

Subject name	Address	Effective date
Howard-Love, Kimberly	Springfield, OH	10/20/2005
Marder, Charles	Plano, TX	10/20/2005
Mikolinnas, Thomas	Worcester, MA	9/22/2005
Slusher, Kevin	Shreveport, LA	10/20/2005
Zimmerman, Seth	Port Washington, NY	10/20/2005

Dated: October 6, 2005.

Katherine B. Petrowski,

Director, Exclusions Staff, Office of Inspector General.

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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, 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.

N- and 2-Substituted Benztropine Compounds and Use Thereof for Treating Mental Disorders

Amy H. Newman et al. (NIDA)

U.S. Provisional Application filed 24 Aug 2005 (HHS Reference No. E-234-2005/0-US-01).

Licensing Contact: Marlene Shinn-Astor; 301/435-4426; shinnm@mail.nih.gov.

Dopamine is a neurotransmitter that exerts important effects on locomotor activity, motivation and reward, and cognition. The dopamine transporter (DAT) is expressed on the plasma membrane of dopamine synthesizing neurons. It is responsible for clearing

dopamine released into the extracellular space, thereby regulating neurotransmission. The dopamine transporter plays a significant role in neurotoxicity and human diseases, such as Parkinson's disease, drug abuse (especially cocaine addiction), Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder (ADD/ADHD), and a number of other CNS disorders. Therefore, the dopamine transporter is a strong target for research and the discovery of potential therapeutics for the treatment of these indications.

Benztropine and its analogs bind with high affinity to the DAT and inhibit dopamine reuptake, but generally do not produce behavioral effects comparable to those produced by cocaine. Recent benztropine analogs have been shown to (1) reduce cocaine-induced stimulant effects, (2) retain long-lasting actions, and (3) lack significant abuse liability. These data suggest that this class of compounds may be useful medications for human diseases where dopamine-related behavior is compromised, especially in situations in which an agonist treatment is indicated.

Although the benztrropines bind with high affinity to the DAT without substitution in the 2-position of the tropane ring, only a substituent in the S-configuration is tolerated at DAT, in direct contrast to cocaine and its analogs that must have the 2-position substituent in the R-configuration. In this invention, substitution at the S-2-position of 4',4"-difluoro-or 4',4"-dichlorobenztrropines with various functional groups such as alkyl, aryl, alkyl, alcohol, ether, etc., as well as substitution at the tropane nitrogen were achieved and have demonstrated high affinity and selectivity for the DAT over the other monoamine transporters as well as muscarinic receptors, without a significant cocaine-like behavioral profile.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Novobiocin Analogues as Anticancer Agents

Leonard M. Neckers (NCI) et al.

U.S. Provisional Application No. 60/624,566 filed 03 Nov 2004 (HHS Reference No. E-065-2005/0-US-01).
Licensing Contact: George Pipia; 301/435-5560; pipiag@mail.nih.gov.

Functional Hsp90 requires C-terminal homodimerization of two molecules of Hsp90. Novobiocin competes with ATP for binding to the C-terminus and studies demonstrated that this binding results in degradation of Hsp90 protein through ubiquitination and ultimately transportation to proteasome for proteolysis. Twenty three analogs of novobiocin were prepared and screened for their activity against Hsp90 and the most active derivatives were identified. Novobiocin was previously identified as an inhibitor of type II topoisomerases and has been used clinically for more than a decade for the treatment of cancer. However recent studies have shown that novobiocin selectively inhibits the maturation of Hsp90 dependent proteins. In addition to its effect on Hsp90, novobiocin has been shown to reverse drug resistance and increase the intracellular concentration of topoisomerase II drugs such as Etoposide and tubulin binding drugs, such as Taxol, making cells more susceptible to chemotherapeutics and induction of apoptosis.

