

Cripto-1 (CR1) is a member of the epidermal growth factor (EGF)-related families of peptides and is involved in the development and progression of various human carcinomas. In particular, CR1 overexpression has been detected in 50–90% of carcinomas of the colon, pancreas, stomach, gallbladder, breast, lung, endometrium and cervix. Current methodologies of cancer detection, *e.g.* immunohistochemistry, can be time consuming, inconvenient and oftentimes, inaccurate, and therefore, a need exists for more efficient, reliable and less time consuming methods of detection. The invention relates to such a method of detection. The inventors disclose methods for the detection and quantification of CR1 in human milk, using an ELISA-based protocol. Thus, this test could be used to more effectively detect and perhaps stage cancers. Additionally, should particular tumor cells, *e.g.* breast tumor cells, express a sufficiently high level of CR1, it may be possible to use the disclosed assay to detect and measure CR1 in human serum and/or plasma. Claims to these routes of detection are also present in the patent application. As such, a novel, efficient and useful *in vitro* diagnostic and prognostic test is now available to suitable commercial partners.

Improving Chemotherapy by Increased Killing of Tumor Cells and Protection of Normal Cells Through p38 Kinase Inhibition

Dmitry Bulavin and Albert J. Fornace, Jr. (NCI)

DHHS Reference Nos. E-235-2000/0-US-01 filed 07 Nov 2000 and E-235-2000/0-PCT-02 filed 06 Nov 2001 (PCT/US01/47669)

Licensing Contact: Catherine Joyce; 301/435-5031; joycec@od.nih.gov

Responses to genotoxic stress include the initiation of cell-cycle arrest and the maintenance of cell-cycle arrest during DNA repair. Although maintenance of G2/M checkpoints is known to involve Chk1, Chk2/Rad53 and upstream components, the mechanisms involved in initiation of the G2/M checkpoint are less well defined. The inventors have discovered that p38 kinase has a critical role in the initiation of a G2/M delay after genotoxic stress such as ultraviolet radiation. The inventors contemplate that p38 MAPK inhibition will enhance the efficacy of chemotherapy by inhibiting the initiation of G2/M arrest in stressed cells and promoting the progression of such cells into M phase.

The above-mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Pyrimidine Phosphorylase as a Target for Imaging and Therapy

RW Klecker and JM Collins (FDA)
DHHS Reference Nos. E-156-1999/0-US-01 filed 19 Jan 2001 and E-156-1999/0-PCT-02 filed 18 Jan 2002 (PCT/US02/01216)

Licensing Contact: Brenda Hefti; 301/435-4632; heftib@od.nih.gov

The present invention describes methods to diagnose and monitor the treatment of tumors with high expression of thymidine phosphorylase (TP). Overexpression of TP has been shown to correlate with angiogenesis, and this fact can be used, via TP's enzyme function, to preferentially label angiogenic cells through the introduction of relevant precursors. These precursors consist of labeled thymine analogues which are converted by TP into retained cell-components. This can allow for the non-invasive imaging of tumors with high angiogenic activity. The technique can also be used to kill tumor cells by providing the analogues in higher concentrations or with therapeutic isotopes so as to be toxic to cells with high TP levels.

Dated: December 13, 2002.

Jack Spiegel,

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 agencies 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.

Tryptophan as a Functional Replacement for ADP-ribose-arginine in Recombinant Proteins

Dr. Joel Moss *et al.* (NHLBI), DHHS Reference No. E-160-2002/0-US-01 filed 28 Jun 2002 Licensing Contact: Marlene Shinn; 301/435-4426; shinnm@od.nih.gov.

Bacterial toxins such as cholera toxin and diphtheria toxin catalyze the ADP-ribosylation of important cellular target proteins in their human hosts, thereby, as in the case of cholera toxin, irreversibly activating adenylate cyclase. In this reaction, the toxin transfers the ADP-ribose moiety of Nicotinamide Adenine Dinucleotide (NAD) to an acceptor amino acid in a protein or peptide. ADP-ribosylation leads to a peptide/protein with altered biochemical or pharmacological properties. Mammalian proteins catalyze reactions similar to the bacterial toxins. The ADP-ribosylated proteins represent useful pharmacological agents, however, their use is limited by the inherent instability of the ADP-ribose-protein linkage.

The NIH announces a new technology wherein recombinant proteins are created that substitute phenylalanine or tryptophan for an arginine, thereby making the protein more stable, and better suited as agents for therapeutic purposes. The modification creates an effect similar to ADP-ribosylation of the arginine. An example of a protein that can be modified is the defensin molecule, which is a broad-spectrum antimicrobial that acts against infectious agents and plays an important role in the innate immune defense in vertebrates.

