

from the public. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:**

Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 19, 2006, FDA announced that a meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee would be held on June 2, 2006, from 8:30 a.m. to 3:30 p.m. On page 20111, in the second and third columns, the *Procedure* portion is amended to read as follows:

*Procedure:* 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 May 19, 2006. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of the committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. 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 May 19, 2006.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: May 18, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E6-8088 Filed 5-25-06; 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.

**Tetrahalogenated Compounds Useful as Inhibitors**

*Description of Technology:* Cancer is the second leading cause of death in United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2006. A major drawback of the existing chemotherapies is the cytotoxic side-effects that are associated with them. Thus, there is a need to develop new therapeutic approaches with reduced side-effects.

Anti-angiogenic therapy is a recent approach in cancer therapeutics targeting the formation of blood vessels that are necessary for tumor growth. Recently, the anti-angiogenic molecule bevacizumab (Avastin) has gained approval from the FDA for the first-line treatment of metastatic colon cancer in combination with standard chemotherapy. Another promising anti-angiogenic molecule is thalidomide. Thalidomide has been approved as an anti-cancer agent and for other use in Europe and Australia. However, its use as a drug has been limited by its effect as a teratogen, necessitating the development of new thalidomide analogs with improved efficacy and reduced toxicity.

This technology describes synthesis of several tetrahalogenated thalidomide derivatives that are potentially more anti-angiogenic than thalidomide. More specifically, two series of analogs based on two major common pharmacophores have been synthesized. One series preserves the thalidomide common structure, while the other series contains a different common structure

(tetrafluorobenzamides). Several analogs from both series have shown significant anti-angiogenic properties, *in vitro*. This technology has therapeutic potential for a broad spectrum of cancer related diseases alone, or in combination with existing therapies.

*Applications:* Novel tetrahalogenated thalidomide analogs containing the thalidomide pharmacophore with improved anti-angiogenic activity; Novel tetrahalogenated thalidomide analogs containing a different common structure (tetrafluorobenzamides) with considerable anti-angiogenic activity; Use of the compounds for the treatment of several cancers; Use of the compounds for the treatment other diseases including autoimmune diseases.

*Market:* 600,000 deaths from cancer related diseases estimated in 2006. The technology platform involving novel anti-angiogenic small molecule cancer therapy technology has a potential market of more than 2 billion U.S. dollars. The technology platform has additional market in treating several other clinical problems such as autoimmune diseases.

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

*Inventors:* William D. Figg (NCI), Erin Lepper (SAIC), *et al.*

*Publications:*

SS Ng *et al.*, "Antitumor effects of thalidomide analogs in human prostate cancer xenografts implanted in immunodeficient mice," *Clin Cancer Res.* 2004 Jun 15; 10 (12 Pt 1):4192-7.

WL Dahut *et al.*, "Randomized phase II trial of docetaxel plus thalidomide in androgen-independent prostate cancer," *J Clin Oncol.* 2004 Jul 1; 22 (13): 2532-9.

S Kumar *et al.*, "Antimyeloma activity of two novel N-substituted and tetrafluorinated thalidomide analogs," *Leukemia* 2005 Jul; 19 (7):1253-61.

*Patent Status:* U.S. Provisional Application filed 13 Apr 2006 (HHS Reference No. E-080-2006/0-US-01).

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

*Licensing Contact:* David A. Lambertson, PhD.; 301-435-4632; [lambertson@od.nih.gov](mailto:lambertson@od.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Center for Cancer Research, Medical Oncology Branch, Molecular Pharmacology Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize tetrafluorinated compounds as anti-cancer therapeutics.

Please contact Dr. W. Figg at 301-402-3623 for more information.

### Anti-Notch-1 Monoclonal Antibodies for Inducing Cellular Differentiation and Apoptosis

*Description of Technology:* As cancer cells progress towards more aggressive forms, they often become highly resistant to drug or radiation-induced apoptosis, generally through the loss of function p53, a gene which can trigger apoptosis in response to DNA damage. Thus, novel strategies to induce apoptosis in tumor cells, especially p53-deficient cells, is an attractive and an active area of research.

