

Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Mr. Richard M. Taffet, Director, Client Services Division; Office of Human Resources, Office of the Director, National Institutes of Health, Room 2-D234, East Jefferson Street, Bethesda, MD 20892-8503, or call the non-toll-free number 301-402-6627, or e-mail your comments or request, including your address, to: [Taffetr@mail.nih.gov](mailto:Taffetr@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 this publication.

Dated: February 26, 2007.

**Richard M. Taffet,**

Director, Client Services Division, OHR, OD, National Institutes of Health.

[FR Doc. 07-1087 Filed 3-8-07; 8:45 am]

BILLING CODE 4140-10-M

## 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.

#### Methods of Treating Conditions Characterized by Unwanted or Excessive Presynaptic Neuronal Activity or Secretion

**Description of Technology:** Botulinum toxins are highly potent neurotoxins produced by the spore-forming bacterium, *Clostridium botulinum*. Poisoning by any of the seven known botulinum toxin serotypes, designated A to G, results in impaired communication between nerve and muscle that causes paralysis in patients and possible death by respiratory failure. Injections of botulinum toxins A and B have been approved for treating disorders associated with uncontrollable muscle contractions. However, the use of approved botulinum toxins is limited by their temporary duration of action, the development of neutralizing antibodies after repeated injections, and cross-reactivity with autonomic neurons. Thus, an interest exists in finding new ways to achieve longer-lasting effects using botulinum toxins.

This technology describes a novel method for treating diseases by combining two botulinum toxins, botulinum toxin A and B. Researchers at the FDA have shown that the combination of the A and B toxins is synergistic, improves muscle paralysis characteristics compared to individually administered serotypes, and produces a longer duration of action and a faster onset of paralysis. The synergistic effect allows lower doses compared to single use of either toxin and should help reduce resistance after repeated use. This technology is beneficial for the treatment of diseases already known to be treatable with botulinum toxins, such as facial wrinkles, headaches, muscle spasms, and cervical dystonia. This technology is also suitable to treat other diseases, such as strabismus, hemifacial spasms, facial nerve damage, and hyperhidrosis (excessive sweating).

Available for licensing are methods and pharmaceutical compositions for administering a combination of botulinum toxin A and B to treat unwanted or excessive presynaptic neuronal activity or secretion.

**Application:** Alternative therapy for diseases treatable with individual botulinum toxins; such therapies include Botox®, Botox Cosmetic®, and Myobloc®.

**Market:** Patients who are currently prescribed individual toxins for treatment of diseases such as strabismus, blepharospasm, cervical dystonia, and cosmetic wrinkle reduction.

**Development Status:** Pre-clinical data is available.

**Inventors:** James E. Keller (CBER/FDA).

**Publications:** JE Keller. Recovery from botulinum neurotoxin poisoning in vivo. *Neuroscience* 2006 May 12;139(2):629-637.

**Patent Status:** U.S. Provisional Application No. 60/773,412 filed 15 Feb 2006 (HHS Reference No. E-172-2005/0-US-01).

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

**Licensing Contact:** Norbert Pontzer, PhD, J.D.; 301/435-5502; [pontzern@mail.nih.gov](mailto:pontzern@mail.nih.gov).

**Collaborative Research Opportunity:** The FDA Center for Biologics Evaluation and Research, Laboratory of Respiratory and Special Pathogens, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact James E. Keller, PhD, at 301/ for more information.

#### Synergistic Effect of TGF-Beta Blockade and Immunogenic Agents on Tumors

**Description of Technology:**

Overcoming immune suppression in cancer patients is a major challenge for the success of cancer immunotherapy. TGF-β and its receptors are expressed in essentially all tissues, and they have been found to be important in many cellular processes including cell growth inhibition. The inhibition of TGF-β signaling has been shown to have an inhibitory effect on tumor growth. However, TGF-β also has immunosuppressive properties.

Cancer vaccines are one of many therapies available for treatment and prevention. In particular, vaccines that elicit immune responses have been used to treat or control tumor growth that has evaded immunosurveillance. However, these vaccines have demonstrated limited success.

Available for licensing is a method for synergistically affecting tumor growth involving the administration of an agent that blocks the TGF-β signaling pathway, in combination with an immunogenic agent. The agent that blocks the TGF-β signaling pathway may inhibit the immunosuppressive effects of TGF-β, while the immunogenic agent is believed to enhance an immune response. Surprisingly, the combination of such elements produces a synergistic effect. The administration of the 1D11.16 anti-TGF-β antibody in combination with the human papilloma virus E7(49-57) peptide enhances tumor regression in an animal model. The administration of the 1D11.16 anti-TGF-β antibody in

combination with irradiated CT26 cells enhances tumor regression in another mouse model. The investigators found that administering the combination of agents is more effective than the sum of their individual effects.

