

obtaining high dimensional experimental data, such as gene expression profiling data, filtering the data, reducing the dimensionality of the data through use of one or more methods, training a supervised pattern recognition method, ranking individual data points from the data, choosing multiple data points from the data based on the relative ranking, and using the multiple data points to determine if an unknown set of experimental data indicates a diseased condition, a predilection for a diseased condition, or a prognosis about a diseased condition.

Artificial neural networks (ANNs) are computer-based algorithms capable of pattern recognition particularly suited to making diagnoses. ANNs do not require explicit encoding of process knowledge in a set of rules and can be trained from examples to recognize and categorize complex patterns. ANNs learn more efficiently when the data to be input into the neural network is preprocessed. Various ANN approaches to the analysis of data have seen extensive application to biomedical problems, including those in the areas of diagnosis and drug development. Unsupervised neural networks are also extensively used for the analysis of DNA microarray data.

The technology is further described in J. Khan *et al.*, "Classification and diagnostic prediction of cancers using gene expression profiling and artificial neural networks," *Nature Medicine*, 7(6):673-679, June 2001.

Selections of Genes

Javed Khan and Paul S. Meltzer (NHGRI), *et al.*

U.S. Patent Application No. 10/159,563 filed 31 May 2002 (DHHS Reference No. E-324-2001/1-US-01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435-4507; thalhamc@mail.nih.gov.

The invention provides selections of genes expressed in a cancer cell that function to characterize such cancer, and methods of using the same for diagnosis and for targeting the therapy of selected cancers. In particular, methods are provided to classify cancers belonging to distinct diagnostic categories, which often present diagnostic dilemmas in clinical practice, such as the small round blue cell tumors (SRBCTs) of childhood, including neuroblastoma (NB), rhabdomyosarcoma (RMS), Burkitt's lymphoma (BL), and the Ewing family of tumors (EWS). More specifically, the invention is an application of Artificial Neural Networks (ANNs) for the diagnostic classification of cancers based on gene expression profiling data

derived from cDNA microarrays. The ANNs were trained using as models. The ANNs then correctly classified all samples tested and identified the genes most relevant to the classification. Their study demonstrated the potential applications of these methods for tumor diagnosis and for the identification of candidate targets for therapy. The uniqueness of this method is taking gene expression data generated by microarrays, minimizing the genes from the original 1000s to less than 100, identifying which genes are the most relevant to a classification, which gives an immediate clue to the actual biological processes involved, not just surrogate markers which have no bearing on the biology.

The technology is further described in J. Khan *et al.*, "Classification and diagnostic prediction of cancers using gene expression profiling and artificial neural networks," *Nature Medicine* 7(6): 673-679, June 2001.

Dated: February 1, 2005.

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, DHHS.

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.

Methods for Prophylaxis and Treatment of HER-2/neu Tumors

John C Morris, Jay A. Berzofsky, Yoshio Sakai, Jong-Myun Park, Masake Terabe (all of NCI).

Serial Nos. PCT/US2003/034362 filed 29 Oct 2003 (DHHS Reference No. E-025-2003/1-PCT-1) and 60/422,395 filed 30 Oct 2002 (DHHS Reference No. E-025-2003/0-US-01).

Licensing Contact: Susan S. Rucker; (301) 435-4478; ruckersu@mail.nih.gov.

This application relates to methods for cancer prophylaxis and treatment. More particularly, the application relates to methods for the treatment and prophylaxis of cancers caused by the activity of the HER-2/neu/erbB-2 gene employing immunotherapy. Such cancers include breast cancers, cancers of the female genital tract and some cancers of the gastrointestinal tract.