Using a model constituted by a p53-deficient mouse leukemia cell line, PHS scientists found that: (1) Antisense synthetic DNA oligonucleotides and stable incorporation of an antisense gene (a model for gene therapy) targeting notch-1, when given together with a differentiation-inducing antitumor drug, cause the cells to respond by massive apoptosis rather than differentiation; (2) stable incorporation of an antisense notch-1 gene increases apoptosis in these cells even in the absence of any antitumor drugs. This suggests that antisense Notch-1 treatment, by antisense oligonucleotides or by gene therapy, may be used alone or together with anti-cancer drugs to cause apoptosis in tumor cells.

This invention provides compositions, pharmaceutical compositions, and methods for stimulating/increasing cell differentiation, and is particularly related to the treatment of tumors which have increased Notch-1 expression. A polyclonal and/or monoclonal antibody generated against human Notch-1 Epidermal Growth Factor ("EGF") that recognizes an extracellular epitope of Notch-1 and that stimulates target cell differentiation in the presence of a differentiation inducing agent is disclosed as is the hybridoma which produces these antibodies.

*Inventors:* Lucio L Miele and Chana Y. Fuchs (FDA).

*Patent Status:* PCT Application No. PCT/US99/23162 filed 01 Oct 1999, which published as WO 00/20576 on 13 Apr 2000 (HHS Reference No. E-176-1998/1-PCT-01); U.S. Patent Application No. 11/069,208 filed 28 Feb 2005, claiming priority to 02 Oct 1998 (HHS Reference No. E-176-1998/1-US-08).

*Licensing Contact:* David A. Lambertson, PhD.; 301-435-4632; [lambertsond@od.nih.gov](mailto:lambertsond@od.nih.gov).

### Novel Bis-Acridones as Anti-Tumor Agents: Potential for Treating Drug Resistant Tumors

*Description of Technology:* Cancer is the second leading cause of death in United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2006. Current chemotherapies are mostly based on the use of small molecules. A major drawback of these existing chemotherapies is the acquired or inherent resistance of certain tumors against these drugs. Treating resistant tumors has been a major challenge in the successful management of cancer, necessitating the development of new therapies to treat resistant tumors and thus expanding the life expectancy of cancer patients.

The present invention discloses novel derivatives of Bis-acridones and related molecules and their pharmaceutically acceptable salts and their use as anti-tumor agents. Some of the derivatives have high anti-tumor activity both *in vitro* and *in vivo*. In addition to its anti-tumor activity these above mentioned compounds have been shown to be potent irreversible inhibitors of P-glycoprotein, a member of the ABC transporter protein family that has a major role in conferring multi-drug resistance. Therefore, these compounds have the potential of being used in combination with traditional chemotherapy to treat drug resistant tumors. In addition, to its anti-neoplastic property some of the derivatives of this family of compounds have been shown to have anti-HIV property.

*Inventors:* Christopher J. Michejda *et al.* (NCI).

*Publications:*

WM Cholody *et al.*, "Bisimidazoacridones and related compounds: New antineoplastic agents with high selectivity against colon tumors," *J Med Chem.* 1995 Aug 4; 38 (16): 3043-52.

JA Turpin *et al.*, "Inhibition of acute-, latent-, and chronic-phase human immunodeficiency virus type 1 (HIV-1) replication by a bistriazoloacridone analog that selectively inhibits HIV-1 transcription," *Antimicrob Agents Chemother.* 1998 Mar; 42 (3):487-94.

*Patent Status:* U.S. Patent No. 5,508,289 issued 16 Apr 1996 (HHS Reference No. E-106-1994/0-US-01); European Patent No. 0750612 issued.

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

*Licensing Contact:* Michelle A. Booden, PhD.; 301-451-7337; [boodenm@mail.nih.gov](mailto:boodenm@mail.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Center for Cancer Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize certain derivatives of Bis-acridones and related molecules as well as their pharmaceutically acceptable salts as anti-tumor agents. Please contact Kathy Higinbotham at 301-846-5465 or [higinbok@mail.nih.gov](mailto:higinbok@mail.nih.gov) for more information.

Dated: May 19, 2006.

**David R. Sadowski,**

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

[FR Doc. E6-8167 Filed 5-25-06; 8:45 am]

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#### Antibodies That Specifically Recognize S100A15, a Protein Involved in Epidermal Differentiation and Inflammation

*Description of Technology:* This technology describes rabbit polyclonal antibodies that recognize the human and mouse S100A15 proteins. S100A15 is involved in epidermal differentiation