ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Weekly Reporting			
States	50	52	3
Territories	5	52	1.5
Cities	2	52	3
Annual Reporting			
States	50	1	16
Territories	5	1	10
Cities	2	1	16

Dated: November 8, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22315 Filed 11–14–07; 8:45 am]

BILLING CODE 4163–18–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.

Human T-box Transcription Factor Brachyury as a Target for Cancer Immunotherapy: Identification of Epitopes of Human Brachyury as Targets for T-cell Mediated Lysis of Tumors

Description of Technology: Identification of tumor antigens is essential in advancing immune-based therapeutic interventions in cancer. Transcription factors that control mesoderm have been implicated in tumor cell invasion and metastasis. Brachyury, a member of the T-box transcription factor family, is a highly conserved protein and a fundamental player in mesoderm (epithelial-to-mesenchymal transition, i.e. EMT) specification in multicellular organisms.

This invention describes the identification of the human transcription factor Brachyury as a novel target for cancer immunotherapy for the treatment of several tumors such as tumors of lung, intestine, stomach, kidney, bladder, uterus, ovary, and testis, and chronic lymphocytic leukemia. This is the first demonstration that (a) a T-box transcription factor and (b) a molecule implicated in mesodermal development (EMT) can be a potential target for human T-cell mediated cancer immunotherapy.

Applications:

1. Brachyury can be targeted for cancer immunotherapy.

2. Epitopes of the Brachyury protein that could be used to expand human T-lymphocytes for T-cell mediated lysis of tumors.

3. The technology can be developed as a cancer vaccine.

Advantages:

1. This technology can be delivered with the U.S. government owned fowl pox vector.

2. *In vitro* proof of concept data are available.

Benefits: This is the first demonstration that (a) a T-box transcription factor and (b) a molecule implicated in mesodermal development (EMT) can be a potential target for human T-cell mediated cancer immunotherapy. This technology has the potential of becoming a successful therapy for metastatic cancers.

Inventors: Jeffrey Schlom, *et al.* (NCI, CCR, LTIB)

Development Status: In vivo studies are ongoing.

Relevant Publication: C Palena, DE Polev, KY Tsang, RI Fernando, M Litzinger, LL Krukovskaya, AV Baranova, AP Kozlov, J Schlom. The human T-box mesodermal transcription factor Brachyury is a candidate target for T-cell-mediated cancer immunotherapy. Clin Cancer Res. 2007 Apr 15;13(8):2471–2478.

Patent Status: U.S. Provisional Application filed 28 Feb 2007 (HHS Reference No. E–074–2007/0–US–01).

Licensing Status: This technology is available for licensing under an exclusive or non-exclusive patent license.

Licensing Contact: Michelle Booden, PhD.; 301/451–7337; *boodenm@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Laboratory of Tumor Immunology and Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cancer vaccines aimed at targeting Brachyury. Please contact John D. Hewes, PhD. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Diagnostic Ovarian Cancer Biomarkers

Description of Technology: Ovarian cancer is one of the most common malignancies. Warning symptoms generally do not occur until the tumor has already spread beyond the ovary. As a result, patients are diagnosed with advanced stages of ovarian cancer and their prognosis is poor. Five year

survival rate for these patients is only fifteen percent and despite a clinical response of eighty percent to surgery and chemotherapy, most patients experience tumor recurrence within two years of treatment. The overwhelming majority of patients will eventually develop chemoresistance and lose their batter against cancer.

The inventors have discovered 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 ovarian cancer in its early stages.

Available for licensing is a gene profile that is indicative of patient survival. Unlike other biomarkers that are determined from discrete patient groups at either end of the survival spectrum, this profile is based upon expressed genes in late stage, high-grade papillary serous ovarian tumors. This predictive patient survival profile is based upon the theory that gene expression for advanced late stage ovarian cancer is more likely to develop aggressive, recurrent disease.

Also available for licensing is a gene signature that can predict whether a patient will respond positively to chemotherapy, show an initial response but will relapse within six months of completing chemotherapy, or not respond to chemotherapy. This methodology may enable clinicians to identify patients who need alternative chemotherapy regiment and to recommend cancer treatment appropriately.

