

other expressed forms are specific to particular cancer(s).

**Advantages and Applications:** Simple, rapid, RT-PCR based diagnostic test to detect BORIS isoforms in cancer patients; Profiling of BORIS splice variants can be useful as a diagnostic tool for the detection of cancers; BORIS can be a therapeutic target antigen for immunotherapeutic and/or siRNA based treatments for cancer; BORIS can be used in combination with other established immunogens for immunotherapeutic treatment of several cancers.

**Market:** Approximately 600,000 deaths from cancer related diseases are estimated in 2007. The technology, involving a differential expression of BORIS isoforms in cancer, can be useful for the diagnostics and treatment of several cancers having a potential market of more than 7 billion U.S. dollars.

**Development Status:** The technology is currently in the pre-clinical stage of development.

**Inventors:** Victor V. Lobanenko et al. (NIAID).

**Patent Status:** U.S. Provisional Application No. 60/841,342 filed 31 Aug 2006 (HHS Reference No. E-117-2006/0-US-01).

**Licensing Status:** Available for exclusive and non-exclusive licensing.

**Licensing Contact:** Mojdeh Bahar, J.D.; 301/435-2950; baharm@mail.nih.gov.

**Collaborative Research Opportunity:** The NIAID Laboratory of Immunopathology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods of cancer diagnostics and treatment based on detection of *BORIS* isoforms. Please contact Cecilia Pazman at pazmance@niaid.nih.gov or (301) 451-3526 for more information.

Dated: May 23, 2007.

**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.

#### A MicroRNA Profile for Androgen Responsive Prostate Cancer

**Description of Technology:** This invention describes a microRNA gene expression profile in prostate cancers that correlates with androgen responsiveness. Most prostate cancers are androgen sensitive and can be treated with anti-androgen therapies. Tumors non-responsive to anti-androgen therapy are more aggressive and needs alternative therapeutic interventions. Additionally, the microRNAs discovered can also be potential targets for developing new prostate cancer drugs.

**Applications:** MicroRNA expression profile can help physicians take informed treatment action on an individual basis.

**Advantages:** *In vitro* proof-of-concept data available.

**Inventors:** Dr. Chang Hee Kim *et al.* (NCI).

**Related Publications:** A manuscript directly related to this technology will be available as soon as it is accepted for publication.

**Patent Status:** U.S. Provisional Application No. 60/906,742 filed 12 Mar 2007 (HHS Reference No. E-142-2007/0-US-01).

**Licensing Status:** Available for exclusive and non-exclusive licensing.

**Licensing Contact:** Thomas P. Clouse, J.D.; 301/435-4076; clousetp@mail.nih.gov.

**Collaborative Research Opportunity:** The NCI/SAIC-Frederick, Advanced Technology Program, Laboratory for Molecular Technology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or

commercialize microRNA diagnostic markers in cancer. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

#### A Gene Expression Signature Identifying Pro-Angiogenic Genes in Ovarian Tumor Endothelial Cell Isolates

**Description of Technology:** Cancer is a heterogeneous disease that requires multimodality therapy. Most of the therapeutic approaches for ovarian cancer have focused on chemotherapy, which primarily targets proliferating tumor cells. Women with ovarian cancer are typically asymptomatic and they are often diagnosed at an advanced stage and have poor survival. Despite an 80% positive patient response rate to surgery and chemotherapy, most patients will experience tumor recurrence within two years. A majority of women who die of ovarian cancer will have ovarian epithelial carcinomas.

The inventors have discovered a unique proangiogenic biomarkers isolated from ovarian endothelial cells. By targeting tumor angiogenesis by inhibiting endothelial cells that support tumor growth, this technology provides methods to diagnose an ovarian cancer in its early stages.

**Applications:** Method to diagnose and treat ovarian cancer in its early stage; Novel early stage ovarian cancer biomarkers; Therapeutic targets and compositions that inhibit ovarian tumors such as siRNA.

**Market:** Ovarian cancer is the seventh most common cancer and the fifth leading cause of cancer death in the U.S.; An estimated 15,310 deaths in the U.S. in 2006.

**Development Status:** The technology is currently in the pre-clinical stage of development.

**Inventors:** Michael J. Birrer (NCI) *et al.*

**Publication:** C Lu *et al.* Gene alterations identified by expression profiling in tumor-associated endothelial cells from invasive ovarian carcinoma. Cancer Res. 2007 Feb 15;67(4):1757-1768.

**Patent Status:** U.S. Provisional Application No. 60/901,455 filed 14 Feb 2007 (HHS Reference No. E-095-2007/0-US-01).

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

**Licensing Contact:** Jennifer Wong; 301/435-4633; wongje@mail.nih.gov.

**Collaborative Research Opportunity:** The National Cancer Institute, Cell and Cancer Biology Branch, Molecular Mechanisms Section, 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](mailto:hewesj@mail.nih.gov) for more information.

