

the control of the cell cycle and alterations in CDK expression, function, or regulation and are associated with diseases characterized by cellular proliferation. Increasing CDK activity has been reported in many cancers. Likewise, the loss of inhibitory activity has been observed in a wide variety of primary human tumors and human tumor-derived cell lines, including lung, breast, brain, bone, skin, bladder, kidney, ovary, liver, colon, and pancreas as well as in leukemia. These compounds have also been found to potently inhibit GSK3beta activity which has recently been linked to a variety of cellular processes and several disparate areas of biology. In particular, GSK3beta activity has been strongly implicated in Alzheimer's as well as cardiac failure. Thus, the compounds of this invention offer unique opportunities for a variety of indications.

Applications: CDK/GSK3beta inhibitor therapeutics for the treatment of several indications including various cancers, neurodegenerative diseases, and cardiac conditions.

Development: Pre-clinical stage of development.

Inventors: Daniel W. Zaharevitz *et al.* (NCI).

Publication: DW Zaharevitz *et al.* Discovery and initial characterization of the paullones, a novel class of small-molecule inhibitors of cyclin-dependent kinases. *Cancer Res.* 1999 Jun 15;59(11):2566–2569.

Patent Status: HHS Reference No. E-025-1998/0—

- U.S. Patent No. 6,610,684, issued August 26, 2003;
- Australian Patent Nos. 780528 and 778735, issued March 24, 2005 and December 16, 2004;
- Canada Patent Application No. 2335115, filed June 16, 1999;
- Japanese Patent Application No. 2000-554735, filed June 16, 1999;
- United Kingdom Patent No. 1086105, validated March 01, 2006 ((E-025-1998/0-GB-09);
- French Patent No. 1086105, validated March 01, 2006 (E-025-1998/0-FR-10); and
- German Patent No. 69930120.3, validated March 16, 2006 (E-025-1998/0-DE-11).

Licensing Status: Available for licensing.

Licensing Contact: Whitney A. Hastings; 301-451-7337; hastings@mail.nih.gov.

Dated: May 13, 2009.

Richard U. Rodriguez,
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.

Antibody and Immunotoxin Treatments for Mesothelin-Expressing Cancers

Description of Technology: Mesothelin is a cell surface protein that is highly expressed in aggressive cancers such as malignant mesothelioma, ovarian cancer and pancreatic cancer. As a result, mesothelin is an excellent candidate for tumor targeted immunotherapeutics. However, the antibodies against mesothelin that are available for clinical trials are of murine origin. These antibodies have the potential to elicit immune responses in patients, which may adversely affect the ability to provide patients with repeated doses. Thus, the clinical application of the antibodies may be limited.

In order to address the issue of immunogenicity in patients, NIH inventors have generated anti-mesothelin antibody variable fragments (Fv) of human origin. These antibody

fragments (HN1 and HN2) have the ability to efficiently recognize mesothelin on the surface of numerous cancer cells. As a result, these antibody fragments represent an attractive therapeutic alternative to the murine anti-mesothelin antibodies currently being tested in clinical trials.

Application:

- Use as an antibody therapeutic for mesotheliomas, pancreatic tumors and ovarian tumors.
- Use in an immunotoxin therapeutic for mesotheliomas, pancreatic tumors and ovarian tumors.
- Diagnostic for the detection of mesothelin positive tumors.
- Research agent for the detection of mesothelin.

Advantages:

- Fully human antibody reduces potential immunogenicity, thereby allowing repeated dosing.
- Antibody specificity improves the therapeutic efficacy of the agent.

Development Status: Preclinical stage of development with some pre-clinical data available.

Inventors: Mitchell Ho *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/162,778, filed 24 Mar 2009 (HHS Reference E-091-2009/0-US-01)

Related Technologies/Publications:

- U.S. Patent 6,083,502 entitled "Mesothelium Antigen and Methods and Kits For Targeting It."
- PCT Application PCT/US97/0224 entitled "Mesothelium Antigen and Methods and Kits For Targeting It."
- U.S. Patent 6,809,184 entitled "Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use."
- PCT Application PCT/US98/25270 entitled "Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use."
- U.S. Patent 7,081,518 entitled "Anti-mesothelin antibodies having high binding affinity."
- PCT Application PCT/US00/14829 entitled "Immunoconjugates Having High Binding Affinity Improvement of scFVsr Ab's with Higher Affinity for Mesothelin."

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertson@mail.nih.gov.

