

(b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

Send comments to Carrie N. Klabunde, Ph.D., Epidemiologist, National Cancer Institute, EPN 4005, 6130 Executive Boulevard, Bethesda, Maryland 20892-7344. Telephone: (301) 402-3362; Fax: (301) 435-3710 E-mail: ck97b@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 18, 2004

Rachelle Ragland-Green,

NCI Project Clearance Liaison, 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.

Mouse Monoclonal Antibody (4G11) Against Insulin-Like Growth Factor I Receptor

Peter Nissley, Peta-Gay Jackson-Booth, Cheryl Terry, Brett Lackey, Martyna Lopaczynska (NCI)

DHHS Reference No. E-342-2004/0-US-01

Licensing Contact: John Stansberry; (301) 435-5236; stansbej@mail.nih.gov.

The insulin-like growth factor I receptor (IGF-IR) is emerging as a molecular target for cancer treatment. Prospective studies in humans provide evidence for a relationship between circulating levels of both IGF-I and IGF binding protein 3 (IGFBP-3) and the risk for the development of cancers of the prostate, breast, lung, and colon. Many human cancers express or over-express components of the IGF signaling pathway, in particular IGF-II and the IGF-I receptor. This technology describes a mouse monoclonal antibody that binds the insulin-like growth factor I receptor. The IGF-IR monoclonal antibody 4G11 blocks binding of IGF-I to its receptor and promotes down regulation of the receptor in MCF-7 breast cancer cells, MG-63 osteosarcoma cells and a panel of colon cancer cells. Additionally, 4G11 stimulated down-regulation of the IGF-I receptors in MCF-7 cells results in inhibition of Akt and MAPK activation by IGF-I. This monoclonal antibody has utility as a laboratory reagent for immunoprecipitations, and as an inhibitor of the IGF-I signaling pathway. A humanized form of monoclonal antibody 4G11 would potentially have utility as a therapeutic to treat a variety of cancers in which IGF-IR signaling has been shown to be important. This research is partially described in *Horm Metab Res* 2003; 35: 850-856.

Beta-Glucuronidase Cleavable Prodrugs of O6-Alkylguanine-DNA Alkyltransferase Inactivators

Robert C. Moschel *et al.* (NCI) U.S. Provisional Application filed 08 Sep 2004 (DHHS Reference No. E-307-2004/0-US-01)

Licensing Contact: George Pipia; (301) 435-5560; [pipia@mail.nih.gov](mailto:pipiag@mail.nih.gov).

The present invention relates to prodrugs of inactivators of O6-alkylguanine-DNA alkyltransferase. The prodrugs are cleaved by the beta-glucuronidase enzyme found in tumor cells or co-administered to the patient, and the drugs are targeted for use in cancer treatment in combination with antineoplastic alkylating agent such as

1,3-bis(2-chloroethyl)-1-nitrosourea or temozolomide.

Transcytosis of Adeno-Associated Viruses

John A. Chiorini and Giovanni Di Pasquale (NIDCR)

U.S. Provisional Application filed 08 Sep 2004 (DHHS Reference No. E-298-2004/0-US-01)

Licensing Contact: Jesse Kindra; (301) 435-5559; kindraj@mail.nih.gov.

The invention relates to a method for delivering nucleic acids to a variety of cells including those of the gut, kidney, lung and central nervous system. The underlying cells of such organs are covered by a barrier of endothelial or epithelial cells which can limit the transfer of nucleic acids, or other potentially therapeutic agents, to the underlying target cells. To overcome this limitation, the method employs certain members of the parvovirus family to transcytose the barrier cells. During transcytosis, the virus passes through these barrier cells and can infect cells of the underlying layer. Therefore, this method could facilitate the transfer of nucleic acids to cells that currently available viral vectors are unable to reach.

The method could be applied to the treatment of neurodegenerative diseases such as Parkinson's, Alzheimer's, Huntington's, lysosomal storage diseases, the dominant spinal cerebellar ataxias, and Krabbe's disease without the need for stereotactic injection. The method could potentially also be used in the treatment of genetic muscle disorders such as muscular dystrophy. Several of the viruses described in the invention are serologically distinct and could be used in patients who have developed an immune response to other vectors.

Multimeric Protein Toxins to Target Cells Having Multiple Identifying Characteristics

Stephen Leppla (NIAID), Shi-hui Liu (NIAID), and Thomas Bugge (NIDCR)

U.S. Provisional Application No. 60/543,417 filed 09 Feb 2004 (DHHS Reference No. E-059-2004/0-US-01)

Licensing Contact: Brenda Hefti; (301) 435-4632; heftib@mail.nih.gov.

This technology relates to multimeric bacterial protein toxins which can be used to specifically target cells. Specifically, this is a modified recombinant anthrax toxin protective antigen (PrAg) that has been modified in several ways. First, the PrAg can be activated both by a metalloproteinase (MMP) and by urokinase plasminogen activator (uPA). Second, the native PrAg

lethal factor (LF) binding site has been modified so that only a modified PrAg comprising two different monomers can bind anthrax LF. When administered with an effector component, the recombinant anthrax toxins are toxic only to cells expressing both a MMP and uPA on their surface. This technology is therefore useful for selective methods of treating cancers, because many cancer cells express multiple cell-surface proteases.

