

the long-range physical Master Plan for Rocky Mountain Laboratories in Hamilton, Montana. The decision accounts for potential growth in RML personnel, possible land acquisitions, and consequent construction of new administrative and research space over the 20-year planning period.

The decision was based upon review and careful consideration of the impacts identified in the FEIS and public comments received throughout the NEPA process.

Dated: April 28, 2009.

Daniel G. Wheeland,

Director, Office of Research Facilities Development and Operations, National Institutes of Health.

[FR Doc. E9-10290 Filed 5-4-09; 8:45 am]

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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.

Ratio Based Biomarkers for the Prediction of Cancer Survival

Description of Technology: The AKT pathway plays a key role in the regulation of cellular survival, apoptosis, and protein translation and has been shown to have prognostic significance in a number of cancers. Recently, the inventors have identified several functions of the AKT pathway in

certain cancers, such as extrahepatic cholangiocarcinoma (EHCC).

This technology describes compositions, methods and kits for identifying, characterizing biomolecules expressed in a sample that are associated with the presence, the development, or progression of cancer. Utilizing multiplex tissue immunoblotting, the inventors have demonstrated that PTEN expression, PTEN/p-AKT ratios, and PTEN/p-mTOR ratios can predict the survival of cancer patients. These biomarkers may provide useful diagnostic information for cancer patients as well as identify patients appropriate for mTOR analog-based chemotherapy or agents directed against AKT.

Applications

- Diagnostic and Prognostic tool to detect the presence of cancer and predict the relative cancer survival rate for a subject with cancer.
- Method of identifying patients appropriate for therapies targeted to the AKT pathway.
- A kit for detecting cancer associated proteins in a sample.

Development Status: Pre-clinical stage of development.

Market: Extrahepatic cholangiocarcinoma (EHCC) is a malignant neoplasm of biliary tract epithelia, and constitutes approximately 80-90% of all cholangiocarcinomas. Surgical resection is the mainstay of treatment, but results in only an approximately 20% 5-year survival rate. Neoadjuvant therapies, including chemotherapy, radiation therapy, and photodynamic therapy have also failed to show significant survival benefit, thus emphasizing the need for prognostic and predictive biomarkers.

Inventors: Stephen M. Hewitt and Joon-Yong Chung (NCI).

Publications

1. JY Chung *et al.* The expression of phospho-AKT, phospho-mTOR, and PTEN in extrahepatic cholangiocarcinoma. *Clin Cancer Res.* 2009 Jan 15;15(2):660-667.

2. JY Chung *et al.* Transfer and multiplex immunoblotting of a paraffin embedded tissue. *Proteomics* 2006 Feb;6(3):767-774.

3. JY Chung *et al.* A multiplex tissue immunoblotting assay for proteomic profiling: a pilot study of the normal to tumor transition of esophageal squamous cell carcinoma. *Cancer Epidemiol Biomarkers Prev.* 2006 Jul;15(7):1403-1408.

Patent Status: U.S. Provisional Application No. 61/114,501 filed

January 14, 2009 (HHS Reference No. E-025-2009/0-US-01).

Licensing Status: Available for licensing.

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

Modulating Expression of the Metastasis Suppressor MxA

Description of Technology: The invention discloses compounds that could be used to inhibit metastases. The compounds of the current invention were discovered by high-throughput screening of a novel cell line engineered with a MxA reporter. The compounds could be used to treat metastatic cancers including prostate and melanomas by increasing MxA expression.

MxA expression reduces cell motility and metastases in a mouse model. Cells expressing MxA produced smaller tumors in engrafted mice compared to controls. When injected into mouse spleens, cells expressing MxA showed a significantly delayed metastasis, and the mice survived significantly longer than controls. Expression of MxA reduced cellular motility of prostate cancer cell lines in vitro and reduced cellular motility and invasiveness of the highly metastatic melanoma cell line LOX. In addition to the use of the instant MxA compounds as antimetastatic agents, MxA is a known effective anti-viral agent and the MxA-inducing compounds could be used to treat infections sensitive to the antiviral activity of MxA, which potentially include myxovirus-associated disease.

Applications

- Treatment or prevention of cancers using MxA-targeted small molecule therapeutics.
- MxA diagnostic to identify metastatic potential in tumor biopsies.
- Treatment or prevention of a myxovirus-associated infection, including seasonal and avian flu, using MxA-inducing small molecule therapeutics.

Development Status: Identifying lead compounds for clinical development using structure-activity relationship (SAR) analysis.

Inventors: Jane B. Trepel *et al.* (NCI).

