antiretroviral agents in treatment-experienced patients with evidence of HIV–1 replication despite ongoing antiretroviral therapy. On September 6, 2007, the meeting 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 to make 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 its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to adisability, 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).

Dated: July 5, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–13560 Filed 7–11–07; 8:45 am]

BILLING CODE 4160–01–S

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.

Compounds 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 occur in many human tumor cells and cells transformed by oncoproteins. Inhibiting these STAT proteins has great therapeutic potential in the treatment of certain cancers.

The current invention describes a family of short peptides that bind to the N-terminus domains of STAT proteins and their use as therapeutic agents. These compounds are the first inhibitors that can directly bind to N-domains of STATs 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 disorders.

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 disorders; 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).

Relevant Publications: A manuscript directly related to the above technology will be available as soon as it is accepted for publication.

Patent Status: U.S. Provisional Application No. 60/940,916 filed 30 May 2007 (HHS Reference No. E–164–2007/0–US–01).

Licensing Status: Available for exclusive and non-exclusive license.

Licensing Contact: Adaku Nwachukwu, J.D.; 301/435–5560; *madua@mail.nih.gov*.

Benztropinamine 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 therapeutics for the treatment of these indications.

Benztropine and its analogs are an important class of dopamine transport

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 benztropine 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 benzhydrylether moiety of the benztropine analogs was replaced with the isosteric benzhydrylamine system in order to reduce hydrolysis of the less stable ether function, observed in the benztropine 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).

Publication: P Grundt; TA Kopajtic, JL Katz, AH Newman. N–8–substituted-benztropinamine analogs as selective dopamine transporter ligands. Bioorg Med Chem Lett. 2005 Dec 15;15(24):5419–5423.

Patent Status: U.S. Provisional Application No. 60/689,746 filed 10 Jun 2005 (HHS Reference No. E–089–2005/0–US–01); International Application No. PCT/US2006/22401 filed 07 Jun 2006, which published as WO 2006/135715 on 21 Dec 2006 (HHS Reference No. E–089–2005/0–PCT–02).

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

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

Dated: July 5, 2007.

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]

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, 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.

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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 strucural 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.

Inventors: Ettore Appella *et al.* (NCI).

U.S. Patent Status: U.S. Provisional Application No. 60/850,218 (HHS Reference No. E–288–2006/0–US–01).

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 (Sdccag1) from humans. Sdccag1 is inactive in human lung cancer cells but active in normal lung cells. When full length Caliban or Sdccag1 is expressed in human lung cancer cells they lose their tumorigenicity. This suggests that Caliban/Sdccag1 could be used as both a therapeutic and diagnostic for cancer.

Applications: Using gene therapy to replace the inactive gene with full length Caliban/Sdccag1 to treat cancer(s); A diagnostic assay that can determine whether the tumor