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, 2019

DRAFT AGENDA

During the morning session, the particular matter for this meeting will be review and discussion of the FDA Reauthorization Act of 2017 (FDARA) mandated Relevant Pediatric Molecular Target List now posted on the FDA website: https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OCE/ucm544641.htm. FDA is required by statute to review and update the previously approved and published lists. The focus of the discussion will be limited to two target "classes" included in the Relevant Pediatric Molecular Target List: (1) targets linked to cell lineage and (2) targets on normal immune cells and cells in the tumor microenvironment. Planned introductory presentations will be on: (1) cell-based therapy approaches to childhood cancer and (2) novel membrane antigen determinants in pediatric tumors.

During the afternoon session, information will be presented to gauge investigator interest in exploring potential pediatric development plans for a product in 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 this product 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 product under consideration is ONC201, presentation by Oncoceutics Inc.

9:00 a.m.	Call to Order and Introduction of Subcommittee	**Alberto S. Pappo, MD** Chairperson, pedsODAC
9:05 a.m.	Conflict of Interest Statement	**Lauren Tesh Hotaki, PharmD, BCPS** Designated Federal Officer, ODAC
9:10 a.m.	Introductory Remarks	**Gregory H. 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
9:15 a.m.	**GUEST SPEAKER PRESENTATION**	
	Immunotherapies for Pediatric Cancer: Current Status and Future Prospects with an Emphasis on Targets	**Crystal Mackall, MD** Ernest and Amelia Gallo Family Professor of Pediatrics and Medicine Director, Stanford Center for Cancer Cell Therapy Director, Parker Institute for Cancer Immunotherapy at Stanford Associate Director, Stanford Cancer Institute Stanford University
9:45 a.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

9:55 a.m.	**GUEST SPEAKER PRESENTATION**	
	Discovery and Development of Optimal Immunotherapeutic Targets for Childhood Cancers	**Kristopher Bosse, MD** Assistant Professor of Pediatrics Perelman School of Medicine at the University of Pennsylvania Evan Lindberg Neuroblastoma Research Scholar Attending Physician, Division of Oncology Children's Hospital of Philadelphia
10:25 a.m.	Clarifying Questions	
10:35 a.m.	**BREAK**	
10:50 a.m.	**OPEN PUBLIC HEARING**	
11:20 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Call to Order and Introduction of Subcommittee	**Alberto S. Pappo, MD** Chairperson, pedsODAC
1:10 p.m.	Conflict of Interest Statement	**Lauren Tesh Hotaki, Pharm.D, BCPS** Designated Federal Officer, ODAC
1:15 p.m.	Introductory Remarks	**Gregory Reaman, MD**
1:20 p.m.	**INDUSTRY PRESENTATION - ONC201**	**Oncoceutics Inc.**
	ONC201: The First Imipridone for the Treatment of H3 K27M-mutant High Grade Glioma	**Wolfgang Oster, MD, PhD** Chief Executive Officer, Oncoceutics Inc. **Josh Allen, PhD** Senior Vice President of R&D, Oncoceutics Inc. **Patrick Wen, MD** Professor, Neurology, Harvard Medical School Director, Center For Neuro-Oncology Dana-Farber Cancer Institute **Sabine Mueller, MD, PhD** Assistant Professor of Clinical Neurology University of California at San Francisco Hellen Diller Family Comprehensive Cancer Center

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DRAFT AGENDA (cont.)

1:40 p.m.	Clarifying Questions	
1:50 p.m.	**OPEN PUBLIC HEARING**	
2:20 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:20 p.m.	FDA Closing Remarks	**Gregory Reaman, MD**
3:30 p.m.	**ADJOURNMENT**	