pheochromocytoma and endolymphatic sac tumors).

Renal clear cell carcinoma (RCC) develops in approximately 75% of VHL patients by age 60 and is a leading cause of death in this population. Inactivation (mutation or methylation) of the VHL gene is associated with greater than 90% of all clear cell RCC (including sporadic cases) (Nickerson *et al.* Clin Cancer Res 2008;14:4726–34). Thus, subjects with compromised VHL function represent a significant population that has or is at risk for developing cancer, including RCC. There is data that HIF–2α may be important in all or most cancers (Franovic *et al.* Proc Natl Acad Sci U S A 2009;106:21306–11).

Inventors: W. Marston Linehan (NCI), Tracey A. Rouault (NICHD), James B. Mitchell (NCI), Murali K. Cherukuri (NCI).

Patent Status: U.S. Provisional Application No. 61/265,194 filed 30 Nov 2009 (HHS Reference No. E–133–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Sabarni Chatterjee, Ph.D.; 301–435–5587; *chatterjeesa@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Urologic Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of Tempol to target HIF–2α in cancer. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Chimeric Anti-human ROR1 Monoclonal Antibodies

Description of Invention: Available for licensing are mouse anti-human receptor tyrosine kinase-like orphan receptor 1 (ROR1) monoclonal antibodies (mAbs). ROR1 is a signature cell surface antigen for B-cell chronic lymphocytic leukemia (B–CLL) and mantle cell lymphoma (MCL) cells, two incurable B-cell malignancies that are newly diagnosed in approximately 15,000 and 3,500 patients per year, respectively, in the United States. Currently, there are no therapeutic mAbs that specifically target B–CLL or MCL cells. Anti-ROR1 mAbs may be linked to chemical drugs or biological toxins thus providing cytotoxic delivery to malignant B-cells and not normal cells. Additionally, these antibodies can be fused to radioisotopes and can be used to diagnose B–CLL and MCL malignancies.

Applications:

- B–CLL and MCL antibody therapeutics.
- Method to diagnose B–CLL and MCL.

Advantages: Selective targeting to malignant B–CLL and MCL cells.

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

Market:

- The monoclonal antibody market is one of the fastest growing sectors of the pharmaceutical industry with a 48.1% growth between 2003 and 2004 and the potential to reach $30.3 billion in 2010. This growth rate is driven by the evolution of chimeric and humanized to fully humanized antibody therapeutics.
- Approximately 18,500 patients with ROR1-expressing B-cell malignancies are newly diagnosed annually in the United States.

Inventors: Christoph Rader and Sivasubramanian Baskar (NCI).

Related Publications:

1. S Baskar *et al.* Unique cell surface expression of receptor tyrosine kinase ROR1 in human B-cell chronic lymphocytic leukemia. Clin Cancer Res. 2008 Jan 15;14(2):396–404. [PubMed: 18223214]

2. M Hudecek *et al.* The B-cell tumor associated antigen ROR1 can be targeted with T-cells modified to express a ROR1-specific chimeric antigen receptor. Blood. 2010 Aug 11; Epub ahead of print. [PubMed: 20702778]

Patent Status:

- U.S. Provisional Application No. 61/172,099 filed 23 Apr 2009 (HHS Reference No. E–097–2009/0–US–01).
- PCT Application No. PCT/US10/32208 filed 23 Apr 2010 (HHS Reference No. E–097–2009/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Experimental Transplantation and Immunology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize anti-ROR1 mAbs, antibody-drug conjugates, radioimmunoconjugates, bispecific antibodies, and other therapeutic or diagnostic modalities. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: August 23, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–21349 Filed 8–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–0031–N]

Medicare Program; Listening Session Regarding the Implementation of Section 10332 of the Patient Protection and Affordable Care Act, Availability of Medicare Data for Performance Measurement

DATE: September 20, 2010.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a listening session to receive comments regarding implementation of section 10332 of the Patient Protection and Affordable Care Act (the Affordable Care Act), which amended section 1874 of the Social Security Act: Availability of Medicare Data for Performance Measurement. The purpose of the listening session is to solicit input from potential stakeholders on key components of the design of the program. We are soliciting input on the types of organizations that may be interested in receiving data as qualified entities under this provision; the criteria such organizations will have to meet for participation; procedures for CMS to approve interested organizations for participation; provider communities and geographic areas that might be served by these entities; data elements required, and the sources and types of other data that these organizations might match to Medicare claims; challenges in calculating performance measures from the data, and issues related to the identification, selection, and reporting of the performance measures.

DATES: *Meeting Date:* The listening session will be held on Monday, September 20, 2010 from 9 a.m. until 1 p.m. Eastern Daylight Time (e.d.t.).

Deadline for Meeting Registration and Request for Special Accommodations: Registration opens on August 27, 2010. Registration must be completed by 5 p.m. e.d.t. on September 16, 2010. Requests for special accommodations

must be received by 5 p.m. e.d.t. on September 16, 2010.

Deadline for Submission of Written Comments or Statements: Written comments or statements may be sent via mail, fax, or electronically to the address specified in the **ADDRESSES** section of this notice and must be received by 5 p.m. e.d.t. on September 27, 2010.

