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Imaging With Positron-Emitting Taxanes as a Guide to Antitumor Therapy

Jerry M. Collins, Raymond W. Klecker, Lawrence Anderson (FDA)
Serial No. 60/155,061 filed 21 Sep 1999

The present application discloses the use of positron-emitting compounds to label taxane type drugs. This invention also describes methods of synthesizing these taxane type compounds. Further, methods to guide treatment of solid tumors, with labeled taxanes, are also disclosed in the present application. Advantages of using this technology include: (1) Avoidance of exposing patients to toxic drugs that have no potential for benefit; (2) ability to rapidly determine whether a given tumor will be likely to respond to a particular drug; and (3) the ability to monitor the impact of various dosages, schedules, and modulators for delivery, *in situ*, at the actual tumor under treatment conditions.

Conjugate Vaccine for *Neisseria Meningitidis*

Xin-Xing Gu (NIDCD) and Chao-Ming Tsai (FDA)
Serial No. 60/148,021 filed 10 Aug 1999

The invention discloses a vaccine which comprises lipooligosaccharide (LOS) isolated from *N. meningitidis* and conjugated to a carrier protein. The invention also discloses a method of making the acellular vaccine. The method consists of two main steps. In the first step the lipooligosaccharide (LOS), chosen so it does not contain the lacto-N-neotetraose human antigen (LNnT), is detoxified by a novel procedure which uses hydrazine to remove the O-linked fatty acids. In the second step, the detoxified LOS (dLOS) is covalently conjugated to a carrier protein such as Tetanus Toxoid (TT). The dLOS produced in step 1 is 10,000 fold less toxic than the parent LOS. The conjugate vaccine exhibited a high level of immunogenicity as evidenced by the high titer of IgG antibody to native LOS, obtained in mice and rabbits. The rabbit antisera produced by the conjugate vaccine of one *N. meningitidis* strain (strain 7880, A,L10) exhibited bactericidal activity and cross reactivity with heterologous *N. meningitidis* strains. A conjugate vaccine made in this method may be multivalent, composed of dLOSs from different strains and/or immunotypes of *N. meningitidis* and will thus protect against all types of *N. meningitidis*, including type B.

A portion of this invention was disclosed in a poster by Tsai, Gu and Quakyi at the Fifth Conference of the International Endotoxin Society held in Santa Fe, New Mexico in September 12–15, 1998.

Dated: April 7, 2000.

Jack Spiegel,

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

[FR Doc. 00–9444 Filed 4–14–00; 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, 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 contacting John Peter Kim, at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 264; fax: 301/402–0220; e-mail: jk141n@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

High Speed Parallel Nucleic Acid Sequencing

Thomas D. Schneider, Denise Rubens (NCI)
Serial No. 60/151,580 filed 30 Aug 1999

The present application describes a new method and apparatus for DNA sequencing called Two Dye Sequencing (TDS). This method employs engineered DNA polymerases which are labeled with a fluorophore such as Green Fluorescent Protein (GFP) and are combined with an annealed oligonucleotide primer in a chamber of a microscope field of view capable of detecting individual molecules. Four

nucleotide triphosphates, each labeled on the base with a different fluorescent dye are introduced to the reaction. Light of a specific wavelength is used to excite the fluorophore on the polymerase, which in turn excites the neighboring fluorophore on the nucleotide by Fluorescence Resonance Energy Transfer (FRET). As nucleotides are added to the primer, their spectral emissions provide sequence information of the DNA molecule.

Hydrazide Inhibitors of HIV–1 Integrase

Yves Pommier, Nouri Neamati, Zhaiwai Lin, Terrence R. Burke, Jr. (NCI)
DHHS Reference Nos. E–037–99/0 filed 12 Mar 1999 and E–037–99/1 filed 10 Mar 2000

The human immunodeficiency virus (HIV) is the causative agent of acquired immunodeficiency syndrome (AIDS). Drug-resistance is a critical factor contributing to the gradual loss of clinical benefit to treatments for HIV infection. Accordingly, combination therapies have further evolved to address the mutating resistance of HIV. However, there has been great concern regarding the apparent growing resistance of HIV strains to current therapies.

