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

DRAFT 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.	Introductory Remarks and Implementing FDARA 2017 Provisions: Requirements for Target list, Process for Updating, and Additional Considerations	**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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DRAFT 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 Aurora, Colorado
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** Head, Developmental Therapeutics Division of 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**	

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DRAFT AGENDA (cont.)

1:40 p.m.	Charge to the Subcommittee	
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**	