

**FDA/CDER Office of Clinical Pharmacology and International Society of Pharmacometrics (ISoP)**

**Public Workshop**

**Optimizing Dosages for Oncology Drug Products:**

**Using Modeling and Simulation to Evaluate Effects of Intrinsic and Extrinsic Factors**

**October 16, 2023**

**Food and Drug Administration White Oak Campus or Virtual**

10:00 AM **Welcome & Housekeeping** – Stacy Shord, FDA

10:05 AM **Identifying Optimal Dosages for Specific Populations** – Stacy Shord, FDA

10:15 AM **Session 1: Using Model-Informed Approaches to Develop Oncology Drugs for Pediatric Patients and Older Adults**

Moderator: CJ Musante, Pfizer (ISoP)

10:20 AM *Understanding the Regulations and Recommendations for Drug Development in Pediatrics and Older Adults with Cancer* – Youwei Bi, FDA

10:30 AM *Understanding the Effects of Chronological and Functional Age on Dosage Selection in Older Adults*– Ginah Nightingale, Abbvie

10:50 AM *Model-informed Approaches to Support Dosage Selection in Pediatric Patients* – Tomoyuki Mizuno, University of Cincinnati

11:10 AM *Panel Discussion*

- Youwei Bi, FDA
- Qi Liu, FDA
- Harpreet Singh, FDA
- Tomoyuki Mizuno, University of Cincinnati
- Ginah Nightingale, Abbvie

11:40 AM **Lunch (Kiosk)**

12:45 PM **Session 2: Evaluating How Race, Ethnicity, Geography & Ancestry Influence Dosage Optimization for Oncology Drug Development**

Moderator: Jiang Liu, FDA

12:50 PM *Expanding Clinical Trial Eligibility to Include Relevant Populations* – Olanrewaju Okusanya, FDA

1:00 PM *Clinical Pharmacology Considerations for Evaluation of Race, Ethnicity, Geography, and Ancestry During Drug Development and Regulatory Review* – Anuradha Ramamoorthy, FDA

1:20 PM *The Role of Clinical Pharmacology in Dosage Selection and Design of Multi-Regional Clinical Trials*– Karthik Venkatakrishnan, EMD Serono

- 1:40 PM *PMDA Experience with Dosage Selection - Shinichi Kijima, Pharmaceuticals and Medical Devices Agency*
- 2:00 PM *Panel Discussion*
- Anu Ramamoorthy, FDA
  - Olanrewaju Okusanya, FDA
  - Karthik Venkatakrishnan, EMD Serono
  - Shinichi Kijima, Pharmaceuticals and Medical Devices Agency
- 2:30 PM **Break**
- 2:45 PM **Session 3: Understanding the Effects of Food and Drug-Drug Interactions on Dosage Optimization**
- Moderator: Vijay Ivaturi, University of Maryland School of Pharmacy (ISoP)
- 2:50 PM *Impossible Recommendations Regarding Administration with Food and Use of Concomitant Medications – Brian Booth, FDA*
- 3:00 PM *Leveraging Modeling to Understand the Effects of Food on Dosage Selection– Xinyuan (Susie) Zhang, Daiichi Sankyo*
- 3:20 PM *Leveraging Modeling to Understand the Effects of Concomitant Medications on Dosage Selection– Ping Zhao, Bill & Melinda Gates Foundation*
- 3:40 PM *Panel Discussion*
- Yuching Yang, FDA
  - Rebecca Moody, FDA
  - Brian Booth, FDA
  - Xinyuan (Susie) Zhang, Daiichi Sankyo
  - Ping Zhao, Bill & Melinda Gates Foundation
- 4:10 PM **Summary and Closing Remarks – Wei Gao, EMD Serono (ISoP)**
- 4:30 PM **End**