Friends of Cancer Research co-hosts 2009 Conference on Clinical Cancer Research with Engelberg Center for Health Reform

Conference supported by ASCO, AACR, Lance Armstrong Foundation and Susan G. Komen for the Cure

Building on the success of the conference on clinical cancer research held last year **(Click here for 2008 Conference Report),** the conference this year sought to develop a clear path forward on key issues surrounding the development and regulation of cancer drugs and therapies. The conference this year, held at the Hyatt Regency hotel in Washington DC on Monday, September 14th, 2009 was attended by more than a hundred and seventy five attendees representing a cross-section of academia, industry, advocacy and government.


(L) Commissioner Hamburg


(R) NCI Director Dr. Neiderhuber gives morning keynote.

NCI Director Dr. John Neiderhuber in his opening remarks reiterated that cancer is a special case and that “drugs that work in 10% of the patient population are not a failure in cancer”. He stressed the need for integrating emerging genomic knowledge about tumors into drug development and using that information to better predict prognosis during treatment.

Dr. Hamburg gives lunch keynote

Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration, delivered the afternoon keynote address where she highlighted the importance of taking a rigorous scientific approach to the regulation of drugs and devices. She emphasized that various federal health agencies, particularly the NIH and FDA should capitalize on the scientific expertise of each agency through enhanced collaborations. Such an effort would help advance the missions of each individual agency and ultimately benefit the American people.

There were four panels that discussed specific topics in clinical cancer research:

Panel One: Data Submission Standards and Evidence Requirements

Issue focus: Developing optimized standards for data collection for well-studied cancer therapies to improve the efficiency of safety evaluations without sacrificing the scientific integrity and validity of study results.

Panelists: (L-R) Robert Temple, Food and Drug Administration, Robert Erwin, Marti Nelson Cancer Foundation,Jeffrey Abrams, National Cancer Institute, Gwen Fyfe, Consultant, Richard L. Schilsky, University of Chicago and ASCO at podium.

Taking into account the recommendations that resulted from last year's discussion on data submission standards and an in-depth analysis performed by the ASCO Data Optimization Work Group, the panel provided concrete proposals that would lead to collection of necessary and sufficient toxicity data in the case of supplemental applications. In order to provide additional information about what is acceptable to the agency, FDA will begin to develop a guidance document on this topic.

Panel Two: Blinded Independent Central Review of PFS as an Endpoint

Issue focus: Progression Free Survival or PFS has been accepted as an endpoint in certain clinical trials. However, there still remain concerns about the reliable measurement of PFS as an endpoint. A unique source of bias related to PFS is reader evaluation bias in unblinded trials, which was the focus of this panel, because of the potential for subjective elements to influence the disease progression evaluation.

Panelists: (L-R) Richard Pazdur, Food and Drug Administration, Nancy Roach, C3: Colorectal Cancer Coalition Lori Dodd, National Institute of Allergy and Infectious Diseases, Ohad Amit, GlaxoSmithKline, Will Bushnell, GlaxoSmithKline, and Daniel Sargent, Mayo Clinic at podium.

The panel put forward two proposals to quantify bias and suggested ways of handling to discrepancies between local and central reviewers.
The need for quantifiable metrics to evaluate PFS as an endpoint and the need to objectively evaluate whether BICR is needed are issues that FDA would very much like to reach consensus on. They have indicated that these topics will be the subject of discussion at an Oncologic Drugs Advisory Committee (ODAC) meeting soon.

PANEL 3: Accelerating Development and Approval of Targeted Cancer Therapies

Issue Focus: Proposing specific opportunities for more efficient development, regulatory review, and post-approval evaluation of targeted cancer therapies with companion diagnostics and suggesting a means to overcome these deficiencies.

Panelists: (L-R) Patricia Keegan, Food and Drug Administration, Cindy Geoghegan, Patient and Partners, Anna Barker, National Cancer Institute, David Sidransky, Johns Hopkins University, Stephen Friend, Sage Bionetworks, Ray Woosley, Critical Path Institute, David Epstein, Novartis, David Kessler, UCSF School of Medicine at podium.

Opportunities for more efficient development of targeted cancer therapies include identifying unique molecular targets for specific types and sub-types of cancer, development of an analytically valid and reliable diagnostic test to identify the presence of a molecular target or background mutation and co-development of a diagnostic and therapeutic agent.
The panel explored the potential for a targeted approval paradigm to outline a pathway for the evaluation of targeted cancer therapies and to provide the basis for new levels of coordination and interaction between device and drug developers, as well as between FDA centers.

PANEL 4: Development of Rational Drug Combinations with Investigational Targeted Agents

Issue Focus: Advances in basic research have led to improved understanding of the biological mechanisms of cancer. The complexity of disease biology involving multiple redundancies and pathway crosstalk obligates targeting at least two disparate pathways or molecules to achieve significant therapeutic success. The panel explored specific examples and criteria in which an alternative regulatory process to the existing combination rule would be appropriate and feasible and thus could be adopted by developers.

Panelists: Janet Woodcock, Food and Drug Administration, James Zwiebel, National Cancer Institute, Stuart Lutzker, Genentech, Matthew Ellis, Washington University, St. Louis, Adam Clark, Lance Armstrong Foundation, Charles Erlichman, Mayo Clinic at podium.

The panel examined three specific cases (synthetic lethality, co-enhancement and uni-enhancement) wherein a four-arm factorial clinical trail may perhaps be amended to an adaptive trial involving the combination compared to the standard of care.

Rational drug combinations have the potential for greater efficacy in oncology areas as well as other disease settings. Recognizing this, the FDA will begin to develop a guidance document that specifically addresses the unique challenges surrounding development of therapies involving two (or more) new molecular entities (2NMEs).

Links To Slide Presentations by all Panels:
Panel One Slide Presentation
Panel Two Slide Presentation
Panel Three Slide Presentation
Panel Four Slide Presentation

Additional photographs from the days events:

Janet Woodcock

(L-R) Nancy Roach, Lori Dodd

Mark McClellan

Ellen Sigal

(L-R) Marge Foti, Ray Woosley, Commissioner Hamburg

Richard Pazdur