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

Pediatric Oncology Subcommittee of the
Oncologic Drugs Advisory Committee (pedsODAC) Meeting
June 16, 2023

AGENDA

The subcommittee will discuss considerations related to dosage optimization of new drug and biological products for pediatric patients with cancer. Dosage optimization is an integral aspect of oncology drug development and is important to maximizing the safety, efficacy, and tolerability of new drugs for pediatric cancers. Unique considerations associated with dosage selection and optimization in pediatric oncology include variability in pharmacokinetic and pharmacodynamic parameters by age and size, the need for age-appropriate formulations, potential for toxicities associated with long-term use, and the rarity of pediatric cancers. Representatives from the European Medicines Agency, the pediatric oncology investigator community, and the pharmaceutical industry have also been invited to present.

10:00 a.m.	Call to Order	**Alberto S. Pappo, MD** Chairperson, pedsODAC
10:05 a.m.	Introduction of Subcommittee and Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Acting Designated Federal Officer, pedsODAC
10:10 a.m.	Introductory Remarks	**Martha Donoghue, MD** Associate Director for Pediatric Oncology Oncology Center of Excellence Office of the Commissioner Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:15 a.m.	**FDA PRESENTATIONS**	
	FDA Perspective on Dosage Optimization in Pediatric Oncology	**Kristin Wessel, MD** Medical Officer Division of Oncology 2 OOD, OND, CDER, FDA **Ruby Leong, PharmD, LCDR, USPHS** Clinical Pharmacology Team Leader Division of Cancer Pharmacology I Office of Clinical Pharmacology Office of Translational Sciences, CDER, FDA
10:45 a.m.	Dosage Optimization Considerations for Chimeric Antigen Receptor (CAR) T-Cell Products	**Xiaofei Wang, PhD** Clinical Pharmacology Reviewer Division of Clinical Evaluation General Medicine Office of Clinical Evaluation Office of Therapeutic Products Center for Biologics Evaluation and Research, FDA

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AGENDA (cont.)

11:00 a.m.	Clarifying Questions	
11:15 a.m.	**GUEST SPEAKER PRESENTATIONS**	
	Considerations Related to Dosage Optimisation of New Drug and Biological Products for Paediatric Patients with Cancer - European Regulatory Perspective	**Dominik Karres, MD** Scientific Officer Paediatric Medicines Office Scientific Evidence Generation Department Human Medicines Division European Medicines Agency (EMA) **Olga Kholmanskikh, MD, PhD** Clinical Assessor Federal Agency for Medicines and Health Products – Belgium Member, Oncology Working Party of the EMA Alternate, Committee for Advanced Therapies of the EMA
11:35 a.m.	Pediatric Oncology Drug Development: Dose and Dose Optimization	**Elizabeth Fox, MD, MSCR** Member, Department of Oncology Senior Vice President Clinical Research Administration St. Jude Children's Research Hospital Vice-Chair, Pediatric Early Phase Trial Network and Developmental Therapeutics Committee Children's Oncology Group
11:55 a.m.	Dosage Optimization of New Drug and Biological Products for Pediatric Patients with Cancer: A Perspective from the Biopharmaceutical Industry	**Samuel C. Blackman, MD, PhD** Co-founder and Head of Research and Development Day One Biopharmaceuticals, Inc.
12:15 p.m.	Clarifying Questions	
12:30 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:15 p.m.	Closing Remarks	**Martha Donoghue, MD**
3:30 p.m.	**ADJOURNMENT**	