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

***Pediatric Oncology Subcommittee of the***
***Oncologic Drugs Advisory Committee (pedsODAC) Meeting***
May 22, 2024

**DRAFT AGENDA**

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*Amendments made by Section 504 of the 2017 FDA Reauthorization Act (FDARA) to section 505B of the Food, Drug, and Cosmetic Act required, for original applications submitted on or after August 18, 2020, pediatric investigations of certain targeted cancer drugs with new active ingredients, based on molecular mechanism of action rather than clinical indication. The Subcommittee will discuss perspectives relating to implementation of this legislation and its impact on pediatric cancer drug development.*

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| 10:00 a.m. | Call to Order | **Alberto S. Pappo, MD**<br>Chairperson, pedsODAC |
| 10:05 a.m. | Introduction of Subcommittee and Conflict of Interest Statement | **Jessica Seo, PharmD, MPH**<br>Acting Designated Federal Officer, pedsODAC |
| 10:10 a.m. | Introductory Remarks | **Nicole Drezner, MD**<br>Deputy Director<br>Division of Oncology 2 (DO2)<br>Office of Oncologic Diseases (OOD)<br>Office of New Drugs (OND), CDER, FDA |
| 10:15 a.m. | **FDA PRESENTATIONS** | |
| | Pediatric Oncology Drug Development: An Update After FDARA 2017 Implementation | **Marjilla Seddiq, MD**<br>Medical Officer<br>DO2, OOD, OND, CDER, FDA<br><br>**Ramjay Vatsan, PhD**<br>Associate Director for Policy<br>Office of Gene Therapy (OGT)<br>Office of Therapeutic Products (OTP)<br>Center for Biologics Evaluation and Research (CBER)<br>FDA |
| 10:50 a.m. | **GUEST SPEAKER PRESENTATIONS** | |
| | European Perspective on Complementary US and EU Regulations in Support of Global Development | **Dominik Karres, MD**<br>Senior Scientific Officer<br>Paediatric Medicines Office<br>Scientific Evidence Generation Department<br>Human Medicines Division<br>European Medicines Agency (EMA)<br><br>**Maria Sheean, PhD**<br>Scientific Officer<br>Paediatric Medicines Office<br>Scientific Evidence Generation Department<br>Human Medicines Division, EMA |

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**DRAFT AGENDA (cont.)**

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| 11:10 a.m. | Clarifying Questions | |
| 11:30 a.m. | **GUEST SPEAKER PRESENTATIONS (cont.)** | |
| | Impact of RACE Act: COG Perspective | **Brenda J. Weigel, MSc, MD**<br>Professor and Division Director<br>Pediatric Hematology/Oncology<br>University of Minnesota<br>Chair, Developmental Therapeutics COG |
| 11:50 a.m. | Research to Accelerate Cures and Equity (RACE) for Children ACT - Implementation and Impact<br>Industry Perspective | **Ruchi Gupta, MS**<br>Program Director, Regulatory Affairs<br>Genentech, Inc. |
| 12:10 p.m. | European academic perspectives on international trial collaboration in paediatric oncology | **Pamela Kearns, MBChB, BSc (Hons), PhD, FRCPCH**<br>Chair of Clinical Paediatric Oncology<br>Director, Institute of Cancer and Genomic Sciences<br>University of Birmingham<br>President of ITCC |
| 12:30 p.m. | Clarifying questions | |
| 12:45 p.m. | **LUNCH** | |
| 1:30 p.m. | **OPEN PUBLIC HEARING** | |
| 2:30 p.m. | Questions to the Subcommittee and Subcommittee Discussion | |
| 3:30 p.m. | Closing Remarks | **Martha Donoghue, MD**<br>Associate Director for Pediatric Oncology and Rare Cancers<br>Oncology Center of Excellence (OCE)<br>Office of the Commissioner (OC)<br>Associate Director, Pediatric Oncology (Acting)<br>OOD, OND, CDER, FDA |
| 3:45 p.m. | **ADJOURNMENT** | |