This research is described, in part, in: Yu XM, Shen G, Neckers L, Blake H, Holzbeierlein J, Cronk B and Blagg BSJ. "Hsp90 Inhibitors Identified from a Library of Novobiocin Analogues," *J. Am. Chem. Soc.*, in press.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Anticancer Effects of Novel Vitamin D Receptor Antagonists

Julianna Barsony (NIDDK)

U.S. Provisional Application No. 60/300,409 filed 22 Jun 2001 (HHS Reference No. E-213-2001/1-US-01).
PCT Patent Application No. PCT/US02/19774 filed 20 Jun 2002 (HHS Reference No. E-213-2001/2-PCT-01).

U.S. Patent Application No. 10/481,052 filed 16 Dec 2003 (HHS Reference No. E-213-2001/2-US-02).

Licensing Contact: Mojdeh Bahar; 301/435-2950; baharm@mail.nih.gov.

The present invention relates to cancer therapeutics. Specifically, this invention relates to novel selective vitamin D receptor modulators (SEDM), also known as vitamin D receptor antagonists. Methods of treatment resulting in inhibition of cell growth, inducement of cell differentiation, inhibition of breast cancer growth, and inhibition of parathyroid hormone secretion in mice are disclosed.

Vitamin D does not have significant biological activity. Rather, it must be metabolized within the body to its hormonally active form, calcitriol. Calcitriol acts through the vitamin D receptor (VDR) to regulate important functions, such as calcium homeostasis, cell proliferation and differentiation, and immune functions. Many cancers contain VDR and, therefore respond to calcitriol. In such cancers, low concentrations of calcitriol stimulate growth and high concentrations inhibit growth. High doses of calcitriol and calcitriol analogues, however, cause hypercalcemia, limiting the use of this hormone for cancer treatment.

The present invention relates to derivatives of calcitriol that have been synthesized in a manner similar to the principles developed to create estrogen receptor modulators (SERM). These vitamin D receptor modulators bind well to VDR, inhibit their ability to stimulate cancer cell growth and increase their ability to induce cell differentiation. In mice, SEDM inhibited human breast cancer growth without causing hypercalcemia. The technology disclosed herein may also be used for the prevention of breast cancer, treatment and/or prevention of other types of conditions or diseases, such as, but not limited to, prostate, colorectal, and lung cancers, leukemia, primary or metastatic melanoma, glyoma, and parathyroid diseases.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Zebularine, A Stable and Orally Active Inhibitor of Cytosine DNA Methyltransferase Capable of Reactivating Dormant Tumor Suppressor and Inhibiting Tumor Growth

Victor E. Marquez (NCI) et al.

U.S. Provisional Application No. 60/309,242 filed 31 Jul 2001 (HHS Ref. No. E-081-2001/0-US-01).

U.S. Provisional Application No. 60/311,435 filed 10 Aug 2001 (HHS Ref. No. E-081-2001/1-US-01).

PCT Application No. PCT/US02/24223 filed 30 Jul 2002, which published as WO 03/012051 on 13 Feb 2003 (HHS Ref. No. E-081-2001/2-PCT-01).

U.S. Patent Application No. 10/485,438 filed 30 Jan 2004 (HHS Ref. No. E-081-2001/2-US-06).

Licensing Contact: John Stansberry; 301/435-5239; stansbej@mail.nih.gov.

DNA methyltransferases (also referred to as DNA methylases) transfer methyl groups from the universal methyl donor S-adenosyl methionine to specific sites on a DNA molecule. When gene sequences contain many methylated cytosines, they are less likely to be expressed. Several such 'silenced' genes are now known to be an important contributing factor in many cancers where expression of tumor suppressor genes has been suppressed. Preventing DNA methyltransferase production, or inhibiting the enzyme, may allow tumor suppressor genes that have been silenced by hypermethylation to be re-activated. Re-activation of tumor suppressor genes is intended to stop or slow tumor growth by restoring growth control mechanisms. Thus, there exists a need for an effective and stable inhibitor of DNA methylation.

