

claiming priority to 04 Oct 2002 (HHS Reference No. E-247-2002/1-US-02).

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

*Licensing Contact:* Peter Soukas; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

Dated: February 27, 2008.

**Bonny Harbinger,**

*Deputy Director, 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.

#### Novel Adjuvant Therapy Using TIMP-2 Variants

*Description of Technology:* Angiogenesis inhibitors are drugs that are being used in cancer therapy to block the development of new blood vessels which could potentially cut off a tumor's supply of oxygen and nutrients. This in turn might stop the tumor from growing and spreading to other parts of the body.

Human protein tissue inhibitor of metalloproteinases-2 (TIMP-2) has been shown to inhibit angiogenesis *in vivo* independent of metalloproteinase inhibition. The inventors have demonstrated that TIMP-2, as well as TIMP-2 variants lacking

metalloproteinase inhibitor activity can revert aggressive tumor cell phenotype to a more differentiated state. In addition, TIMP-2 and the TIMP-2 variants also sensitize tumor cells to the induction of apoptosis by cytotoxic drugs (doxorubicin), thereby enhancing their effectiveness. Novel methods of cancer therapy are disclosed using TIMP-2 or TIMP-2 variants that combine the known anti-angiogenic activity of TIMP-2, with direct tumor-differentiating and chemo-sensitizing activity of TIMP-2.

*Applications:*

TIMP-2 or TIMP-2 variants can be administered for the inhibition of tumor cell growth and promotion of tumor cell differentiation.

TIMP-2 or TIMP-2 variants can be administered to enhance the cytotoxic activity of a chemotherapeutic agent.

Adjuvant therapy has application in the treatment of wide variety of carcinomas or melanomas.

*Advantages:*

A novel cancer therapy that combines the known anti-angiogenic activity of TIMP-2, with a novel direct tumor-differentiating and chemo-sensitizing activity of TIMP-2.

Enhances cytotoxicity of conventional chemotherapeutic agents when combined with TIMP-2 or TIMP-2 variants.

*Development Status:* *In vivo* and *in vitro* experiments have been conducted. The technology continues to be developed.

*Market:*

600,000 deaths from cancer related diseases estimated in 2007.

The technology platform involving novel anti-angiogenic cancer therapy technology has a potential market of more than 2 billion U.S. dollars.

*Inventors:* William G. Stetler-Stevenson et al. (NCI).

*Publication:* DW Seo, H Li, L Guedez, PT Wingfield, T Diaz, R Salloum, BY Wei, WG Stetler-Stevenson. TIMP-2 mediated inhibition of angiogenesis: an MMP-independent mechanism. *Cell*. 2003 Jul 25;114(2):171-180. [*PubMed abs*]

*Patent Status:* U.S. Provisional Application No. 60/953,352 filed 01 Aug 2007 (HHS Reference No. E-297-2007/0-US-01).

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

*Licensing Contact:* Surekha Vathyam; 301-435-4076; [vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov).

*Collaborative Research Opportunity:* The NCI Laboratory of Extracellular Matrix Pathology, Cell and Cancer Biology Branch, is seeking statements of capability or interest from parties interested in collaborative research to

further develop, evaluate, or commercialize novel cancer therapy methods using TIMP-2 variants. Please contact John D. Hewes, Ph.D., at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### Mucin Genes as a Diagnosis Marker for Pulmonary Fibrosis

*Description of Technology:* Familial pulmonary fibrosis (FPF) is a rare type of interstitial lung disease for which there is currently no cure. FPF is part of a group of interstitial lung diseases called idiopathic interstitial pneumonias (IIP) that lead to hypoxic respiratory insufficiency. The current invention has identified genes that are associated with FPF, and a possible means of early detection and treatment. The invention discloses an association between FPF and mutations in the genes encoding the MUC2 and MUC5AC mucins that predispose a subject to IIP. The occurrence of single nucleotide polymorphisms (SNPs) in these mutant genes further enable a significant diagnostic association between these polymorphisms and both familial and sporadic forms of pulmonary fibrosis. This invention may also have diagnostic value for other IIPs including idiopathic pulmonary fibrosis (IPF); a disease that presents late in life and is lethal within 4-5 years of diagnosis.

This technology presents opportunities for early detection of subjects at high risk for the development of pulmonary fibrosis, and possibly other similar diseases such as asthma, chronic obstructive pulmonary disease (COPD) and obliterative bronchitis, which also involve fibrosis of the airways. It is also conceivable that mucin, and synthetic molecules that mimic it, may be used as therapeutic agents for the prevention and treatment of pulmonary fibrosis.

*Applications:* Diagnosis of diseases involving pulmonary fibrosis.

*Inventors:* David A. Schwartz (NIEHS), Luranell H. Burch (NIEHS), et al.