The methods claimed involve the use of a HER-2/neu vaccine employing recombinant non-replicating adenovirus expressing a HER-2/neu/erbB-2 gene. In a preferred embodiment the vaccine comprises a recombinant non-replicating adenoviral vector encoding a HER-2/neu/erbB-2 gene that is expressed as a truncated HER-2/neu/erbB-2 protein. Antigen presenting cells, such as dendritic cells infected with the recombinant adenoviral vector, process and present the truncated HER-2/neu/erbB-2 protein, thereby stimulating an immune response. Preferred HER-2/neu/erbB-2 proteins contain regions of the extracellular domain and the transmembrane domain of the intact HER-2/neu/erbB-2 gene product and do not contain any tyrosine kinase domains.

This work has been published in part in Sakai, Y, *et al.* *Cancer Research* 64(21): 8022 (Nov 1 2004) and as WO 2004/041065 (May 21 2004).

Antibodies and Polypeptides to AAMP-1 for Use in Diagnosis and Therapy of AAMP-1-Expressing Cancers

Lance Liotta *et al.* (NCI).

U.S. Patent No. 6,274,134 issued 14 Aug 2001 (DHHS Reference No. E-084-1991/1-US-01); Australian Patent No. 684806 issued 23 Apr 1998 (DHHS Reference No. E-084-1991/1-AU-05).

Licensing Contact: Thomas Clouse; (301) 435-4076; clousetp@mail.nih.gov.

Angio-associated migratory cell protein (AAMP-1) was first isolated from a human melanoma cell line as a motility-associated cell protein. AAMP-1 contains two immunoglobulin domains,

six WD40 repeats, and a heparin-binding domain. *In vitro*, over expression of AAMP-1 promotes tumor cell invasion and metastasis as well as angiogenesis. AAMP-1 was later found to be over expressed in endothelial cells, cytotrophoblasts, and poorly differentiated colon adenocarcinoma cells found in lymphatics. In addition, gene expression studies have shown that AAMP-1 is over expressed in breast and gastrointestinal tumors.

The issued patents claim proteins, polypeptides, and recombinant polyclonal antibodies specific to AAMP-1 and their use in diagnostic and therapeutic applications. The antibodies are specific and can detect formalin-fixed antigen and SDS-denatured antigen.

These antibodies can be used for detailed expression studies of AAMP-1 in different cancer cell lines. The antibodies could also be used to promote cell adhesion to a substrate, promote tissue acceptance of prostheses, and promote wound healing. The antibodies could also be used to detect AAMP-1 in patient's sera as a useful diagnostic marker for multiple carcinomas including high nuclear grade ductal carcinoma *in situ* (Clinical Cancer Research Dec 2002 8:3788-95).

Dated: January 31, 2005.

Steven M. Ferguson,

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

[FR Doc. 05-2394 Filed 2-7-05; 8:45 am]

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 the following meeting.

The meeting 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/or contract proposals 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 and/or contract proposals, the disclosure of which would

constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, RFA CA-05-002 and CA-05-006-IMAT.

Date: March 9-10, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Sherwood Githens, PhD, Scientific Review Administrator, Special Review and Logistics Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executives Blvd., Bethesda, MD 20892, 301/435-1822, *githens@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 2, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committees Policy.

[FR Doc. 05-2349 Filed 2-7-05; 8:45 am]

BILLING CODE 4140-01-M

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 the following meeting.

The meeting 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: National Cancer Institute Special Emphasis Panel Special Emphasis Panel or Review of R25 Applications.

Date: March 30-31, 2005.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham City Center Hotel, 1143 New Hampshire Ave., NW., Washington, DC 20037.

Contact Person: David E. Maslow, PhD, Chief, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard—Room 8117, Bethesda, MD 20892-7405, (301) 496-2330.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 2, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-2350 Filed 2-7-05; 8:45 am]

BILLING CODE 4140-01-M

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 the following meeting.

The meeting 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: National Cancer Institute Special Emphasis Panel Transdisciplinary Research on Energetics and Cancer.

Date: March 2-3, 2005.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Mary Jane Slesinski, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8045, Bethesda, MD 20892, 301/594-1566.