antiretroviral drugs in treatment-experienced patients with evidence of HIV–1 replication despite ongoing antiretroviral therapy. On September 6, 2007, the committee will be closed to permit discussion and review of trade secret and/or confidential information.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm, click on the year 2007 and scroll down to the appropriate advisory committee link.

**Procedure:** On September 5, 2007, from 8 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 21, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested for their presentation on or before August 14, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 13, 2007.

**Closed Committee Deliberations:** On September 6, 2007, from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will be asked to provide feedback on a Phase 3 protocol in the development of a new indication.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to disability, please contact Cicely Reese at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).


Randall W. Lutter, Deputy Commissioner for Policy.

**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 National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Compound Binding to the N-Terminal Domains of STAT Proteins as Therapeutic Agents**

Description of Technology: Signal transducer and activator transcription (STAT) proteins, specifically STAT1, 2, 3, 4, 5a, 5b, and 6, are involved in the cellular and biological processes of cell proliferation, differentiation, apoptosis, host defense, and transformation. Constitutively active STAT proteins may occur in many human tumor cells and cells transformed by oncogenes.

Inhibiting STAT proteins is advantageous in the treatment of certain cancers.

The current invention describes a family of short peptides that bind to the N-terminus of STAT proteins and use their as therapeutic agents. The current invention described here is the first inhibitors that can directly bind to N-domains of STAT proteins and exhibit a direct inhibitory effect. STAT1, 3, and 5 inhibitors can serve as potent therapeutic agents for the treatment of a variety of tumors and STAT 4 inhibitors can be used to control autoimmune diseases.

Applications and Modality: Other applications for this technology include using STAT1, STAT3 and STAT5 inhibitors for the treatment of various tumors; using STAT4 inhibitors to control autoimmune diseases; and using STAT inhibitors as research tools to study the function of STAT proteins.

Market: There were approximately 600,000 deaths from cancer related diseases estimated in 2006. In 2006, the cancer drug market was estimated to be $25 billion.

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

Inventors: Nadya I. Tarasova et al. (NCI).

**Benzotropine Analogs as Dopamine Transport Inhibitors**

Description of Technology: Dopamine is a neurotransmitter that is directly involved in motor activity, motivation and reward, and cognition. The dopamine transporter is expressed on the plasma membrane of dopamine neurons and is responsible for clearing dopamine released into the extracellular space, thereby regulating neurotransmission. The dopamine transporter plays a significant role in neuropsychiatric diseases, such as Parkinson’s disease, drug abuse (especially cocaine addiction), Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder (ADD/ADHD), narcolepsy and a number of other CNS disorders. Therefore, the dopamine transporter is a target for research and potential therapeutic treatments for the treatment of these indications.

Benzotropine and its analogs is an important class of dopamine transport inhibitors.
inhibitors that are indicated for the treatment of cocaine abuse and ADHD. They bind with high affinity to the dopamine transporter and block dopamine uptake, but generally do not produce behavioral effects comparable to those produced by cocaine. In animal models of drug abuse, many benzotropine analogs have been shown to (1) Reduce cocaine-induced locomotor stimulation, (2) have long-lasting effects, and (3) lack a significant abuse liability. This suggests they may be useful medications for the treatment of human diseases where dopamine-related behavior is compromised, especially in situations in which an (partial) agonist treatment is indicated.

However, some of the reported analogs have limited or poor solubility in aqueous systems or poor stability characteristics. To remedy this, the 3-position benzhydryl ether moiety of the benzotropine analogs was replaced with the isosteric benzhydrylamine system in order to reduce hydrolysis of the less stable ether function, observed in the benzotropine series, and further reduce lipophilicity to ultimately increase water solubility and bioavailability for improved therapeutic formulation and utility.

Inventors: Amy H. Newman et al. (NIDA).


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

Licensing Contact: Tara L. Kirby, Ph.D.; 301/435–4426; tarak@mail.nih.gov


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

[FR Doc. E7–13541 Filed 7–11–07; 8:45 am]

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.

Cyclic Phosphopeptide Inhibitors of Protein Phosphatase 2C Delta, Wip1

Description of Technology: This technology involves the development of specific peptides that can be used as anti-cancer agents, particularly as promoters of apoptosis. The inventors have modified the natural substrate of the Wip1 protein phosphatase in order to produce the inhibitors, allowing for specific and efficient inhibition of Wip1. These peptides represent the first Wip1 peptide inhibitors. The inhibitors can be combined with other pro-apoptosis therapeutics to improve patient survival, providing an advantage to previous pro-apoptosis approaches.

Wip1 (PP2Cdelta or PPM1D) is a protein phosphatase that negatively regulates cell-cycle arrest and apoptosis by preventing p53-mediated cell-cycle arrest and apoptosis. Wip1 is overexpressed in several human cancers, including breast cancer, ovarian clear cell adenocarcinoma and neuroblastoma, suggesting it may play an important role in oncogenesis. Inhibiting Wip1 may be a necessary step for inducing apoptosis and prohibiting tumor growth, accentuating the need for Wip1-directed therapies. Because these peptide inhibitors are the first specific Wip1 inhibitors, they represent the first opportunity to pursue this therapeutic strategy.

Applications: Applicable as anti-cancer therapeutics for a wide variety of tumors, including breast cancer, ovarian cancer, and neuroblastomas. Inhibitors can also be combined with other cancer therapeutics.

Advantages: Inhibitors are designed based on structural similarity to the native substrate, providing a high degree of specificity to the target. First inhibitors directed to Wip1 as a target for cancer therapy.

Benefits: Cancer is the second leading cause of death in the United States, with approximately 600,000 cancer-related deaths occurring in 2006 alone. Wip1 inhibitors may provide a social benefit by reducing that number or improving the quality/length of patient life. Furthermore, the cancer therapeutic market is expected to reach $27 billion by 2009. Because these molecules are the first inhibitors of Wip1, there is an opportunity to occupy a significant niche in that predicted market.


Licensing Contact: David A. Lambertson, Ph.D.; Phone: (301) 435–4632; E-mail: lambertsond@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute Center for Cancer Research, Laboratory for Cell Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Cyclic Phosphopeptide Inhibitors of Protein Phosphatase 2C Delta, Wip1. Please contact John D. Hewes, Ph.D. at 301/435–3121 or hewesj@mail.nih.gov for more information.

A Gene Therapy to Treat Lung Cancer

Description of Technology: This invention relates to the identification of a new tumor suppressor gene named Caliban from Drosophila melanogaster and Serologically determined colon cancer antigen gene 1 (Sdcag1) from humans. Sdcag1 is inactive in human lung cancer cells but active in normal lung cells. When full length Caliban or Sdcag1 is expressed in human lung cancer cells they lose their tumorigenicity. This suggests that Caliban/Sdcag1 could be used as both a therapeutic and diagnostic for cancer.

Applications: Using gene therapy to replace the inactive gene with full length Caliban/Sdcag1 to treat cancer(s). A diagnostic assay that can determine whether the tumor