

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)**

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
June 20, 2018

AGENDA

The particular matter for this meeting will be review and discussion of a list of molecular targets for which evidence and/or biologic rationale exist to determine their potential relevance to the growth or progression of one or more pediatric cancers and a list of those targets deemed unlikely to be associated with the growth or progression of pediatric tumors. These lists are expected to fulfill the statutory obligation of the Food and Drug Administration Reauthorization Act (FDARA) and provide some guidance to industry in planning for initial Pediatric Study Plan submissions for new drug and/or biologic products in development for cancer in accordance with the amended provisions of the Pediatric Research Equity Act. The committee will review and discuss considerations other than scientific relevance that FDA will include in decision making with respect to the need and timing of pediatric evaluation of specific new drug and biologic products. The committee will discuss possible criteria and mechanisms for the prioritization by sponsors and the clinical investigator community of select targeted new agents for pediatric evaluation especially in the setting of multiple same in class agents. Preliminary discussion will focus on approaches to coordination and collaboration for pediatric clinical investigations of new agents that might be pursued to efficiently accommodate international regulatory requirements and global pediatric product development. The open public hearing sessions are: Topic 1: Target List, Topic 2: FDARA Implementation, and Topic 3: Mechanisms to Assure Efficiency and to Enhance Global Coordination Through International Collaboration.

8:00 a.m. Call to Order and Introduction of Subcommittee **Alberto S. Pappo, MD**
Chairperson, pedsODAC

8:05 a.m. Conflict of Interest Statement **Lauren Tesh, PharmD, BCPS**
Designated Federal Officer, ODAC

Topic 1: Target List

8:10 a.m. Implementing FDARA 2017 Provisions:
Facilitating Precision Cancer Medicine for
Children **Gregory H. Reaman, MD**
Associate Director Oncology Sciences
Office of Hematology and Oncology Products
(OHOP)
Office of New Drugs (OND), CDER, FDA
Associate Director for Pediatric Oncology
Oncology Center of Excellence, FDA

8:40 a.m. Clarifying Questions

8:50 a.m. **OPEN PUBLIC HEARING**

9:10 a.m. Charge to the Subcommittee

9:15 a.m. Questions to the Subcommittee/Subcommittee Discussion

9:30 a.m. **BREAK**

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AGENDA (cont.)

Topic 2: FDARA Implementation

9:40 a.m. **SPEAKER PRESENTATION**

Scientific and Logistical Considerations in
Applying “The List”

Lia Gore, MD

Professor of Pediatrics, Medical Oncology, and
Hematology
University of Colorado Anschutz Medical Campus
Chief, Pediatric Hematology/Oncology/Bone
Marrow Transplant
The Ergen Family Endowed Chair in Pediatric
Oncology
Children's Hospital Colorado, Center for Cancer
and Blood Disorders

10:10 a.m. Clarifying Questions

10:20 a.m. **GUEST SPEAKER PRESENTATIONS**

Implications of the 2017 FDA Reauthorization
Act on Pediatric Cancer Drug Development: An
Industry Perspective

Lisa Bollinger, MD

Vice President, Regulatory Affairs
Amgen, Inc

10:50 a.m. Clarifying Questions

11:00 a.m. Investigator Perspectives on New Agent
Prioritization and Challenges with Multiple
Same in Class Agents

Elizabeth Fox, MD

Professor of Pediatrics, the Perelman School of
Medicine at the University of Pennsylvania
Head, Developmental Therapeutics in Oncology,
Children’s Hospital of Philadelphia

11:30 a.m. Clarifying Questions

11:40a.m. **LUNCH**

12:40 p.m. **GUEST SPEAKER PRESENTATIONS (CONT.)**

Industry Perspective on Prioritization of
Pediatric Relevant Targets and Molecules

Hubert N. Caron, MD, PhD

Principle Medical Director
Pediatric Oncology Drug Development Group
Hoffmann-La Roche Ltd.

1:10 p.m. Clarifying Questions

1:20 p.m. **OPEN PUBLIC HEARING**

1:40 p.m. Charge to the Subcommittee

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AGENDA (cont.)

1:45 p.m. Questions to the Subcommittee /Subcommittee Discussion

2:05 p.m. **BREAK**

Topic 3: Mechanisms to Assure Efficiency and to Enhance Global Coordination Through International Collaboration

2:15 p.m. **GUEST SPEAKER PRESENTATIONS**

Recommendations for International
Collaborations and Coordination

Gilles Vassal, MD, PhD
Head, Clinical and Translational Research
Division
Gustave Roussy

2:45 p.m. Addressing Challenges to Global Coordination

Christina Bucci-Rechtweg, MD
Head, Pediatric & Maternal Health Policy
Global Regulatory Affairs
Novartis Pharmaceuticals

3:15 p.m. Clarifying Questions

3:25 p.m. **OPEN PUBLIC HEARING**

3:45 p.m. Charge to the Subcommittee

3:50 p.m. Questions to the Subcommittee /Subcommittee Discussion

4:20 p.m. Closing Comments

Gregory Reaman, MD

4:30 p.m. **ADJOURNMENT**