The inventors have discovered a potent inhibitor of DNA methylation (Zebularine) that can specifically reactivate silenced tumor suppressor genes. This agent can be used to inhibit methylation and thereby combat certain cancers that have been linked to hypermethylation. This agent has also been shown in initial animal testing to be active orally and is more stable than some other agents in this same area of therapy and is a suitable candidate for further pre-clinical and clinical development as an anti-cancer agent to be used as monotherapy and/or as an adjunct to existing anti-cancer therapeutics.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Compositions and Methods of Specifically Targeting Tumors

Dr. Raj K. Puri (FDA) et al.

U.S. Patent No. 6,428,788 issued 06 Aug 2002 (HHS Reference No. E-266-1994/1-US-01).

Licensing Contact: Jesse S. Kindra; 301/594-4697; kindraj@mail.nih.gov.

A chimeric molecule that binds specifically to IL-13 receptors has been identified. The molecule, IL13-PE38QQR, targets tumor cells with less binding to healthy cells. The improved specific targeting of this molecule is premised upon the discovery that tumor cells overexpress IL-13 receptors at extremely high levels and that binding of IL-13-PE38QQR can be blocked to IL-4 receptors in normal cells. This phenomenon permits the use of lower dosages of chimeric molecules along with IL-4 receptor blocker to deliver effector molecules to targeted tumor cells.

This invention may be useful in the treatment of cancer. The targeting method could be used in conjunction with current methods, *e.g.*, chemotherapy to help maintain the healthy cells. To date, IL13-PE38QQR has been shown to be effective against a variety of solid tumor cancers in animal models including adenocarcinoma, brain cancer and AIDS associated Kaposi's sarcoma.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

1,2-Dihydroellipticines with Activity Against CNS-Specific Cancer Cell Lines

Rudiger D. Haugwitz (NCI) et al.

U.S. Patent No. 5,272,146 issued 21 Dec 1993 (HHS Reference No. E-110-1992/0-US-01).

U.S. Patent No. 5,441,941 issued 15 Aug 1995 (HHS Reference No. E-110-1992/0-US-02).

Licensing Contact: George G. Pipia; 301/435-5560; [pipia@mail.nih.gov](mailto:pipiag@mail.nih.gov).

The present invention is directed, in general, to methods for treating human cancers and in particular to new compounds which cross the blood brain barrier and retain activity against CNS specific cancer cell lines, to pharmaceutical formulations containing such compounds, and to methods for the treatment of cancer.

This research is described, in part, in Jurayj *et al.*, "Design and Synthesis of Ellipticinium Salts and 1,2-Dihydroellipticines with High Selectivities against Human CNS

Cancers in vitro," J. Med. Chem. 37(4):2190-2197, 1994.

Dated: October 10, 2005.

Steven M. Ferguson,

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

[FR Doc. 05-21010 Filed 10-19-05; 8:45 am]

BILLING CODE 4140-01-P

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 552b(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 Review of Conference Grants (R13s)

Date: November 8-9, 2005.

Time: 8 a.m. to 8 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call)

Contact Person: Deborah P. Beebe, Director, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, NIH, Two Rockledge Center, Room 1700, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435-0260, beebed@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.937, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 11, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-21020 Filed 10-19-05; 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 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 Review of Research Project (Cooperative Agreement) Applications

Date: November 15, 2005.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Shelley S. Sehnert, PhD, Scientific Review Administrator, Review Branch, NIH/NHLBI, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892-7924, 301/435-0303, ssehnert@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Review of Research Project Grant Applications (R01s)

Date: November 17, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: YingYing Li-Smerin, PhD, MD, Scientific Review Administrator, Division of Extramural Affairs, Review Branch, National Heart, Lung, and Blood Institute, NIH, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20814, 301/435-0275, lismerein@nhlbi.nih.gov.

(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 Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 11, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-21022 Filed 10-19-05; 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 552b(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: Heart, Lung, and Blood Initial Review Group.Heart, Lung, and Blood Program Project Review Committee.

Date: December 1, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Jeffrey H. Hurst, PhD, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute/NIH, 6701 Rockledge Drive, RM 7208, Bethesda, MD 20892, (301) 435-0303, hurstj@nhlbi.nih.gov.

(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 Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 11, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-21024 Filed 10-19-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 meetings.