**Applications:** A method of cancer combination therapy based on immunotherapeutics.

**Development Status:** The invention is in the clinical stages of development.

**Inventors:** Masaki Terabe (NCI) et al.

**Publications:**

1. PCT patent publication WO 2006/089251, August 24, 2006.

2. M Terabe et al. Transforming growth factor-beta production and myeloid cells are an effector mechanism through which CD1d-restricted T cells block cytotoxic T lymphocyte-mediated tumor immunosurveillance: abrogation prevents tumor recurrence. *J Exp Med.* 2003 Dec 1;198(11):1741-1752.

**Patent Status:** U.S. Provisional Application No. 60/654,329 filed 17 Feb 2005 (HHS Reference No. E-019-2005/0-US-01); PCT Application No. PCT/US2006/005888 filed 16 Feb 2006 (HHS Reference No. E-019-2005/0-PCT-02).

**Licensing Availability:** Available for exclusive and non-exclusive licensing.

**Licensing Contact:** Jennifer Wong; 301/435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov)

#### **Arylthioindole Tubulin Polymerization Inhibitors and Methods of Treating or Preventing Cancer Using Same**

##### *Description of Technology:*

Microtubules are involved in a variety of cellular functions including motility, division, shape maintenance, and intracellular transport. Tubulin is the major protein component in microtubules, and interference with microtubule assembly leads to an increase of cells in metaphase arrest. Inhibition of microtubule function using tubulin targeted agents are widely used in the treatment of cancer.

This invention describes novel arylthioindole derivatives, 3-arylthioindole-2-carboxylic acid esters derivatives, having excellent affinity for tubulin and excellent efficacy as inhibitors of the growth of MCF-7 breast cancer cells. These new chemical compounds have the potential to result in more effective therapeutics for the treatment of neoplastic diseases.

**Applications:** Therapeutic for proliferative diseases such as cancer.

**Market:** 600,000 deaths from cancer related diseases estimated in 2006.

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

**Inventors:** Ernest Hamel (NCI) et al.

**Publications:**

1. G De Martino, MC Edler, G La Regina, A Coluccia, MC Barbera, D

Barrow, RI Nicholson, G Chiosis, A Brancale, E Hamel, M Artico, R Silvestri. New arylthioindoles: potent inhibitors of tubulin polymerization. 2. Structure-activity relationship and molecular modeling studies. *J Med Chem.* 2006 Feb 9;49(3):947-954.

2. G De Martino, G La Regina, A Coluccia, MC Edler, MC Barbera, A Brancale, E Wilcox, E Hamel, M Artico, R Silvestri. Arylthioindoles, potent inhibitors of tubulin polymerization. *J Med Chem.* 2004 Dec 2;47(25):6120-6123.

**Patent Status:** PCT Application No. PCT/US2005/035896 filed 05 Oct 2005 (HHS Reference No. E-323-2004/0-PCT-02).

**Licensing Availability:** Available for exclusive or non-exclusive licensing.

**Licensing Contact:** Jennifer Wong; 301/435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

Dated: March 2, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-4182 Filed 3-8-07; 8:45 am]

**BILLING CODE 4140-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **Clinical Center; Notice of Meeting**

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The 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:** NIH Advisory Board for Clinical Research.

**Date:** March 23, 2007.

**Time:** 10 a.m. to 2 p.m.

**Agenda:** To discuss progress of activities related to research opportunities, training, planning and funding in the NIH intramural clinical research program.

**Place:** National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4-2551, Bethesda, MD 20892.

**Contact Person:** Maureen E. Gormley, Executive Secretary, Mark O. Hatfield Clinical Research Center, National Institutes of Health, Building 10, Room 6-2551, Bethesda, MD 20892, 301/496-2897.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

Any interested person may file written comments with the committee by forwarding the statements 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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: March 2, 2007.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-1099 Filed 3-8-07; 8:45 am]

**BILLING CODE 4140-01-M**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Cancer Institute; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the President's Cancer Panel, February 12, 2007, 8 a.m. to February 12, 2007, 6 p.m., University of Mississippi, Medical Center, 2500 North State Street, Jackson, MS 39216 which was published in the **Federal Register** on January 11, 2007, 72 FR 1335.

Due to inclement weather, this meeting is amended to reschedule the closed session on February 12, 2007, 4 p.m.-6 p.m. to March 8, 2007, 11 a.m.-1 p.m. as a telephone conference. The meeting is closed to the public.

Dated: March 5, 2007.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-1109 Filed 3-8-07; 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