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

Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 21 -22, 2017

AGENDA

One June 21, 2017, information will be presented to gauge investigator interest in exploring potential pediatric development plans for three products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) APX-005M, presentation by Apexigen, Inc.; (2) PM01183 (lurbinectedin), presentation by PharmaMar USA Inc.; and (3) ASP2215 (gilteritinib), presentation by Astellas Pharma Global Development, Inc.

8:00 a.m.	Call to Order and Introduction of Committee	**Alberto Pappo, MD** Chairperson, Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC)
8:05 a.m.	FDA Introductory Remarks	**Gregory Reaman, MD** **Associate Office Director** Associate Director for Pediatric Oncology Oncology Center of Excellence Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
	Topic 1: APX-005M	
8:15 a.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS** Designated Federal Officer, pedsODAC
8:20 a.m.	**INDUSTRY PRESENTATIONS**	**Apexigen, Inc.**
	APX005M, *A CD40 Agonistic Monoclonal Antibody*	**Ovidiu C. Trifan, MD, PhD** Chief Medical Officer Apexigen, Inc.
8:40 a.m.	Clarifying Questions from Subcommittee	
8:50 a.m.	Open Public Hearing	
9:10 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
10:10 a.m.	**BREAK**	
	Topic 2: PM01183 (lurbinectedin)	
10:25 a.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**

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10:30 a.m.	**INDUSTRY PRESENTATIONS**	**Pharma Mar USA, Inc.**
	Lurbinectedin (PM01183) for the treatment of Ewing Sarcoma and Neuroblastoma	**Arturo Soto, MD** Clinical Department Director Oncology Business Unit Pharma Mar, S.A.
10:50 a.m.	Clarifying Questions from Subcommittee	
11:00 a.m.	Open Public Hearing	
11:20 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
12:20 p.m.	**LUNCH**	
	Topic 3: ASP2215 (Gilteritinib)	
1:20 p.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**
1:25 p.m.	**INDUSTRY PRESENTATIONS**	**Astellas Pharma Global Development, Inc.**
	Gilteritinib for Treatment of Pediatric Patients with FLT3/ITD AML	**Andrew Krivoshik, MD, PhD** Vice President of Medical Sciences Oncology Astellas
1:45 p.m.	Clarifying Questions from Subcommittee	
1:55 p.m.	Open Public Hearing	
2:15 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:15 p.m.	**ADJOURN**	

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AGENDA (cont.)

One June 22, 2017, information will be presented to gauge investigator interest in exploring potential pediatric development plans for two products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) olaratumab, presentation by Eli Lilly and Company and (2) prexasertib, presentation by Eli Lilly and Company.

8:00 a.m.	Call to Order and Introduction of Committee	**Alberto Pappo, MD** Chairperson, Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC)
8:05 a.m.	FDA Introductory Remarks	**Gregory Reaman, MD** **Associate Office Director** Associate Director for Pediatric Oncology Oncology Center of Excellence Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
	Topic 1: Olaratumab	
8:15 a.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS** Designated Federal Officer, pedsODAC
8:20 a.m.	**INDUSTRY PRESENTATIONS**	**Eli Lilly and Company**
	LARTRUVO™ (Olaratumab) in Advanced Soft Tissue Sarcoma	
	Introduction	**Allen Melemed, MD, MBA** Distinguished Medical Fellow & Senior Director, Global Regulatory Affairs Eli Lilly and Company
	Olaratumab Development in Adults & Pediatrics	**Volker Wacheck, MD** Senior Medical Director, Olaratumab Eli Lilly and Company
8:40 a.m.	Clarifying Questions from Subcommittee	
8:50 a.m.	Open Public Hearing	
9:10 a.m.	Questions to the Subcommittee and Subcommittee Discussion	

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AGENDA (cont.)

10:10 a.m.	**BREAK**	
	Topic 2: Prexasertib	
10:25 a.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**
10:30 a.m.	**INDUSTRY PRESENTATIONS**	**Eli Lilly and Company**
	Prexasertib (LY2606368), A CHK1 Inhibitor	**Allen Melemed, MD** Distinguished Medical Fellow and Sr. Director Global Regulatory Affairs Eli Lilly and Company **Aimee Bence Lin, PhD** Research Advisor, Prexasertib Eli Lilly and Company
10:50 a.m.	Clarifying Questions from Subcommittee	
11:00 a.m.	Open Public Hearing	
11:20 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
12:00 p.m.	**ADJOURN**	