Novel Human Cancer Antigen, NY ESO-1/CAG-3, and Gene Encoding Same

Rong-fu Wang (EM), Steven A. Rosenberg (NCI)

U.S. Provisional Application No. 60/061,428 filed 08 Oct 1997 (DHHS Reference No. E-265-1997/0-US-01); PCT Application No. PCT/US98/19609 filed 21 Sep 1998, which published as WO 99/18206 on 15 Apr 1999 (DHHS Reference No. E-265-1997/0-PCT-02); U.S. Patent Application No. 09/529,206 filed 21 Sep 1998 (DHHS Reference No. E-265-1997/0-US-04)

Licensing Contact: Jesse Kindra; (301) 435-5559; kindraj@mail.nih.gov.

The current invention embodies the identification, isolation and cloning of a gene encoding a novel tumor antigen, NY ESO-1/CAG-3, as well as cancer peptides thereof and antigenic cancer epitopes contained within the cancer peptides. This novel antigen is recognized by cytotoxic T lymphocyte clones derived from the TIL586 (tumor infiltrating lymphocyte) cell line in an HLA restricted manner.

The inventors believe that cancer peptides which are encoded by the NY ESO-1/CAG-3 gene represent potential cancer vaccines, protecting an individual from development of cancer by inhibiting the growth of cells or tumors which express the NY ESO-1/CAG-3 antigen. Also embodied in the invention are pharmaceutical compositions comprising the NY ESO-1/CAG-3 antigen, peptide, or an antigenic cancer epitope thereof in combination with one or more immunostimulatory molecules. These compositions represent potential anticancer therapeutics, stimulating NY ESO-1/CAG-3-specific T cells to elicit an anti-cancer immunogenic response and thereby eliminating or reducing the cancer. While these vaccines and pharmaceutical compositions may be developed for use against a variety of cancers, data obtained to date indicate that they may be of particular value for use against melanoma.

Methods for diagnosing cancer via the detection of NY ESO-1/CAG-3 are also embodied in the invention.

Method for Inhibiting Angiogenesis

Elise C. Kohn, Lance A Liotta, and Riccardo Alessandro (NCI)
U.S. Patent No. 5,744,492 issued 28 Apr 1998 (expires 28 Apr 2015) (DHHS Reference No. E-220-1993/1-US-01)
Licensing Contact: John Stansberry; (301) 435-5236; stansbej@mail.nih.gov and

Combinatorial Therapy for Protein Signaling Diseases

Arpita Mehta (NCI), Lance Liotta (NCI), Emmanuel Petricoin (FDA)
U.S. Provisional Application No. 60/453,629 filed 10 Mar 2003 (DHHS Reference No. E-039-2003/0-US-01)
Licensing Contact: Michael Shmilovich; (301) 435-5019; shmilovm@mail.nih.gov.

Angiogenesis is a composite of regulated proliferation and regulated invasion occurring in a variety of normal and pathologic conditions. In this invention, the claimed compound and its related analogs are useful for inhibiting angiogenesis in a host and offer a novel approach to the treatment of cancer, diabetic retinopathy, hemangiomas, vasculidities, macular degeneration and other disease associated with angiogenesis. Additionally, the compound has shown efficacy at lower doses when co-administered with other anti-angiogenesis agents.

Refer to issued patent 5,744,492 (April 28, 1998), and journal articles: *PNAS* (1995) 92(5):1307-11, and *In Vivo* (1996) 10(2):153-60.

Dated: October 22, 2004.

Steven M. Ferguson,

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

[FR Doc. 04-24166 Filed 10-28-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; Interagency Autism Coordinating Committee

The National Institutes of Health (NIH) hereby announces a meeting of the Interagency Autism Coordinating Committee (IACC) to be held on November 19, 2004, on the NIH campus in Bethesda, Maryland.

The Children's Health Act of 2000 (Pub. L. 106-310), Title I, Section 104, mandated the establishment of an IACC

to coordinate autism research and other efforts within the Department of Health and Human Services. In April 2001, Secretary Tommy Thompson delegated the authority to establish the IACC to the NIH. The National Institute of Mental Health (NIMH) at the NIH has been designated the lead for this activity.

The IACC meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: Interagency Autism Coordinating Committee.

Date: November 19, 2004.

Time: 9 a.m.-4:30 p.m.

Agenda: Discussion of autism activities across Federal agencies.

Place: National Institutes of Health, 31 Center Drive, Building 31, Conference Room 10 (6th floor), Bethesda, Maryland 20892.

Contact Person: Ann Wagner, Ph.D., Division of Services and Intervention Research, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 7142, MSC 9633, Bethesda, Maryland 20892. E-mail: wagner@mail.nih.gov. Phone: 301-443-4283.

Any member of the public interested in presenting oral comments to the Committee may notify the contact person listed on this notice at least 5 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Presentations may be limited to 5 minutes; both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding his/her statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and, when applicable, the business or professional affiliation of the interested person.

Information about the meeting and online registration forms are also available on-line on the NIMH home page at <http://www.nimh.nih.gov/autismiacc/index.cfm>.

Dated: October 20, 2004.

Raynard S. Kington,

Deputy Director, National Institutes of Health.

[FR Doc. 04-24168 Filed 10-28-04; 8:45 am]

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