*Publication:* MP Steele, MC Speer, JE Loyd, KK Brown, A Herron, SH Slifer, LH Burch, MM Wahidi, JA Phillips III, TA Sporn, HP McAdams, MI Schwarz, DA Schwartz. Clinical and Pathologic Features of Familial Interstitial Pneumonia. *Am J Respir Crit Care Med*. 2005 Nov 1;172(9): 1146-1152.

*Patent Status:* U.S. Provisional Application No. 60/992,079 filed 03 Dec 2007 (HHS Reference No. E-016-2007/0-US-01).

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

*Licensing Contact:* Jasbir (Jesse) S. Kindra, J.D., M.S.; 301-435-5170; [kindraj@mail.nih.gov](mailto:kindraj@mail.nih.gov).

### **P53 and VEGF Regulate Tumor Growth of NO<sub>2</sub> Expressing Cancer Cells**

*Description of Technology:* The increased expression of nitric oxide synthase 2 (NOS2), an inducible enzyme that produces nitric oxide (NO), has been found in a variety of human cancers. It also has been shown that NOS2-specific inhibitors can reduce the growth of experimental tumors in mice. These findings suggest a pathophysiological role for NO in the development and progression of cancer. However, the function of NO and NOS2 in carcinogenesis is uncertain. NO had been found to either inhibit or stimulate tumor growth, and high concentrations of NO also are known to induce cell death in many cell types including tumor cells. On the other hand, low NO concentrations found in human tissue can have an opposite effect and protect against programmed cell death, or apoptosis, from various stimuli. The role of NO and NOS2 in tumor progression, particularly with respect to p53, therefore need to be further defined.

This invention comprises methods of screening for modulators of NOS2 expression in p53 mutant cells, both *in vivo* and *in vitro*, as well as methods for predicting the chemotherapeutic benefit of administering NOS2-inhibitors to cancer patients. It has been demonstrated that NOS2-expressing cancer cells with wild-type p53 have reduced tumor growth in athymic nude mice whereas NOS2-expressing cancer cells with mutated p53 have accelerated tumor growth. Therefore, this invention has potential application for a number of cancers that overexpress NOS2 and have a high frequency of p53 mutations, including breast, brain, head, neck, lung and colon cancers.

#### *Applications:*

Method to treat cancer with NOS2 inhibitors.

Method to screen for NOS2 modulators.

Method to predict therapeutic benefits of NOS2 inhibitors in patients.

#### *Market:*

An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.

600,000 deaths caused by cancer in the U.S. in 2006.

Cancer is the second leading cause of death in United States.

It is estimated that market for cancer drugs would double to \$50 billion a year in 2010 from \$25 billion in 2006.

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

*Inventors:* Stefan Ambs and Curt Harris (NCI).

#### *Publications:*

1. JE Goodman *et al.* Nitric oxide and p53 in cancer-prone chronic inflammation and oxyradical overload diseases. *Environ Mol Mutagen.* 2004;44(1):3-9.

2. LJ Hofseth *et al.* Nitric oxide in cancer and chemoprevention. *Free Radic Biol Med.* 2003Apr 15;34(8):955-968.

#### *Patent Status:*

U.S. Patent Application No. 11/195,006 filed 01 Aug 2005 (HHS Reference No. E-223-1998/0-US-04).

U.S. Patent Application No. 09/830,977 filed 02 May 2001 (HHS Reference No. E-223-1998/0-US-03).

PCT Patent Application No. PCT/US1999/27410 filed 17 Nov 1998 (HHS Reference No. E-223-1998/0-PCT-02).

U.S. Provisional Patent Application No. 60/109,563 filed 23 Nov 1998 (HHS Reference No. E-223-1998/0-US-01).

*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).

Dated: February 26, 2008.

**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**

#### **Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel, Member

Conflicts: Musculoskeletal Rehabilitation Sciences.

*Date:* March 18, 2008.

*Time:* 4 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* John P. Holden, PhD, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-496-8551, [holdenjo@csr.nih.gov](mailto:holdenjo@csr.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.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Infectious Diseases Microbiology Fellowships.

*Date:* March 19-20, 2008.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Alexander D. Politis, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, 301-435-1150, [politis@csr.nih.gov](mailto:politis@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Cancer Drug and Therapeutics Development SBIR/STTR.

*Date:* March 20-21, 2008.

*Time:* 9 a.m. to 8 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Steven B. Scholnick, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7804, Bethesda, MD 20892, 301-435-1719, [scholnis@csr.nih.gov](mailto:scholnis@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflicts: Skeletal Muscle and Exercise Physiology.

*Date:* March 20, 2008.

*Time:* 3:30 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* John P. Holden, PhD, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-496-8551, [holdenjo@csr.nih.gov](mailto:holdenjo@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Developmental Pharmacology.

*Date:* March 26, 2008.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).