteins using a variety of conventional protein modification chemistries. The technology is offered as a combination of probe + monoclonal antibodies against the probe (three clones). The probe can be used for labeling and tagging cell surface and integral membrane proteins as well as soluble proteins. The monoclonal antibodies were tested and found effective for immunoprecipitation, western blot, and

flow cytometry. Once tagged, the modified proteins can be detected or isolated using an antibody reactive with the probe. Several possible probes and monoclonal antibodies that react with them are described. These probes and their corresponding antibodies have significant advantages over the biotin-avidin system.

Advantages: Reversibility of binding for protein isolation; Lack of high, non-specific binding to cell surfaces; Ability to incorporate isotopic ^{125}I label in the probe for tracking tagged proteins in vivo.

Applications: Protein labeling; Protein isolation.

Development Status: In vitro data available.

Inventors: Yossef Raviv *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 60/906,166 filed 09 Mar 2007 (HHS Reference No. E-162-2006/0-US-01).

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

Cross-protective Influenza Vaccine That Protects Against Lethal H5N1 Challenge

Description of Technology: Concerns about a potential influenza pandemic and its prevention are a regular part of health news, with bird (avian) influenza (prominently including H5N1 strains) being a major concern. Vaccination is one of the most effective ways to minimize suffering and death from influenza. Currently, there is not an effective way to vaccinate against avian influenza without knowing what subtype and strain will circulate. The technology described here relates to use of influenza A matrix 2 (M2) protein of a sequence derived from one subtype to induce immunity protective against infection with other subtypes, an approach made possible by the fact that M2 is highly conserved among different influenza strains. The M2 component can be expressed from a DNA vaccine or recombinant viral vector, can be a protein or peptide, or can involve immunizing with one form and boosting with another, for example a DNA or viral vector followed by or preceded by a polypeptide. The M2 component can be used either alone or in combination with other influenza components, and can be administered with or without adjuvant. Specifically, mouse studies showed that the DNA vaccine priming followed by recombinant adenoviral boosting with constructs expressing M2 from an H1N1 strain protected against a lethal challenge with an H5N1 strain. Such cross-protection would be beneficial in a seasonal or pandemic influenza vaccine product. The current

approach offers several advantages over traditional influenza vaccine approaches, including (a) ease and speed of production without need for eggs, (b) vaccine manufacture not based upon surveillance to determine dominant strain(s), and (c) effectiveness despite antigenic shift for the components HA and NA of circulating viruses.

Application: Influenza vaccine.

Development Status: Animal (mouse) data available.

Inventors: Suzanne L. Epstein *et al.* (CBER/FDA).

Patent Status: U.S. Provisional Application No. 60/786,152 filed 27 Mar 2006 (HHS Reference No. E-076-2006/0-US-01); PCT Application No. PCT/US2007/007679 filed 27 Mar 2007 (HHS Reference No. E-076-2006/1-PCT-01).

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

Collaborative Research Opportunity: The Center for Biologics Evaluation and Research, Office of Cellular, Tissue, and Gene Therapies, Division of Cellular and Gene Therapies, Gene Therapy and Immunogenicity Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize matrix 2 (M2) vaccines protective against influenza A subtypes, including high-pathogenicity avian strains, differing from the strain from which the vaccine was derived. Please contact Dr. Suzanne Epstein at 301-827-0450 or suzanne.epstein@fda.hhs.gov for more information.

Targeting Poly-Gamma-Glutamic Acid To Treat Staphylococcus Epidermidis and Related Infections

Description of Invention: Over the past decade, *Staphylococcus epidermidis* has become the most prevalent pathogen involved in nosocomial infections. Usually an innocuous commensal microorganism on human skin, this member of the coagulase-negative group of staphylococci can cause severe infection after penetration of the epidermal protective barriers of the human body. In the U.S. alone, *S. epidermidis* infections on in-dwelling medical devices, which represent the main type of infection with *S. epidermidis*, cost the public health system approximately \$1 billion per year. Importantly, *S. epidermidis* is frequently resistant to common antibiotics.

Immunogenic compositions and methods for eliciting an immune response against *S. epidermidis* and other related staphylococci are claimed. The immunogenic compositions can

include immunogenic conjugates of poly- γ -glutamic acid (such as γ DLPGA) polypeptides of *S. epidermidis*, or related staphylococci that express a γ PGA polypeptide. The γ PGA conjugates elicit an effective immune response against *S. epidermidis*, or other staphylococci, in subjects to which the conjugates are administered. A method of treating an infection caused by a *Staphylococcus* organism that expresses CAP genes is also disclosed. The method can include selecting a subject who is at risk of or has been diagnosed with the infection by the *Staphylococcus* organism which expresses γ PGA from the CAP genes. Further, the expression of a γ PGA polypeptide by the organism can then be altered.

Application: Prophylactics against *S. epidermidis*.

Developmental Status: Preclinical studies have been performed.

Inventors: Michael Otto, Stanislava Kocianova, Cuong Vuong, Jovanka Voyich, Yufeng Yao, Frank DeLeo (NIAID).

Publication: S Kocianova *et al.* Key role of poly-gamma-DL-glutamic acid in immune evasion and virulence of *Staphylococcus epidermidis*. J Clin Invest. 2005 Mar;115(3):688-694.