Collaborative Research Opportunity:

The National Cancer Institute Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further

develop, evaluate, or commercialize antibody-based treatments of mesothelin-expressing cancers. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Simple Biosensors Based on Electrical Percolation Biological Semiconductors

Description of Technology: The invention offered for licensing is in the field of biosensors with application in diagnostics and in regulation of implantable biomedical devices. More specifically, it is related to biological semiconductors based on the electrical percolation of single-walled carbon nanotubes (SWNTs). The nanotubes are embedded with biological ligands (e.g., antibodies). The electrical resistance of a semiconducting SWNT is found to dramatically increase upon the actuation by a specific antigen. Measurement of the change in resistance correlates with the concentration of the specific antigen and thus provides for quantitative determination and diagnostics of biological samples. The simple printing fabrication of electrical percolation biological semiconductors (EPBSC) can facilitate assembly of numerous types of gates (e.g., antibodies, DNA, etc.) and print many of such gates on the same chip for the creation of biological CPUs for various biomedical applications, including direct biodetection and regulation of implantable biomedical devices.

Applications:

(a) Miniaturized biosensors for various biomedical applications, including: (i) Direct biodetection of microbial pathogens and their toxins ii) diagnostics and prognostics of human diseases (e.g., cancer, cardiovascular, or other biomarkers) (iii) detection and analysis of nucleic acids (e.g., DNA, RNA) (iv) detection and analysis of other analytes (carbohydrates, fatty acids, organic or inorganic compounds).—Point of Care (POC) diagnostics (e.g., Physician's office, home-use)

—Military applications (e.g., remote sensing of biowarfare agents)

(b) Monitor food safety and detection of environmental pollution.

(c) Regulation of implantable biomedical devices such as insulin pumps or artificial hearts.

(d) New generation of personal detectors (e.g., food allergens, cardiovascular event, etc.).

Advantages:

(a) The electrical percolation biological semiconductors (EPBSC) are relatively simple to assemble, and do not require specialized fabrication facilities or experience which may broaden the use of EPBSC in a similar

way that PDMS (Polydimethylsiloxane) technology has broadened the use of lab-on-a-chip.

(b) Many EPBSC can be fabricated into the same chip enabling simultaneous detection of many analytes.

(c) Electronic based EPBS detection enable simple digital signal amplification and analysis.

(d) EPBSC can be relatively stable with respect to retention of biological viability and thus can be stored for a long period of time before use.

(e) EPBSC enable device miniaturization.

(f) EPBSC are relatively simple to use and may not require special equipment or a skilled operator. Thus, these biosensors can be utilized in a Physician Office setting, for military applications and for possibly remote sensing for detections of biowarfare materials.

(g) EPBSC devices will offer speed of detection, ease of use, and it will be inexpensive to make.

Development Status: Proof of concept was demonstrated. For example, using anti-Staphylococcal Enterotoxin B (SEB) IgG antibodies as a gate, and the SEB antigen as an actuator, the inventors could detect as little as 0.1 ng/mL of SEB.

Market: According to market research reports from 2003–2004 the global market for biosensors was projected to grow from approximately \$7.0 billion in 2004 to approximately \$9.5 billion in 2009, an average annual growth of about 7.0%. Ninety-nine percent (99%) of the biosensor's market is dominated by biomedical and life sciences, while only one percent (1.0%) with applications in environmental monitoring.

Because of the unique advantages offered by this technology (i.e., diversity of applications, simplicity of use and low cost), there is a good probability that if technically successful it will become commercially successful and financially rewarding.

Inventors: Avraham Rasooly (NCl) *et al.*

Patent Status: U.S. Provisional Application No. 61/115,546 filed 18 Nov 2008, entitled "Electrical Percolation Biomedical Semiconductors" (HHS Reference No. E-040-2009/0-US-01).

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D., MBA; 301-435-4616; UR7a@nih.gov; Michael Shmilovich, JD; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Cancer Diagnostic Program, and the Food and Drug Administration, the Center for

Devices and Radiological Health, Office of Science and Engineering Laboratories, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Electrical Percolation Biological Semiconductors for biodetection. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

C57BL/6J Embryonic Stem Cell Lines Generated Using Serum-Free Media

Description of Technology: NIH investigators have generated Embryonic Stem (ES) cell clones from C57BL/6J mice in a defined medium. These cell lines enable direct genetic alteration of mice in a pure genetic background.

