Model-Informed Drug Development in Oncology

February 1, 2018

FDA White Oak Great Room

Workshop Co-chairs

Amy E. McKee, M.D.
FDA

René Bruno, Ph.D.
Past-President, ISoP

Yaning Wang, Ph.D.
FDA

Jin Y. Jin, Ph.D.
President, ISoP

AGENDA

8:00 AM	**Welcome and Workshop Objectives** – ***Issam Zineh, Pharm.D.*** **(FDA)**
8:10 AM	**Challenge and Opportunity of MIDD in Oncology** – ***Janet Woodcock, M.D.*** **(FDA)**
SESSION I:	**Non-clinical MIDD in Oncology**
	Moderator: ***Jin Y. Jin, Ph.D.*** **(Genentech)**
8:35 AM	**Models in Support of Drug Combinations and Dosing** – ***Sergey Aksenov, Ph.D.*** **(AstraZeneca)**
9:00 AM	**Modeling of Bispecific Monoclonal Antibody** – ***Armin Sepp, Ph.D.*** **(GlaxoSmithKline)**
9:25 AM	**Simultaneous Preclinical and Clinical Efficacy and Safety Modeling to Recommend Phase 2 Doses for Cancer Drug Combinations** – ***Dean Bottino, Ph.D.*** **(Takeda)**
9:50 AM	**PANEL DISCUSSION**
	Morning speakers and the following additional panelists: ***Haleh Saber*** **(FDA)**
10:20 AM	**BREAK**

Model-Informed Drug Development in Oncology

February 1, 2018

FDA White Oak Great Room

SESSION II: **Clinical MIDD in Oncology**

Moderator: ***Sandeep Dutta, Ph.D.*** **(Amgen)**

10:40 AM **Beyond MTD: Integrating Non-safety Endpoints into Oncology Dose-finding**
– *Stuart Bailey, Ph.D.* (Novartis)

11:05 AM **Novel Endpoints in Clinical Trials to Accelerate and Streamline Drug Development**
– *Tito Fojo, M.D., Ph.D.* (Columbia University)

11:30 AM **Joint Modeling of Tumor Kinetic and Overall Survival**
– *Jérémie Guedj, Ph.D.* (INSERM, Paris)

11:55 AM **LUNCH (on your own)**

1:00 PM **Inspiring Examples: Model-informed decisions in clinical development**

- Clinical Perspective: Bringing the Community Care Setting Into the Learning Versus Confirming Paradigm – ***Michael Maitland, M.D., Ph.D.*** **(Inova)**
- Case Example I: Characterization of Post-progression Outcomes as a Function of Time on Treatment – ***David Turner, Ph.D.*** **(Merck)**
- Case Example II: Modeling of Tumor Kinetics and Overall Survival to Identify Prognostic and Predictive Biomarkers of Efficacy for Durvalumab – ***Yanan Zheng, Ph.D.*** **(MedImmune)**
- Case Example III: Tumor Growth Dynamic-Overall Survival Modeling with Ipilimumab in Melanoma – ***Amit Roy, Ph.D.*** **(Bristol-Myers Squibb)**
- Case Example IV: Applications of Tumor Growth Inhibition-Overall Survival Models to Support Atezolizumab Combination Studies – ***René Bruno, Ph.D.*** **(Genentech/Roche)**
- Case Example V: Using Modeling Approach to Inform the Decision at Early Drug Development Stage – ***Jingwen (Jenny) Zheng, Ph.D.*** **(Pfizer)**

2:30 PM **PANEL DISCUSSION**

Session II speakers and the following additional panelists:
Nam Atiqur Rahman **(FDA)**, ***Jerry Yu*** **(FDA)**

3:00 PM **BREAK**

Model-Informed Drug Development in Oncology

February 1, 2018

FDA White Oak Great Room

SESSION III:	**MIDD Before and After Approval**
	Moderator: Yaning Wang, Ph.D. (FDA)
3:15 PM	**Model Informed Development of Abemaciclib: Collaboration, Computation, and Communication** **– *Kellie Turner-Jones, Ph.D.* (Eli Lilly)**
3:40 PM	**Model-Informed Analysis During NDA/BLA Review** **– *Chao Liu, Ph.D.* (FDA)**
4:05 PM	**MIDD Applied Post-Approval: Examples with Ibrutinib, a BTK Inhibitor** **– *Daniele Ouellet, Ph.D.* (Janssen)**
4:30 PM	**PANEL DISCUSSION**
	Session III speakers and the following additional panelists: ***Lei Nie (FDA), Patricia Keegan (FDA)***
5:00 PM	**Meeting Summary – *Jin Y. Jin, Ph.D.* (ISoP President)**
5:10 PM	**Closing Remarks – *Amy E. McKee, M.D.* (FDA)**
5:20 PM	**MEETING ADJOURNS**