Publications

1. JF Mushinski, P Nguyen, LM Stevens, C Khanna, S Lee, EJ Chung, MJ Lee, YS Kim, WM Linehan, MA Horisberger, JB Trepel. Inhibition of tumor cell motility by the interferon-inducible GTPase MxA. *J Biol Chem.* 2009 Mar 18; online publication ahead of print.

2. G Athauda, A Giubellino, JA Coleman, C Horak, PS Steeg, MJ Lee, J Trepel, J Wimberly, J Sun, A Coxon, TL Burgess, DP Bottaro. c-Met ectodomain shedding rate correlates with malignant potential. *Clin Cancer Res.* 2006 Jul 15;12(14 Pt 1):4154–4162.

Patent Status: U.S. Patent Application No. 11/663,936 filed March 27, 2007 (HHS Reference No. E-257-2004/0-US-06) and foreign counterparts.

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute, Medical Oncology 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, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Targeted Recombinant Adenoviral Vectors

Description of Technology: The current invention embodies recombinant adenoviral vectors for use in targeted gene transfer. The method by which these vectors are generated involves no molecular modifications to the adenovirus genome, and allows for the production of vectors targeted specifically to virtually any cell line of choice. Specifically, the vectors are generated by directly linking biotin to the capsid of adenovirus particles. The particles are then treated with streptavidin and subsequently incubated with a biotinylated targeting moiety which is capable of recognizing a specific marker which is expressed on the surface of selected cells. The resulting adenoviral vectors are useful for gene transfer, and can be targeted to virtually any cell type of interest via incubation with a specific targeting moiety.

To date, the inventors have demonstrated that these vectors can be specifically directed to target and infect hematopoietic cell lines which display the c-kit receptor, and are capable of achieving high levels of gene expression in these cell lines. Also, these vectors can be specifically directed to cell surface markers such as CD34, CD44 and others through antibodies directly attached to the biotinylated adenoviral vectors. Such gene transfer represents a gene therapy approach upon which the development of specific therapies against a broad range of diseases may be based, including immunodeficiency

diseases, blood cell disorders, and various cancers.

Applications

- Adenovirus with gene plus Biotinylation kit with streptavidin with ligand or antibody for gene of interest
- Biotin linking kits with methods for use

Development Status: Delivery of the biotinylated recombinant adenoviral vector in vitro for use in targeted gene transfer.

Inventors: Jonathan Keller *et al.* (NCI).

Publications

1. JS Smith, JR Keller, NC Lohrey, CS McCauslin, M Ortiz, K Cowan, SE Spence. Redirected infection of directly biotinylated recombinant adenovirus vectors through cell surface receptors and antigens. *Proc Natl Acad Sci U S A.* 1999 Aug 3;96(16):8855–8860.

2. S Ponnazhagan, G Mahendra, S Kumar, JA Thompson, M Castillas Jr. Conjugate-based targeting of recombinant adeno-associated virus type 2 vectors by using avidin-linked ligands. *J Virol.* 2002 Dec;76(24):12900–12907.

3. M Brandon Parrott, KE Adams, GT Mercier, H Mok, SK Campos, MA Barry. Metabolically biotinylated adenovirus for cell targeting, ligand screening, and vector purification. *Mol Ther.* 2003 Oct;8(4):688–700.

Patent Status

- U.S. Patent 6,555,367 issued April 29, 2003 (HHS Reference No. E-193-1997/0-US-03).
- U.S. Patent Application Publication No. US2003/0175973, published September 18, 2003 (HHS Reference No. E-193-1997/0-US-04).

Licensing Status: Available for licensing.

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

Dated: April 27, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9-10300 Filed 5-4-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control, Initial Review Group, (NCIPC, IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned review group:

Times and Date: 12:30 p.m.–1 p.m., May 20, 2009 (Open). 1 p.m.–3 p.m., May 20, 2009 (Closed).

Place: Teleconference, Toll Free: 888-793-2154.

Participant Passcode: 4424802.

Status: Portions of the meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92-463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of individual research cooperative agreement applications submitted in response to Fiscal Year 2009 Requests for Applications related to the following individual research announcement: RFA-EH-09-002 "Program to Expand State Public Health Laboratory Capacity for Newborn Bloodspot Screening (U01)".

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Jane Suen, Dr.P.H., M.S., NCIPC, CDC, 4770 Buford Highway, NE., Mailstop F-62, Atlanta, Georgia 30341, *Telephone:* (770) 488-4281.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 24, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9-10292 Filed 5-4-09; 8:45 am]

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