ADDRESSES: *Meeting Location:* The listening session will be held in the main auditorium of the Central Building of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Registration and Special Accommodations: Persons interested in attending the meeting or participating by teleconference must register by completing the on-line registration via the CMS Web site at *http://www.cms.gov.* Individuals who require special accommodations should send an e-mail request to colleen.bruce@cms.hhs.gov or by regular mail to Colleen Bruce at the address specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: For further information regarding the September 20, 2010 listening session contact Colleen Bruce at (410) 786–5529. You may also send inquiries about this listening session by e-mail to *colleen.bruce@cms.hhs.gov* or by regular mail at Centers for Medicare & Medicaid Services, Mail Stop C5–19–16, 7500 Security Boulevard, Baltimore, MD 21244–1850.

All persons planning to make a statement in person at the listening session are encouraged to submit statements in writing at the listening session and should subsequently submit the information electronically by the timeframe specified in the **DATES** section of this notice.

I. Background

Section 10332 of the Patient Protection and Affordable Care Act (the Affordable Care Act) adds a new subsection to section 1874 of the Social Security Act (the Act), which requires that the Secretary of the Department of Health and Human Services (the Secretary) to make data available to qualified entities for the evaluation of the performance of providers of services and suppliers by January 1, 2012. A qualified entity is a public or private entity that meets qualifications established by the Secretary and that proposes to use claims data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use. These data will be standardized extracts of Medicare Parts A, B, and D claims data for one or more specified geographic areas and time periods requested by a qualified entity. This provision specifies that the Secretary shall take such actions as deemed necessary to protect the identity of individual beneficiaries. The data shall be made available to qualified entities at a fee equal to the cost of making such data available.

Section 1874 of the Act states that a qualified entity requesting data under this subsection must:

- Submit a description of the methodologies it will use to evaluate the performance of providers and suppliers;
- Use standard/endorsed measures, or alternative measures if the Secretary so determines;
- Include data made available under this subsection with claims data from other sources in the evaluation of performance of providers of services and suppliers;
- Only use data made available, and information derived from an evaluation of the performance of providers and suppliers, for the reports required by this provision;
- Include in the reports an understandable description of the measures, risk adjustment methods, physician attribution methods, other applicable methods, and data specifications and limitations;
- Receive prior review by the Secretary of the format of proposed reports;
- Make the information available confidentially, to any provider or supplier prior to the public release of such report; and
- Only include information on a provider of services or supplier in aggregate form.

This section must be implemented by January 1, 2012.

II. Listening Session Format

The listening session will be held on September 20, 2010. Employers, health plans and their representatives, measure developers, health care providers and professionals, professional associations, consumer organizations, community representatives, and other interested stakeholders are invited to participate, in person or by teleconference. The session will begin at 9:00 a.m. e.d.t. with an overview of the objectives for the session and a brief summary of the requirements of section 10332 of the Affordable Care Act. Beginning at approximately 9:30 a.m. e.d.t., the remainder of the meeting will be devoted to presenting the questions for comment and receiving comments on design and policy options in four topic areas—(1) Eligibility criteria and the application process for qualified entities; (2) definition and selection of quality and performance measures; (3) data extraction and distribution process; and (4) data privacy and security requirements, including oversight. The agenda will provide opportunities for brief two-minute comments from on-site session attendees regarding the questions for comment and design and policy options. As time allows, telephone participants will also have the opportunity to provide brief two-minute comments. The meeting will conclude by 1 p.m. with brief comments on our next steps. The opinions and alternatives provided during this meeting will assist us as we develop requirements for this program. We anticipate posting background materials and the questions for comment on the CMS Web site at *http://www.cms.gov/* approximately two weeks before the session.

III. Registration Instructions

For security reasons, any persons wishing to attend this meeting must register by the date listed in the **DATES** section of this notice. Persons interested in attending the meeting or participating by teleconference must register by completing the on-line registration via the designated Web site at *http://www.cms.gov.* The on-line registration system will generate a confirmation page to indicate the completion of your registration. Participants should print this page as his or her registration receipt.

Individuals may also participate in the listening session by teleconference. Registration is required as the number of call-in lines will be limited. The call-in number will be provided upon confirmation of registration.

An audio download and transcript of the listening session will be available within two weeks after completion of the listening session through the CMS Web site at *http://www.cms.gov.*

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. The on-site check-in for visitors will begin at 8:15 a.m. e.d.t. We recommend that participants allow sufficient time to complete security checkpoints.

Security measures include the following:

• Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.

• Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

• Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

We note that individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 18, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–21369 Filed 8–26–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Institutional Training Grant Applications II.

Date: September 1, 2010.

Time: 12:30 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NEI, 5635 Fishers Lane, Rockville, MD 20892. (Telephone Conference Call)

Contact Person: Anne E. Schaffner, PhD, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *aes@nei.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: August 23, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–21346 Filed 8–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Cardiovascular and Renal 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: Cardiovascular and Renal 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 September 20, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., White Oak Bldg. 32, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8540, email: *anuja.patel@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. 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: The committee will discuss new drug application (NDA) 22–512, dabigatran etexilate mesylate capsules, sponsored by Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed indication of prevention of stroke in patients with atrial fibrillation (abnormally rapid contractions of the atria, the upper chambers of the heart).

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 September 8, 2010. 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 August 30, 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