a. Adult patients for whom therapy with an IV agent is clinically appropriate, based upon one or more of the following reasons:
(i) patient not responding to either oral or inhaled antiviral therapy, or
(ii) drug delivery by a route other than IV (e.g., enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible, or
(iii) the clinician judges IV therapy is appropriate due to other circumstances.
b. Pediatric patients for whom an IV agent is clinically appropriate because:
(i) patient not responding to either oral or inhaled antiviral therapy, or
(ii) drug delivery by a route other than IV (e.g., enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible).

C.5. Health Care Providers will ensure that patients with known or suspected renal insufficiency have creatinine clearance determined prior to peramivir dose calculation and first administration. (See Fact Sheet For Health Care Providers; Dosage and Administration for Impaired Renal Function Dosing).

C.6. Health Care Providers prescribing and/or administering authorized peramivir will ensure that patients with history of severe allergic reaction to any other neuraminidase inhibitor (zanamivir or oseltamivir) or any ingredient of peramivir will not receive authorized peramivir. (See Fact Sheet for Health Care Providers; Product Description.)

C.7. Health Care Providers will only make available additional written information relating to the emergency use of authorized peramivir to the extent that it is consistent with and does not exceed the terms of this letter of authorization (including the facts sheets referenced in Section II of this letter).

C.8. Heath Care Providers will make available to FDA and/or CDC upon request any records maintained in connection with this letter. Upon request, Health Care Providers will report to FDA and/or CDC information with respect to the emergency use of authorized peramivir.

D. BioCryst

D.1. BioCryst will post on its website the following statement: ''For information about the FDA-authorized emergency use of peramivir, please see *www.cdc.gov/h1n1flu/eua*.''

D.2. BioCryst will distribute authorized peramivir only to CDC and/or its designees subject to the terms and conditions of this letter.

D.3 BioCryst will contact FDA concerning the need for any FDA review and approval before any changes are made to the manufacturing, packaging, and labeling processes authorized as of the date of this letter.

D.4. BioCryst (or anyone acting on behalf of BioCryst) will not represent authorized peramivir in a promotional context or otherwise promote authorized peramivir.

D.5. BioCryst will make available to FDA and (as reasonably appropriate) CDC upon request any records maintained in connection with this letter. Upon request, BioCryst will report to FDA and/or (as reasonably appropriate) CDC information with respect to the emergency use of authorized peramivir.

The emergency use of authorized peramivir as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] FDA is authorizing the emergency use of peramivir administered intravenously for treatment of 2009 H1N1 in certain adult and pediatric patients as described in the scope section of this letter (Section II of this letter). For ease of reference, this letter of authorization will also use the term ''authorized peramivir.''
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[3] The activities with respect to authorized peramivir refer to requesting, preparing, prescribing, and/or administering authorized peramivir, unless otherwise specified.

Dated: October 26, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26291 Filed 10–30–09; 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.

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