collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Christine D. Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3070, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301–496–8544 or e-mail your request, including your address to: *Bergc@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 5, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison Office, National Institutes of Health.

[FR Doc. E8–18981 Filed 8–19–08; 8:45 am]

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.

Extracellular Matrix Gene Chips To Detect Metastatic Tumors

Description of Technology: Cancer mortality is primarily associated with metastatic disease and not the primary tumor. Recent evidence suggests that metastatic disease can be an early event and in the majority of patients metastasis starts by the time the disease is diagnosed. Currently however, approximately one third of patients without evidence of tumor dissemination at the time of surgical resection of the primary tumor subsequently develop distant metastases after the tumor is removed. Therefore there is a need for methods of characterizing the early metastatic process for better treatment of cancer.

This invention provides arrays which can be used for detecting the metastatic capacity of a tumor. In particular, these gene chips or microarrays detect the over-expression of the cancer-related extracellular matrix (ECM) modifier proteins Anakin and Bromodomain 4 (Brd4). It has been shown that ECM gene dysregulation is predictive of metastasis in breast cancer and recently Brd4 and Anakin have been identified as metastasis modifiers.

Using the signature profiles of Anakin and Brd4, the inventors have demonstrated that these genes predict survival outcome in affymetrix and glass slide based microarray experiments. As a result, screening for Brd4 and/or Anakin status in tumors could be an important prognostic test and may enable physicians to better stratify patients based on risk of recurrence and progression to metastatic disease.

Applications:

- Detecting metastatic disease in patients diagnosed with cancer.
- Method of characterizing a tumor or cancer by detecting the expression levels of Anakin or Brd4.
- Diagnostic tool to aid clinicians in determining appropriate cancer treatment.

Market:

- Approximately 1,437,180 new cancer cases are expected to be diagnosed in 2008.
- Almost 565,650 people in the U.S. are expected to die of cancer. This is more than 1,500 people a day.

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

Inventors: Kent Hunter and Nigel Crawford (NCI).

Patent Status: U.S. Provisional Application No. 60/970,400 filed 06 Sep 2007 (HHS Reference No. E–093–2007/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute Metastasis Susceptibility Section of the Laboratory of Cancer Biology and Genetics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Brd4 and/or RRP1B (Anakin) prognostic tests. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

NUP98-HOXD13 Transgenic Mice

Description of Technology: Myelodysplastic syndrome (MDS) is collection of closely related blood diseases that arise in the bone marrow characterized by anemia, neutropenia, and thrombocytopenia resulting from hematopoietic stem cell disorders. A variety of genetic aberrations have been associated with MDS, including chromosomal translocations of the NUP98 gene. The only current curative therapy for MDS is allogeneic bone marrow transplant. Without bone marrow transplant, patients either die of progressive pancytopenia or following transformation of MDS to acute myeloid leukemia. Progress in understanding and treating MDS has been hampered by a lack of an animal model that accurately recapitulates all of the features of human MDS. Utilizing a NUP98-HOXD13 (hereafter NHD13) fusion gene, a mouse model was developed to elucidate the biology of MDS. Genetically engineered mice that express an NHD13 transgene display all of the phenotypic features of MDS including peripheral blood cytopenia, bone marrow dysplasia, and transformation to acute leukemia. These mice provide an accurate preclinical model for MDS.

Applications: Model to study MDS and evaluate MDS therapy.

Market: 15,000–20,000 new cases of MDS are diagnosed in the U.S.; 80–90% of patients are older than 60 years old.

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

Inventors: Peter D. Aplan *et al.* (NCI).

Publications:

1. YW Lin et al. Notch1 mutations are important for leukemic transformation in murine models of precursor-T leukemia/lymphoma. Blood. 2006 Mar 15;107(6):2540–2543.

2. YW Lin et al., NUP98-HOXD13 transgenic mice develop a highly penetrant, severe myelodysplastic syndrome that progresses to acute leukemia. Blood. 2005 Jul 1;106(1):287–295.

Patent Status: HHS Reference No. E–071–2007/0—Research Tool.

Licensing Status: Available for non-exclusive licensing.

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

Collaborative Research Opportunity: The Leukemia Biology Section, Genetics Branch, National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the NHD13 mouse model. Please contact John D. Hewes, Ph.D. at 301–435–3121 or 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.

Applications: Anti-tumor agent for gastric, colon, lung, breast, ovarian and pancreatic tumors.

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

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*.

Collaborative Research Opportunity: The National Cancer Institute Structural Biophysics Laboratory is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Conjugates of Ligand, Linker, and Cytotoxic Agent and Related Compositions and Methods of Use. Please contact John D. Hewes, Ph.D. at 301–435–3121 or hewesj@mail.nih.gov for more information.

SH2 Domain Binding Inhibitors

Description of Technology: Signal transduction processes underlie the transfer of extracellular information to the interior of the cell and ultimately to the nucleus. A variety of signal transduction processes are critical for normal cellular homeostasis, with protein-tyrosine kinases (PTKs) playing central roles in many of these pathways. Examples of such PTKs include the PDGF receptor, the FGF receptor, the HGF receptor, members of the EGF receptor family, such as the EGF receptor, erb-B2, erb-B3 and erb-B4, the src kinase family, Fak kinase and the Jak kinase family. Protein-tyrosine phosphorylation that results from the action of PTKs can modulate the activity of certain target enzymes as well as facilitate the formation of specific multi-protein signaling complexes through the actions of homologous protein modules termed Src homology 2 (SH2) domains, which recognize specific phosphotyrosyl containing sequences. A malfunction in this system through tyrosine kinase overexpression and/or deregulation can be manifested by various oncogenic and hyperproliferative disorders, including cancers, inflammation, autoimmune disease, hyperproliferative skin disorders, psoriasis and allergy/asthma, etc. The disclosed compounds, e.g. peptides, preferably, macrocyclic peptides, are Grb2 SH2 domain signaling antagonists with enhanced binding affinity. The claims of the current application are directed to compositions of matter and methods of use which provide for the diagnosis, testing and treatment of the aforementioned disease states.

Applications: For treatment of cancer, inflammation, autoimmune diseases, hyperproliferative skin disorders, psoriasis and asthma.

Development Status: The technology is currently in an early pre-clinical stage of development.

Inventors: Terrence R. Burke, Jr., *et al.* (NCI).

Patent Status:

- U.S. Patent No. 6,977,241 issued 20 Dec 2005 (HHS Reference No. E–262–2000/0–US–03).
- U.S. Patent Application No. 10/517,717 filed 17 Mar 2005, allowed (HHS Reference No. E–262–2000/1-US–03).

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

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov*.

Dated: August 7, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–18982 Filed 8–19–08; 8:45 am]

BILLING CODE 4140–01–P

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