Using a defined media supplement, knockout serum replacement (KSR) with knockout DMEM (KSR-KDMEM), the investigators established ES cell lines from blastocysts of C57BL/6J mice. One specific cell line, HGTC-8 was found to be karyotypically stable and germline competent, both prior to manipulation and after gene targeting. These cell lines transfected more efficiently, and exhibited increased efficiencies of cell cloning and chimera generation, when maintained in KSR-KDMEM.

Applications:

- Generation of knockout mice without the need to backcross.
- Generation of mice via targeted mutations.

Inventors: Jun Cheng, Lisa Garrett-Beal, and Pamela L. Schwartzberg (NHGRI).

Publication: J Cheng, A Dutra, A Takesono, L Garrett-Beal, PL Schwartzberg. Improved generation of C57BL/6J mouse embryonic stem cells in a defined serum-free media. *Genesis*. 2004 June; 39(2):100–104.

Patent Status: HHS Reference No. E-038-2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301-435-5020; vepas@mail.nih.gov.

Identification of Renal Cell Carcinoma Biomarkers

Description of Technology: This invention describes the identification of potential renal cancer biomarkers which could be utilized in the development of a renal cancer diagnostics. The invention identified cancer protein biomarkers from clinically relevant samples including peripheral blood and

fresh frozen tissues. Vast availability of fresh frozen tissues and peripheral blood specimens that are easily obtained could lead to clinical tests amenable to therapeutic, prognostic and even early screening tests for renal cell carcinoma and other malignancies.

Applications: Renal cell carcinoma diagnostics, therapeutics and prognostics.

Market:

- Cancer is the second leading cause of death in the U.S.A. There is an acute need for cancer biomarkers that can be detected from clinically relevant samples and used for early diagnosis, therapeutic follow-up and prognosis of malignant diseases.

- The incidence of renal cell cancer has been rising steadily. Renal Cell Carcinoma is the most common type of kidney cancer, and the most common type in adults, responsible for approximately 80% of cases.

Inventors: Josip Blonder *et al.* (NCI).

Patent Status: PCT Application No. PCT/US2009/037855 filed 20 Mar 2009 (HHS Reference No. E-317-2008/0-PCT-01)

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301-594-6565; tongb@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Proteomics and Analytical Technologies is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize diagnostic, therapeutic and prognostic cancer biomarkers from clinical specimens. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: May 13, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9-11705 Filed 5-19-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine Announcement of Workshop on the Non-Pharmacological Management of Back Pain

ACTION: Notice.

SUMMARY: The National Center for Complementary and Alternative Medicine (NCCAM) invites the research community to participate in an online Workshop on Non-Pharmacological Management of Back Pain. The purpose of this workshop is to identify and explore a range of important and timely clinical research questions related to non-pharmacological interventions to treat back pain. This information will help inform future research directions for NIH and the biomedical scientific field. This workshop will be split into three sessions that will feature presentations and discussions focusing on the current understanding and complexity of chronic back pain, promising questions associated with testable hypotheses, and the relevant outcome measures.

The Workshop will take place on May 27, 2009. Those interested in CAM research are particularly encouraged to view and participate.

Background: The National Center for Complementary and Alternative Medicine (NCCAM) was established in 1999 with the mission of exploring complementary and alternative healing practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals. NCCAM funds research grants that explore the science of CAM. For more information, see <http://nccam.nih.gov/grants/whatnccamfunds/>.

Participating: The Workshop will be broadcast on the Internet and archived on <http://www.videocast.nih.gov/>. Viewers may submit questions for the presenters and panelists by e-mailing nccambkpnwkshp@mail.nih.gov with questions or comments. For more information about what will be covered at the workshop, see <http://nccam.nih.gov/news/events/>.

FOR FURTHER INFORMATION CONTACT: To request more information, visit the NCCAM Web site at <http://nccam.nih.gov/news/events/>, call 301-594-3391 (Edward Culhane) or e-mail at culhane@mail.nih.gov.

Dated: May 12, 2009.

Richard Nahin,

Senior Advisor for Scientific Coordination and Outreach, National Center for Complementary and Alternative Medicine, National Institutes of Health.

[FR Doc. E9-11679 Filed 5-19-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Wednesday, June 10, 2009, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Megan Mickal, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4151, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512523. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss and make recommendations regarding general issues related to the use of ultrafiltration devices in the treatment of extracellular body fluid overload in patients experiencing heart failure. Specifically, the committee will address the use of these devices in patients experiencing heart failure in the following terms: Identifying the most appropriate heart failure patients for whom these treatments should be indicated, determining where these treatments fit within the spectrum of treatment options, and defining what level of clinical evidence is necessary to