Applications:

Method to prognose ovarian cancer and likelihood of aggressive, recurrent ovarian cancer;

Method to predict patient survival with advanced stage ovarian cancer;

Method to predict ovarian patient sensitivity to chemotherapeutic agents;

Methods to identify treatment options to enhance patient's response to chemotherapeutic agents;

Methods to treat ovarian cancer patients with inhibitory proangiogenic agents;

Ovarian cancer therapeutics.

Advantages:

Rapid, easy to use diagnostics;

Tool to choose appropriate cancer treatments which may avoid patient exposure to negative side effects of chemotherapy.

Market:

Ovarian cancer is the fifth most common form of cancer in women in the U.S.;

Ovarian cancer is three times more lethal than breast cancer;

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, *et al.* (NCI).

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. 60/951,073 filed 20 Jul 2007 (HHS Reference No. E–061–2007/0–US–01);

U.S. Provisional Application No. 60/899,942 filed 06 Feb 2007 (HHS Reference No. E–060–2007/0–US–01);

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 Cell and Cancer Biology Branch of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a gene expression profile that predicts ovarian cancer patient response to chemotherapy. Please contact John D. Hewes, Ph.D., NCI Technology Transfer Center, Tel. 301–435–3121 or E-mail: *hewesj@mail.nih.gov* for more information.

A Novel, Inhibitory Platelet Surface Protein (TREM Like Transcript, TLT–1): New Target for the Treatment of Cancer, Infectious Diseases, Cardiac Diseases, and Platelet-Associated Disorders

Description of Technology: Triggering Receptors in Myeloid Cells (TREM) recently were discovered to modulate innate and adaptive immunity. Specifically, TREM1 amplifies the response to sepsis in innate immunity by activating neutrophils and other leukocytes; and TREM2 potentiates dendritic cell maturation in adaptive immunity.

This invention describes a novel, inhibitory platelet surface protein known as TREM like Transcript (TLT–1). TLT–1 is the first inhibitory receptor discovered to reside within the TREM gene locus. Structurally, TLT–1 also possesses inhibitory domains that indicate this regulatory function. TLT–1 is highly expressed in peripheral blood platelets and may modulate many other types of myeloid cells. Additionally, the invention describes specific, human, single chain antibodies (scFvs) that recognize TLT–1.

Applications:

1. This discovery implies the receptor has an important regulatory role in both innate and adaptive immunity.

2. TLT–1 is a potential therapeutic target for thrombosis and other platelet-associated disorders, as well as immune disorders, cancer, septic shock, infectious disease, stroke, heart disease, myocardial infarction, vascular disorders.

3. Detection of soluble TLT–1 in patient plasma suggests the protein is a marker of ongoing coagulopathies.

4. Defective platelet aggregation in TLT–1 null mice confirms a role for the protein in regulation of thrombosis associated with inflammation.

Advantages:

1. *In vitro* proof of concept data available—Three of the anti-TLT–1 scFvs inhibit thrombin-induced aggregation of human platelets in a dose-dependent manner.

2. Complete human origin of these antibodies suggests negligible immunogenicity and minimizes the problem of adverse immune responses in human therapy.

3. Target validation is complete. TLT–1 null mice demonstrate defects in platelet aggregation with no gross bleeding defect.

Development Status: In vitro experiments completed. Target validation with null mice completed. In vivo animal studies with scFv are currently ongoing.

Inventors: Drs. Toshiyuki Mori, *et al.* (NCI)

Patent Status: U.S. Patent Application No. 11/634,331 filed 04 Dec 2006 (HHS Reference No. E–177–2006/0–US–01).

Licensing Contact: Mojdeh Bahar; 301/435–2950; *baharm@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute's Molecular Targets Development Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize antibodies that react specifically with TLT–1. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 5, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–22302 Filed 11–14–07; 8:45 am]

BILLING CODE 4140–01–P