Patent Status: PCT Patent Application No. PCT/US2006/026900 filed 10 Jul 2006 (HHS Reference No. E-263-2005/0-PCT-02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Human Bacterial Pathogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of poly- γ -glutamic acid of staphylococci. Please contact Dr. Michael Otto at motto@niaid.nih.gov for more information.

Improved Expression Vectors for Mammalian Use

Description of Technology: This technology relates to improving levels of gene expression using a combination of a constitutive RNA transport element (CTE) with a mutant form of another RNA transport element (RTE). The combination of these elements results in a synergistic effect on stability of mRNA transcripts, which in turn leads to increased expression levels. Using HIV-1 gag as reporter mRNA, one mutated RTE in combination with a CTE was

found to improve expression of unstable mRNA by about 500-fold. Similarly this combination of elements led to synergistically elevated levels of HIV-1 Env expression. The function of CTEs and RTEs is conserved in mammalian cells, so this technology is a simple and useful way of obtaining high levels of expression of otherwise poorly expressed genes and can be used in a number of applications such as but not limited to improvements of gene therapy vectors, expression vectors for mammalian cells.

Applications: Gene therapy; DNA vaccines; Protein expression.

Development Status: In vitro data available.

Inventor: Barbara Felber *et al.* (NCI).

Patent Status: U.S. Utility Application No. 10/557,129, filed 16 Nov 2005, from PCT Application No. PCT/US04/15776 filed 19 May 2004, which published as WO2004/113547 on 29 Dec 2004 (HHS Reference No. E-223-2003/1-US-03).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute Vaccine Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: July 31, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-15208 Filed 8-3-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council will meet on August 23, 2007 from 1 p.m. to 3 p.m. via teleconference.

The meeting will include review, discussion, and evaluation of grant applications. Therefore, the meeting will be closed to the public as

determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, Section 10(d).

Substantive program information, a summary of the meeting and a roster of Council members may be obtained as soon as possible after the meeting, either by accessing the SAMHSA Committee Web site at www.nac.samhsa.gov, or by contacting the CSAT National Advisory Council Executive Secretary, Ms. Cynthia Graham (see contact information below).

Committee Name: SAMHSA Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: August 23, 2007, from 1 p.m. to 3 p.m.; Closed.

Place: SAMHSA Building, 1 Choke Cherry Road, VTC Room, L-1057, Rockville, Maryland 20857.

Contact: Cynthia Graham, M.S., Executive Secretary, SAMHSA CSAT National Advisory Council, 1 Choke Cherry Road, Room 5-1035, Rockville, Maryland 20857, Telephone: (240) 276-1692, Fax: (240) 276-16890, E-mail: cynthia.graham@samhsa.hhs.gov.

Dated: July 31, 2007.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health, Services Administration.

[FR Doc. E7-15217 Filed 8-3-07; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS-2007-0042]

Privacy Act of 1974; U.S. Customs and Border Protection, Automated Targeting System, System of Records

AGENCY: Privacy Office; Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: This document is a new System of Records Notice (SORN) for the Automated Targeting System (ATS) and is subject to the Privacy Act of 1974, as amended. ATS is an enforcement screening tool consisting of six separate components, all of which rely substantially on information in the Treasury Enforcement Communications System (TECS). ATS historically was covered by the SORN for TECS. The Department of Homeland Security, U.S. Customs and Border Protection (CBP) published a separate SORN for ATS in the **Federal Register** on November 2,

2006. This SORN did not describe any new collection of information and was intended solely to provide increased notice and transparency to the public about ATS. Based on comments received in response to the November 2, 2006 notice, CBP issues this revised SORN, which responds to those comments, makes certain amendments with regard to the retention period and access provisions of the prior notice, and provides further notice and transparency to the public about the functionality of ATS.

TECS is an overarching law enforcement information collection, risk assessment, and information sharing environment. It is also a repository for law enforcement and investigative information. TECS is comprised of several modules that collect, maintain, and evaluate screening data, conduct targeting, and make information available to appropriate officers of the U.S. government. ATS is one of those modules. It is a decision support tool that compares traveler, cargo, and conveyance information against intelligence and other enforcement data by incorporating risk-based targeting scenarios and assessments. As such, ATS allows DHS officers charged with enforcing U.S. law and preventing terrorism and other crimes to effectively and efficiently manage information collected when travelers or goods seek to enter, exit, or transit through the United States.

Within ATS there are six separate and distinct components that perform screening of inbound and outbound cargo, conveyances, or travelers. These modules compare information received against CBP's law enforcement databases, the Federal Bureau of Investigation Terrorist Screening Center's Terrorist Screening Database (TSDB), information on outstanding wants or warrants, information from other government agencies regarding high-risk parties, and risk-based rules developed by analysts using law enforcement data, intelligence, and past case experience. The modules also facilitate analysis of the screening results of these comparisons. In the case of cargo and conveyances, this screening results in a risk assessment score. In the case of travelers, however, it does not result in a risk assessment score.

DATES: The new system of records will be effective September 5, 2007.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Laurence E. Castelli (202-572-8790), Chief, Privacy Act Policy and Procedures Branch, U.S. Customs and Border Protection, Office of