Identification of Anti-HIV Compounds Inhibiting Virus Assembly and Binding of Nucleocapsid Protein to Nucleic Acid

Drs. Robert Shoemaker and Michael Currens (STB, DTP, DCTD, NCI), Drs. Alan Rein and Ya-Xiong Feng (DRP, CCR, NCI), Drs. Robert Fisher, Andrew Stephen, Shizuko Sei, Bruce Crise, and Louis Henderson, and Ms. Karen Worthy (SAIC-Frederick), DHHS Reference No. E-121-2002/0 filed 08 Oct 2002, Licensing Contact: Sally Hu; 301/435-5606; hus@od.nih.gov

This invention identified potent inhibitors of HIV particle assembly and nucleocapsid/nucleic acid binding. Two series of active antiviral compounds are described in this invention. One series

comprises aromatic, antimony-containing compounds while the other an aromatic tricarboxylic acid. Both series have been shown to exhibit anti-HIV viral activity by inhibiting viral particle assembly and by inhibiting the binding of the nucleocapsid protein to nucleic acid and protecting susceptible human cells from the cytopathic effect of HIV. Compounds in both classes show potent activity in mechanistic assays and cell-based antiviral assays and are quite non-toxic in vitro. Thus, these compounds, or derivatives, may be useful in treatment of AIDS patients.

Apparatus and Method for In Vitro Recording and Stimulation of Cells

David Ide (NIMH), George Mentis (NINDS), DHHS Reference No. E-068-2002 filed 05 Jul 2002, Licensing Contact: Dale Berkley; 301/435-5019; berkleyd@od.nih.gov.

The invention is an apparatus that allows in vitro recording and stimulation of neuronal tissue using extracellular and intracellular techniques. This system enables the experimenter to combine commercially available motorized micromanipulators (used to position electrodes for intracellular recordings) with newly designed miniature micromanipulators to perform simultaneously extracellular recordings and/or stimulations. The apparatus consists of a circular plexiglas in vitro chamber, an aluminum base that allows adjustment to securely positioned preparations at various rotated positions during the course of the experiment (without having to reposition the preparation), and a set of several (maximum ten) miniaturized micromanipulators, allowing four-dimensional control. The positioning of the electrodes for extracellular recordings/stimulation is done manually without any motor control. The miniature micromanipulators can also be used to position multi-barrel electrodes for local application of pharmacological agents as well as for different purposes (mini temperature probe, pH probe, outlet or inlet tubing etc). This is a unique system that permits a practical, versatile electrophysiological setup for simultaneous extracellular and intracellular recordings. The apparatus is fully documented and ready for transfer from the laboratory to the commercial environment.

Dated: December 13, 2002.

Jack Spiegel,

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

National Center for Complementary and Alternative Medicine; Notice of 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 National Advisory Council for Complementary and Alternative Medicine (NACCAM).

The meeting will be open to the public as indicated below, 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.

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 discussion 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 Advisory Council for Complementary and Alternative Medicine.

Date: January 27, 2003.

Closed: 8:30 to 11:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Open: 12:30 to 5:30 p.m.

Agenda: The agenda includes opening remarks by Director, NCCAM, concept reviews: Dietary Supplements Resource Center; Health Services Research; Probiotics, and Clinical Research. Presentations: Cancer CAM Working Group; General Principals for Collaboration with NCI; Patient Focus Groups on Cancer and CAM and other business of the Council.

Place: Neuroscience Conference Center, 6001 Executive Boulevard, Conference Rooms C and D, Rockville, MD 20852.

Contact Person: Jane F. Kinsel, Ph.D., Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 496-6701.

The public comments session is scheduled from 5-5:30 p.m. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations are requested to notify Dr. Jane Kinsel, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland, 20892, 301-496-6701, Fax: 301-480-0087 or via email NCCAMES@mail.nih.gov. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later than 5 p.m. on January 17, 2003. Only one representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Jane Kinsel at the address listed above up to 10 calendar days (February 6, 2003) following the meeting.

Copies of the meeting agenda and the roster of members will be furnished upon request by Dr. Jane Kinsel, Executive Secretary, NACCAM, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301-496-6701, Fax 301-480-0087, or via email at NCCAMES@mail.nih.gov. This information will be posted two weeks prior to the meeting on the NCCAM website at NCCAM@nih.gov.

Dated: December 17, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy, NIH.

[FR Doc. 02-32360 Filed 12-23-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of 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 a meeting of the National Heart, Lung, and Blood Advisory Council.