### Conjugates of Ligand, Linker, and Cytotoxic Agent and Related Compositions and Methods of Use

*Description of Technology:* Systemic toxicity of drugs is one of the most serious problems in cancer chemotherapy and frequently is dose limiting. Specific delivery of cytotoxic drugs to cancer cells remains among the most intractable problems of cancer therapy. Targeted delivery of anti-proliferation drugs through the cell surface receptors that are over expressed on cancer cells can reduce systemic toxicity and increase effectiveness of a treatment.

The present invention describes cytotoxic compounds with an intracellular target that can selectively enter tumor cells through specific receptors on the cell surface. The invention also describes a conjugate comprising a cytotoxic agent, a linker arm and a ligand capable of delivering a cytotoxic agent in a cell specific manner. Such conjugates of a cytotoxic agent and a ligand (delivery moiety) have increased selectivity for tumor cells. The toxic moiety and the ligand are joined by a linker arm that is stable in circulation, but is easily cleaved in lysosomes upon internalization of the conjugate. A panel of compounds comprised of a variety of cytotoxic warheads, against various intracellular targets linked to an assortment of ligands, has been developed and tested in a model system. Ligand moieties of these conjugates are capable of specific delivery of cytotoxic agents to receptors that are frequently over expressed in gastric, colon, lung, breast, ovarian and pancreatic tumors. These compounds have the potential to be highly effective anti-tumor agents with considerably little negative effect. This disclosed technology could provide new and exciting methodologies to treat cancer.

*Inventors:* Nadya I. Tarasova *et al.* (NCI)

*Patent Status:* U.S. Patent Application No. 10/505,239 filed 19 Aug 2004, claiming priority to 27 Feb 2002 (HHS Reference No. E-057-2002/2-US-02).

*Licensing Contact:* Adaku Nwachukwu, J.D.; 301/435-5560; [madua@mail.nih.gov](mailto:madua@mail.nih.gov).

### DLC-1 Gene Deleted in Cancers

*Description of Technology:* Chromosomal regions that are frequently deleted in cancer cells are thought to be the loci of tumor

suppressor genes, which restrict cell proliferation. Recurrent deletions on the short arm of human chromosome 8 in liver, breast, lung and prostate cancers have raised the possibility of the presence of tumor suppressor genes in this location.

The inventors have discovered the deletion of human DLC-1 gene in hepatocellular cancer (HCC) cells. They have performed in vitro experiments demonstrating the deletion in over 40% of human primary HCC and in 90% of HCC cell lines. The DLC-1 gene is located on human chromosome 8p21.3-22, a region frequently deleted in many types of human cancer. DLC-1 mRNA is expressed in all normal tissues tested, but it has either no or low expression in a high percentage of several types of human cancer, such as liver, breast, lung, and prostate cancers. Through in vitro and in vivo tumor suppression experiments, the inventors further demonstrated that DLC-1 acts as a new tumor suppressor gene for different types of human cancer.

*Applications:* Method to diagnose HCC; Method to treat HCC patients with DLC-1 compositions; Transgenic model to study HCC and other types of human cancer; DLC-1 compositions.

*Market:* Primary liver cancer accounts for about 2% of cancers in the U.S., but up to half of all cancers in some undeveloped countries; 251,000 new cases are reported annually; post-operative five year survival rate of HCC patients is 30-40%.

*Development Status:* The technology is currently in the pre-clinical stage of development.

*Inventors:* Bao-Zhu Yuan, Snorri S. Thorgeirsson, Nicholas Popescu (NCI).

*Publications:* 1. BZ Yuan *et al.* DLC-1 operates as a tumor suppressor gene in human non-small cell lung carcinomas. *Oncogene*. 2004 Feb 19;23(7):1405-1411.

2. BZ Yuan *et al.* DLC-1 gene inhibits human breast cancer cell growth and in vitro tumorigenicity. *Oncogene*. 2003 Jan 23;22(3):445-450.

3. BZ Yuan *et al.* Promoter hypermethylation of DLC-1, a candidate tumor suppressor gene, in several common human cancers. *Cancer Genet Cytogenet*. 2003 Jan 15;140(2):113-117.

4. BZ Yuan *et al.* Cloning, characterization, and chromosomal localization of a gene frequently deleted in human liver cancer (DLC-1) homologous to rat RhoGAP. *Cancer Res*. 1998 May 15;58(10):2196-2199.

*Patent Status:* U.S. Patent No. 6,897,018 issued 24 May 2005 (HHS Reference No. E-042-1998/0-US-03).

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

*Licensing Contact:* Jennifer Wong; 301/435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov)

*Collaborative Research Opportunity:* The National Cancer Institute, Laboratory of Experimental Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize diagnostics based on tumor suppressor genes. Please contact John D. Hewes, Ph.D., at 301/435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: May 23, 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

#### 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 a meeting of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

*Date:* July 10, 2007.

*Time:* 9 a.m. to 3:30 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference room 10, Bethesda, MD 20892.

*Contact Person:* Brian E. Wojcik, PhD, Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, 6116 Executive Boulevard, Room 2114, Bethesda, MD 20892, (301) 496-7628, [wojcikb@mail.nih.gov](mailto:wojcikb@mail.nih.gov).