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.

Novel Inhibitors of Interleukin-6 for Kaposi Sarcoma Therapy

Description of Invention: The cancer therapy market is forecast to reach $40.9 billion by 2012. With immunosuppressant drugs set for phenomenal growth over the next six years, revenues could reach $26.2 billion by 2014. One market for which there is a significant need for new therapies is cancers induced by Kaposi Sarcoma-associated Herpesvirus (KSHV).

Researchers at the National Cancer Institute have identified novel nucleic acid sequences that act through a unique mechanism to inhibit the expression of interleukin-6 that occurs in cancerous cells transformed by KSHV infection and which promotes cancer cell proliferation. The researchers have also identified a key protein involved in the mechanism which could be inhibited using antibodies.

These inhibitors are likely to be accepted in the marketplace because their unique specificity in mechanism of action gives them a distinct advantage over the mechanisms of other existing therapies.

Applications:

- Therapies for KSHV-induced cancers (Kaposi sarcoma (KS), primary effusion lymphoma (PEL)) and multicentric Castleman disease (MCD).
- Therapies for KSHV infection.
- Therapies for interleukin-6 associated inflammatory diseases.
- Immunosuppression of interleukin-6.

Advantages:

- Utilizes available small-molecule and antibody technologies.
- Targets a key pathway in interleukin-6 production.
- Specificity of mechanism of action may reduce/limit potential side-effects.

Development Status: Pre-clinical.

Inventors: Zhi-Ming Zheng and Jeong-Gu Kang (NCI).

Relevant Publication: JG Kang et al. KSHV infection induces IL6 expression by interrupting microRNA-mediated translational repression. *Submitted.*

Patent Status: U.S. Provisional Application No. 61/241,678 filed 11 Sep 2009 (HHS Reference No. E–296–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The NCI Center for Cancer Research, HIV and AIDS Malignancy Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Prediction of Immune Response Outcomes to Keyhole Limpet Hemocyanin (KLH) Treatment

Description of Invention: Keyhole limpet hemocyanin (KLH) is a large, heterogeneous glycosylated protein that is being tested as an immunotherapeutic agent to treat bladder cancer. KLH is approved for use in parts of Europe and Asia and is in late stage clinical trials in the U.S. KLH immunotherapy however only produces a clinical response in approximately 40–50% of patients, and currently there is no good method to select the subset of patients that will respond best to this treatment. This invention revealed that levels of certain serum antibodies can be used as biomarkers to predict the magnitude of the antibody response to the glycoprotein KLH. The best correlations are obtained by using a combination of markers. Since the size of the antibody response correlates with the clinical response, the invention provides a method to select the subset of patients that may benefit most from this form of treatment.

Applications and Market:

- It is estimated that 70,980 men and women will be diagnosed with and 14,330 men and women will die of cancer of the urinary bladder in 2009;
- Biomarkers for immune response outcomes to keyhole limpet hemocyanin (KLH);
- Patient selection based on prediction of response.

Development Status: Pre-clinical stage of development.

Inventors: Jeffrey C. Gildersleeve and Oyindasola Oyelaran (NCI).

Publications: Manuscript accepted, *Proteomics—Clinical Applications.*

Patent Status: U.S. Provisional Application No. 61/243,849 filed 18 Sep 2009, (HHS Reference No. E–295–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*

Collaborative Research Opportunity: The NCI Center for Cancer Research, Laboratory of Medicinal Chemistry, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a set of serum antibody-based biomarkers for personalized cancer immunotherapy using keyhole limpet hemocyanin (KLH). Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: October 26, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–26313 Filed 10–30–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Gastroenterology and Urology Devices Panel of the Medical Devices 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: Gastroenterology and Urology Devices Panel of the Medical Devices 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 December 11, 2009, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Megan M. Mickal, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301–796–5590, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512523. 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 hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 11, 2009, the committee will discuss and make recommendations on the study designs and endpoints of clinical investigations intended to support approval or clearance of devices indicated for the primary treatment of localized prostate cancer.

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 December 1, 2009. 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 November 23, 2009. 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 November 24, 2009.

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 AnnMarie Williams, Conference Management Staff, 301–796–5966, 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: October 27, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26259 Filed 10–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Ear, Nose, and Throat Devices Panel of the Medical Devices 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: Ear, Nose, and Throat Devices Panel of the Medical Devices 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 December 18, 2009, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: James K. Kane, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6477, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512522. 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 hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 18, 2009, the committee will discuss, make recommendations, and vote on a premarket approval application, sponsored by Envoy Medical Corporation, for the Esteem Totally Implantable Hearing System. The ESTEEM is a totally implantable hearing device that is implanted in the middle ear to help hearing in patients suffering from mild to severe hearing loss that is sensorineural in origin. The Esteem System consists of three implantable components (Sound Processor, Sensor, and Driver), two external programmers (Esteem Programmer and Personal Programmer), an external Intraoperative System Analyzer (ISA) and accessories. The intended use of the ESTEEM is to alleviate hearing loss in adults by replicating the ossicular chain and providing additional gain.

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 December 8, 2009. 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 November 30, 2009. Time allotted for each presentation may be