Conference on Clinical Cancer Research

Wednesday, November 14, 2012 | 8:30AM – 3:00PM
The Washington Marriott | Washington, DC

To address critical issues in the development of new oncology drugs, **Friends of Cancer Research** and **the Engelberg Center for Health Care Reform at Brookings** will co-host the fifth-annual **Conference on Clinical Cancer Research**. This annual conference brings together leaders in cancer drug development from federal health and regulatory agencies, academic research, and the private sector for focused discussions on key issues surrounding the development and regulation of cancer drugs and therapies.

Morning Keynote
Harold Varmus, Director, National Cancer Institute

Afternoon Keynote
Margaret Hamburg, Commissioner, U.S. Food and Drug Administration

Panel One: Re-evaluating Criteria for Accelerated Approval

In order for a potential new therapy to qualify for the accelerated approval pathway, it must treat a serious disease for which there is "unmet medical need"– defined as providing a therapy where none exists or providing a therapy that may be potentially superior to existing therapy. For some life-threatening cancers, many approved therapies may exist but are only marginally effective. Currently, drug sponsors who wish to use the accelerated approval pathway typically test their product in patients who have become refractory to all other options, despite the fact that more heavily pre-treated patients are often less likely to respond to a new therapy. This panel will discuss ways to promote the use of the accelerated approval pathway in earlier disease settings.

Panelists:
Cheryl Jernigan, Scientific Advisory Board, Susan G. Komen for the Cure
David Schenkein, Chief Executive Officer, Agios Pharmaceuticals
Richard Schilsky, Professor of Medicine, University of Chicago
Wyndham Wilson, Head, Lymphoma Therapeutics Section, National Cancer Institute
Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Panel Two: Developing Standards for Breakthrough Therapy Designation

In follow-up to the 2011 session, *Development Paths for New Drugs with Large Effects Seen Early*, **The Advancing Breakthrough Therapies for Patients Act** was proposed to expedite development of new, potential "breakthrough" drugs or treatments that show dramatic responses in early phase studies. In this regulatory pathway, once a promising new drug candidate is designated as a "breakthrough therapy", FDA and the sponsor would collaborate to determine the best path forward to abbreviate the traditional three-phase approach to drug development. While potential abbreviated and condensed trial designs were proposed in the 2011 session, this year's panel will focus on defining the criteria necessary to define a product as a breakthrough therapy.

Panelists:
Daniel Haber, Director, Cancer Center, Massachusetts General Hospital
Sandra Horning, Senior Vice President, Global Head, Clinical Development Hematology/Oncology, Genentech
Percy Ivy, Associate Branch Chief, Investigational Drug Branch, CTEP, National Cancer Institute
Charles Sawyers, Chair, Human Oncology and Pathogenesis Program, Memorial Sloan-Kettering Cancer Center
Wendy Selig, President and CEO, Melanoma Research Alliance
Robert Temple, Deputy Director for Clinical Science, U.S. Food and Drug Administration

Panel Three: Design of a Disease-Specific Master Protocol

With increasing understanding of molecular biology, cancer is being further subset into rare, marker-defined subtypes. Each potential new therapy for a specific cancer is typically tested in independent trials. For every single new trial, the paperwork and process must be redeveloped, increasing trial costs and lengthening the process. To improve efficiency, a master trial could be developed for a particular disease type in which multiple new therapies are tested simultaneously on a rolling basis. Lung cancer could be the prototype disease for this type of trial, because it is a common cancer but with multiple mutations and potential therapeutic targets. This panel will focus on developing a conceptual approach to a nation-wide clinical trial that would have the ability to screen patients upon enrollment and direct them to a component of the trial based on their tumor subtype (i.e. ALK+ or KRAS+) for which a candidate drug was going to be tested.

Panelists:
Jeffrey Abrams, Associate Director, Cancer Therapy Evaluation Program, National Cancer Institute
Karen E. Arscott, Patient Advocate, Lung Cancer Alliance
Roy Herbst, Chief of Medical Oncology, Yale Cancer Center
Shakuntala Malik, Medical Officer, U.S. Food and Drug Administration
Eric Rubin, Vice President, Clinical Research Oncology, Merck
David Wholley, Director, The Biomarkers Consortium, Foundation for the National Institutes of Health

For more information or to register, please contact Heather Chaney at 202.944.6719 or hchaney@focr.org. On the web, find us at: www.focr.org and on Twitter @CancerResrch