It has been found that a certain class of compounds including salicylhydrazides and analogs and derivatives thereof are effective and selective anti-integrase inhibitors which are active in the presence of both Mn(+2) and Mg(+2) and which may be used in the treatment or prevention of infection by HIV and AIDS. The subject invention provides for such compounds and for methods of inhibiting HIV integrase.

Dated: April 5, 2000.

Jack Spiegel,

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

[FR Doc. 00–9446 Filed 4–14–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

“Conference on Challenges in Health Disparity in the New Millennium: A Call to Action”

Notice is hereby given of the NIH Office of Research on Minority Health (ORMH) Conference on Challenges in Health Disparity in the New Millennium: A Call to Action, which will be held April 16–19, 2000, at the

Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW, Washington, D. C. 20001. The conference begins at 8:00 a.m. on April 17, 8:00 a.m. on April 18, and 8:30 a.m. on April 19.

The Office of Research on Minority Health (ORMH), Office of the Director, National Institutes of Health (NIH), is convening this conference. ORMH is a central leadership entity at the NIH for issues related to minority health research and research training. Reports of progress and accomplishments since the founding of ORMH in 1990 and developing a strategic plan for future actions for eliminating health research and research training disparities comprise the agenda of the conference.

Specific conference objectives include:

- Recommending a framework for the ORMH to address continuing disparity in health status of the US population and the international community through the Minority Health Strategic Plan;
- Highlighting the role of the ORMH to address disparity in health status through basic and clinical research and research training in biomedical and behavioral sciences; and
- Promoting partnerships with leaders in Congress, associations, academic institutions, industry, community-based organizations, and other Federal agencies to help eliminate health disparity.

The primary sponsor of this conference is ORMH. Advance information on the conference program and conference registration materials maybe obtained from Debra Rainey, LCLM, LLC, Inc., 1299 Lamberton Drive, Suite 205, Silver Spring, Maryland 20902 (telephone: 301-593-2800).

Dated: April 7, 2000.

Yvonne Maddox,

Acting Deputy Director, National Institutes of Health.

[FR Doc. 00-9445 Filed 4-14-00; 8:45 am]

BILLING CODE 4140-01-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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 a meeting of the Cancer Advisory Panel for

Complementary and Alternative Medicine.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended because the premature disclosure of program documents—PAC and the discussions would likely to significantly frustrate implementation of recommendations.

Name of Committee: Cancer Advisory Panel for Complementary and Alternative Medicine.

Date: April 19, 2000.

Time: 2:30 PM to 5:00 PM.

Agenda: To review and evaluate the Gonzalez Regiment.

Place: National Institutes of Health, 9000 Rockville Pike, Bldg. 31, Room 5B5B, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard Nahin, PhD, Executive Secretary, Cancer Advisory Panel for Complementary, and Alternative Medicine, NCCAM, NIH, 9000 Rockville Pike, Building 31, Room 5B37, Bethesda, MD 20892, 301-594-2013.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Dated: April 6, 2000.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-9436 Filed 4-14-00; 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 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 522b(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 Heart, Lung, and Blood Institute Special Emphasis Panel, Mentored Clinical Scientist Development Awards (K08).

Date: April 12, 2000.

Time: 2:30 PM to 4 PM.

Agenda: To review and evaluate grant applications.

Place: 6701 Rockledge Drive, Room 7214, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: C. James Scheirer, PhD, Chief, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, Rockledge Center II, 6701 Rockledge Drive, Suite 7216, Bethesda, MD 20892-7924, 301-435-0266.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Disease Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 6, 2000.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-9434 Filed 4-14-00; 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 Closed Meetings

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 meetings.

The meetings 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 Heart, Lung, and Blood Institute Special Emphasis Panel Fluorescent Indicator Dyes for Extracellular Ions (SBIR).

Date: May 4, 2000.

Time: 9:00 AM to 11:00 AM.

Agenda: To review and evaluate contract proposals.

Place: 6701 Rockledge Drive, Room 4212, Bethesda, MD 20817 (Telephone Conference Call).