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

Pediatric Oncology Subcommittee of the
Oncologic Drugs Advisory Committee (pedsODAC) Meeting
May 11-12, 2022

DRAFT AGENDA

On May 11, 2022, the subcommittee will discuss the development of a conceptual framework that will inform the decision-making of the FDA on sponsor plans and requests for waivers of early pediatric investigations of molecularly targeted cancer drugs and biologics when multiple same-in-class products are approved and/or in development, recognizing that the rarity of pediatric cancers may preclude the feasibility of investigations of multiple products. Investigation of more than one product may be appropriate when specific product characteristics predict an improved benefit-risk assessment that warrants clinical investigation.

Day 1: May 11, 2022

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	**Joyce Yu, PharmD** Acting Designated Federal Officer, pedsODAC
10:10 a.m.	Developing a Consistent Conceptual Framework to Address Waivers of Pediatric Studies Required by the RACE for Children Act	**Gregory Reaman, MD** Associate Director for Pediatric Oncology Oncology Center of Excellence (OCE) Office of the Commissioner (OC) Associate Director for Pediatric Oncology Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:30 a.m.	**FDA PRESENTATION**	
	Scope of the Current Problem: Examples of Multiple Same in Class Products for Hematologic Malignancies	**Margret Merino, MD** Medical Officer Division of Hematologic Malignancies 2 OOD, OND, CDER, FDA
10:45 a.m.	**GUEST SPEAKER PRESENTATION**	
	European Medicines Agency (EMA)/Paediatric Committee (PDCO) - General Considerations on Waiving Requirements for Pediatric Investigations of Same in Class Products	**Dominik Karres, MD** Scientific Officer Paediatric Medicines Office Scientific Evidence Generation Department Human Medicines Division European Medicines Agency (EMA)

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DRAFT AGENDA (cont.)

11:00 a.m.	**FDA PRESENTATION**	
	Non-Clinical Studies in Decision-Making Related to Pediatric Investigations: FDA Perspective	**Haleh Saber, PhD, MS** Deputy Director Division of Hematology Oncology Toxicology OOD, OND, CDER, FDA
11:15 a.m.	**GUEST SPEAKER PRESENTATION**	
	European Medicines Agency (EMA)/Paediatric Committee (PDCO) - Non-Clinical Considerations in Decision-Making Related to Waiving Requirements for Paediatric Investigations	**Karen Van Malderen, MSc** Non-Clinical Assessor Federal Agency for Medicines and Health Products PDCO Member, EMA Chair of the Non-Clinical Working Group, EMA
11:30 a.m.	**FDA PRESENTATIONS**	
	Clinical Pharmacology Considerations for Same-in-Class Products	**Stacy S. Shord, PharmD, BCOP, FCCP** Deputy Division Director Division of Cancer Pharmacology II Office of Clinical Pharmacology Office of Translational Sciences, CDER, FDA
11:45 a.m.	Central Nervous System Penetration and Pediatric Brain Tumor Considerations for Same-In-Class Products	**Elizabeth S. Duke, MD** Medical Officer Division of Oncology 2 OOD, OND, CDER, FDA
12:00 p.m.	Clarifying Questions	
12:30 p.m.	**LUNCH**	
1:00 p.m.	**GUEST SPEAKER PRESENTATIONS**	
	Product Quality and Formulation Considerations in Decisions Related to Pediatric Investigation of Same in Class Agents	**Siri Wang, PhD** Scientific Director Norwegian Medicines Agency, Oslo, Norway PDCO of the EMA, Netherlands
1:15 p.m.	An Industry Perspective on Waiving Requirements for Pediatric Investigations of Same in Class Products	**Scott J. Diede, MD, PhD** Executive Director Global Clinical Development Merck Research Laboratories

DRAFT AGENDA (cont.)

1:30 p.m.	Clarifying Questions	
1:45 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:15 p.m.	Closing Remarks	**Gregory Reaman, MD**
3:30 p.m.	**ADJOURNMENT**	

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DRAFT AGENDA (cont.)

On May 12, 2022, the subcommittee will consider and discuss the potential utility and steps to validation of an intermediate clinical endpoint, response to induction therapy, in the development of new drugs for the first-line treatment of patients with high-risk neuroblastoma.

Day 2: May 12, 2022

10:00 am.	Call to Order	**Alberto S. Pappo, MD** Chairperson, pedsODAC
10:05 a.m.	Introduction of Subcommittee and Conflict of Interest Statement	**Joyce Yu, PharmD** Acting Designated Federal Officer, pedsODAC
10:10 a.m.	Introductory Remarks	**Gregory Reaman, MD** Associate Director for Pediatric Oncology Oncology Center of Excellence (OCE) Office of the Commissioner (OC) Associate Director for Pediatric Oncology Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:15 a.m.	**FDA AND GUEST SPEAKER PRESENTATIONS**	
	High-Risk Neuroblastoma: Current Treatment and Regulatory Insights	**Diana Bradford, MD** Cross-Discipline Team Leader Division of Oncology 2 OOD, OND, CDER, FDA
	Current Treatment and Regulatory Insights – European Medicines Agency (EMA) and FDA Part II	**Dominik Karres, MD** Scientific Officer Paediatric Medicines Office Scientific Evidence Generation Department Human Medicines Division European Medicines Agency (EMA)
10:45 a.m.	Clarifying Questions	
10:55 a.m.	**GUEST SPEAKER PRESENTATIONS**	
	Accelerating Cure for High-Risk Neuroblastoma	**Leona Knox** Advocate Head of Research, Solving Kids' Cancer UK London, United Kingdom

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DRAFT AGENDA (cont.)

GUEST SPEAKER PRESENTATIONS (CONT.)

	Improving Access to Novel Therapies in High-Risk Neuroblastoma	**Navin Pinto, MD** Associate Professor of Pediatrics University of Washington School of Medicine Attending Physician Cancer and Blood Disorders Center Seattle Children's Hospital
	Multi-stakeholder Perspective on Current and Potential Future Use of End-Induction Response in Patient Care and Drug Development	**Maja Beck Popovic, MD** Professor of Pediatric Hematology Oncology Head of the Pediatric Hematology Oncology Unit University Hospital in Lausanne, Switzerland
11:55 a.m.	Clarifying Questions	
12:15 p.m.	**LUNCH**	
1:00 p.m.	**FDA AND SPEAKER PRESENTATIONS**	
	Steps to Validation of Early Endpoints to Support Drug Development in Neuroblastoma: Key Concepts	**Lisa M. McShane, PhD** Chief, Biometric Research Program Associate Director, Division of Cancer Treatment and Diagnosis National Cancer Institute National Institutes of Health
	Early Endpoint Validation	**Anup Amatya, PhD** Acting Lead Mathematical Statistician Division of Biometrics V Office of Biostatistics Office of Translational Sciences, CDER, FDA
1:45 p.m.	Clarifying Questions	
2:00 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:15 p.m.	Closing Remarks	**Gregory Reaman, MD**
3:30 p.m.	**ADJOURNMENT**	