[FR Doc. E9–29248 Filed 12–7–09; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of the Soy Formula Expert Panel Meeting: Amended Notice

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Availability of telephone conferencing and extension of registration period.

SUMMARY: The CERHR announces the availability of a teleconference line to allow presentation of oral comments at the expert panel meeting on December 16–18, 2009, at the Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA. Information regarding the soy formula expert panel meeting was announced in the **Federal Register** (74 FR 53508) published on October 19, 2009, and is available on the CERHR Web site (*http://cerhr.niehs.nih.gov*). The guidelines and deadlines published in this **Federal Register** notice still apply, except that the deadline for registering to attend or to present oral comments by telephone is now December 11, 2009.

DATES: The expert panel meeting for soy formula will be held on December 16–18, 2009, and convene each day at 8:30 a.m. EST. Persons wishing to attend are asked to register by December 11, 2009, via the CERHR Web site (*http://cerhr.niehs.nih.gov*). Time is set-aside at the expert panel meeting on December 16, 2009, for oral public comments. Individuals wishing to make oral public comments are asked to register online (*http://cerhr.niehs.nih.gov*) or contact Dr. Kristina A. Thayer, CERHR Acting Director, by December 11, 2009, and if possible, send a copy of the statement at that time.

ADDRESSES: The meeting will be held at the Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA. Access to on-line registration to either attend the meeting in person or participate by teleconference line is available on the CERHR Web site (*http://cerhr.niehs.nih.gov*). Public comments and any other correspondence should be submitted to Dr. Kristina A. Thayer, CERHR Acting Director, NIEHS, P.O. Box 12233, Mail Drop K2–04, Research Triangle Park, NC 27709 (mail), 919–541–5021 (telephone), or *thayer@niehs.nih.gov* (e-mail). Courier address: NIEHS, 530 Davis Drive, Room K2154, Morrisville, NC 27560.

FOR FURTHER INFORMATION CONTACT: Dr. Kristina A. Thayer (telephone: 919–541–5021 or e-mail: *thayer@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION:

Teleconferencing

To allow greater public participation at the soy formula expert panel meeting, the NTP will provide a teleconference line to access the public comment session of the meeting. The NTP has reserved a limited number of telephone lines for this call and access availability will be on a first-come, first-served basis. Individuals interested in participating in the meeting by teleconference line must register by December 11, 2009. Those registering to present oral comments by telephone will be provided the access number prior to the meeting. The formal public comment period is scheduled for December 16, 2009, at approximately 9 a.m. until 10 a.m. EST. Oral public comments should not exceed 7 minutes in length and each organization is allowed only one comment slot (in person or by telephone). Every effort will be made to accommodate the public, but the total time allotted for oral comments and the time allotted per speaker by telephone will depend on the number of people who register online to speak. In addition, teleconference participants are encouraged to send a copy of their oral statement or talking points, which can supplement and/or expand the oral presentation, for distribution at the meeting and for the meeting record.

Dated: December 1, 2009.

John R. Bucher,

Associate Director, National Toxicology Program.

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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.

Human Renal Cell Carcinoma (RCC) Cell Lines Derived From Surgically Removed Tumors

Description of Technology: Scientists at the National Institutes of Health (NIH) have developed three cell lines obtained from renal cell carcinoma (RCC) patients. The cell lines, designated 1581 RCC, 1764 RCC, and 2194 RCC, were derived from human tumor samples surgically resected from patients in the inventors' clinic. Each cell line is human leukocyte antigen-A2 (HLA–A2) negative and expresses a variety of known tumor antigens. The 1764 RCC cell line is known to express the HLA–A3 antigen and high levels of nonmutated fibroblast growth factor 5 (FGF–5). These cell lines can be widely used in molecular biology for various assays and to screen for potential therapeutics with activity against RCC. The RCC cell lines can also serve as negative control samples for HLA–A2 expression.

Applications:

- Research tools for examining the common and diverse biological and pathological features of RCC from different patients *in vitro.*
- Research tools for testing the activity of potential anti-cancer drugs against RCC.
- Source for mRNA and protein antigens expressed in kidney cancer.
- Negative control cell lines for HLA–A2 expression in molecular biology.
- Possible starting material for developing a cancer vaccine against RCC.

Advantages:

- *Cell lines are derived directly from RCC patient samples:* These cell lines are anticipated to retain many features of primary RCC samples. Studies performed using these cell lines may have a direct correlation to the initiation, progression, treatment, and prevention of RCC in humans.

• *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]

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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: