

• *Do not express the HLA-A2 allele:* A majority of the cancer vaccines and immunotherapies developed to date have focused on utilizing HLA-A2 restricted tumor epitopes since this HLA allele is largely expressed in the human population. However, therapies restricted to HLA-A2 recognition will not be successful in RCC patients that do not express this allele. For these RCC patients, additional therapies are needed that are directed against epitopes presented by different HLA alleles.

Inventors: Ken-ichi Hanada, Qiong J. Wang, James C. Yang (NCI).

Related Publication: K Hanada *et al.* Identification of fibroblast growth factor-5 as an overexpressed antigen in multiple human adenocarcinomas. *Cancer Res.* 2001 Jul 15;61(14):5511–5516.

Patent Status: HHS Reference No. E-005-2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Samuel E. Bish, Ph.D.; 301-435-5282; bishse@mail.nih.gov.

Small-Molecule Inhibitors of Angiogenesis

Description of Technology: Angiogenesis, the growth of new blood vessels from existing vessels, is a normal and vital process in growth and development. Deregulation of angiogenesis plays a role in many human diseases, including cancer, age-related macular degeneration, diabetic retinopathy, and endometriosis.

NCI investigators have used a cell-based high-throughput screening method to identify a set of anti-angiogenic small molecules. These compounds are highly active, inhibiting both endothelial cell growth and tube formation, and are not cytotoxic. Structure-activity relationship analysis has revealed that these compounds are unrelated to known anti-angiogenic compounds, and hence may operate through a novel mechanism of action. Thus, these compounds would be promising candidates for the development of new anti-angiogenesis therapeutics.

Applications: Development of new anti-angiogenesis therapeutics.

Advantages: These compounds are structurally unrelated to other known anti-angiogenesis compounds, and exhibit high activity without cytotoxicity.

Development Status: *In vivo* studies using xenograft models are underway.

Inventors: Enrique Zudaire Ubani *et al.* (NCI).

Publication: In preparation.

Patent Status: HHS Reference No. E-263-2009/0—U.S. Provisional Application No. 61/230,667 filed 31 Jul 2009.

Related Technology: HHS Reference No. E-281-2007/0—Multicolored Fluorescent Cell Lines for High-Throughput Angiogenesis and Cytotoxicity Screening.

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute Angiogenesis Core Facility is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a new set of non-cytotoxic antiangiogenic small molecules. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Identification of Colorectal Cancer Biomarkers by Serum Protein Profiling

Description of Technology: This invention describes serum features that distinguish colorectal carcinoma malignant patient samples versus healthy samples using surface-enhanced laser desorption ionization time-of-flight (SELDI-TOF) mass spectrometry. By comparing healthy versus malignant samples, the investigators were able to identify thirteen (13) serum features that have been validated using an independently collected, blinded validation set of 55 sera samples. The features are characterized by the mass to charge ratio (*m/z* ratio). The investigators have shown that SELDI-TOF based serum marker protein profiling enables minimally invasive detection of colon cancer with 96.7 percent sensitivity and 100 percent specificity.

Colorectal cancer is the third most common cancer and the third leading cause of cancer-related mortality in the United States. Current diagnostic methods for colorectal cancer have a large non-compliance rate because of discomfort, *e.g.*, sigmoidoscopy or colonoscopy, or have a high rate of false positive results, *e.g.*, fecal occult blood tests. The claimed invention has the potential to be a widely used, easy-to-use, and inexpensive diagnostic.

Inventors: Thomas Ried and Jens Habermann (NCI).

Patent Status: U.S. Patent Application No. 11/886,886 filed 21 Sep 2007 (HHS Reference No. E-106-2005/0-US-03).

Licensing Status: Available for licensing.

Licensing Contact: Surekha Vathyam, Ph.D.; 301-435-4076; vathyams@mail.nih.gov.

Dated: December 2, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9-29250 Filed 12-7-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of November 17, 2009 (74 FR 59195). The amendment is being made to reflect a change in the *Date and Time, Agenda*, and *Procedure* portions of the document. We also are cancelling a session regarding supplemental new drug application (sNDA) 022-059/S-007, TYKERB (lapatinib) tablets, by SmithKline Beecham Ltd. d/b/a GlaxoSmithKline. This portion of the meeting has been cancelled because the issues for which FDA was seeking the scientific input of the Committee have been resolved.

FOR FURTHER INFORMATION CONTACT:

Nicole Vesely, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-6793, FAX: 301-827-6776, e-mail: nicole.vesely@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 2009 (74 FR 59195), FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on December 16, 2009. On page 59195, in the first column, the *Date and Time* portion of the document is changed to read as follows:

Date and Time: The meeting will be held on December 16, 2009, from 9 a.m. to 3 p.m.

On page 59195, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: On December 16, 2009, the committee will discuss supplemental new drug application (sNDA) 021-743/S-016, TARCEVA (erlotinib) tablets, by OSI Pharmaceuticals, Inc. The proposed indication (use) for this product is first-line maintenance, monotherapy (first-choice, single drug) treatment in patients with a form of lung cancer called non-small cell lung cancer (NSCLC) that is either locally advanced (has spread regionally within the lung and/or within chest lymph nodes) or metastatic (has spread beyond the lung), and who have not progressed (including those patients with stable disease) on first-line treatment with platinum-based chemotherapy (a regimen including a platinum drug (cisplatin or carboplatin) plus another chemotherapy drug).

On page 59195, in the third column, the third sentence in the *Procedure* portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m.

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: December 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-29208 Filed 12-7-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Life Support Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 28, 2010, from 8 a.m. to 4:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel telephone number is 301-977-8900.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail:

Kalyani.Bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in Washington, DC area), code 3014512529. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 28, 2010, the committee will discuss the available safety and efficacy data for new drug application (NDA) 22516, CYMBALTA (duloxetine HCL) Capsules, by Eli Lilly and Co., as they relate to the proposed indication of treatment of chronic pain.

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/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

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 January 13, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 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 January 5, 2010. 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 January 6, 2010.

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 a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: December 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-29211 Filed 12-7-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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.