Dose-finding of Small Molecule Oncology Drugs

May 18-19, 2015

Washington Court Hotel, Washington, DC

This workshop will provide a forum for discussion of the best practices on dose finding of small molecule oncology drugs.

AGENDA

	DAY ONE
8:00 am	**Welcome and Workshop Objectives** Amy McKee, MD, FDA Pasi Jänne, MD, PhD, Dana Farber Cancer Institute
SESSION I: SMALL MOLECULE CHARACTERIZATION	
8:05 am	**Pharmacology Matters: Adapting the paradigm of small molecule oncology drug development** Natalie Simpson, PhD, FDA
8:15 am	**Is It Safe: Understanding the Performance of Nonclinical Safety Assessment Models in Predicting Human Outcomes?** Thomas W. Jones, PhD, Eli Lilly & Co
8:45 am	**Nonclinical to clinical correlation of adverse effects of kinase inhibitors** Richard Brennan, PhD, DABT, Sanofi
9:15 am	**30-MINUTE BREAK**
9:45 am	**Safety Lead Optimization of Kinase Inhibitors: Learnings from Attrition and Translation** Donna Dambach, VMD, PhD, Genentech
10:15 am	**Enhancing the Safety of Kinase Inhibitor Oncolytic Drugs: Preclinical/Clinical Opportunities** William Kluwe, PhD, Novartis Pharmaceuticals
10:45 AM	**PANEL DISCUSSION**
Moderators	**Todd Palmby, PhD, FDA and Donna Dambach, VMD,PhD, Genentech** William Kluwe, PhD, Novartis Institutes of Biomedical Research

	Richard Brennan, PhD, Sanofi
	Thomas Jones, PhD, Eli Lilly and Co.
	Eric Rubin, MD, Merck Research Laboratories
	Kourosh Parivar, M.Pharm, Pfizer
	Jose Pinheiro, PhD, Janssen
	Alice Shaw, MD, PhD, Massachusetts General Hospital
	Pasi Jänne, MD, PhD, Dana Farber Cancer Institute
11:45 am	**ONE-HOUR LUNCH (on your own)**
SESSION II:	**DESIGN OF DOSE FINDING STUDIES**
12:45 pm	**Dose Selection for Small Molecule Oncology Drugs: Present State and Future Considerations**
	Nitin Mehrotra, PhD, FDA
1:00 pm	**Optimal dosing for targeted therapies in oncology : Drug development cases leading by example**
	Dinesh De Alwis, PhD, Merck Research Labs
1:30 pm	**Innovations in Dose Finding Clinical Trial Designs**
	Laura Fernandes, PhD, FDA
2:00 pm	**10-MINUTE BREAK**
2:10 pm	**Best practices of adaptive dose finding studies**
	Stuart Bailey, PhD, Novartis Oncology
2:30 pm	**Best practices of adaptive dose finding studies II**
	Jose Pinheiro, PhD, Janssen
3:00 pm	**Dose Optimization of Dasatinib: Phase-1 through Phase-3**
	Amit Roy, PhD, Bristol-Myers Squibb
3:30 pm	**15-MINUTE BREAK**
3:45 pm	**PANEL DISCUSSION**
Moderators	**Lei Nie, PhD, FDA and Eric Rubin, MD, Merck Research Labs**
	Amit Roy, PhD, Bristol Myers Squibb
	Dinesh De Alwis, PhD, Merck Research Labs
	Stuart Bailey, PhD, Novartis Oncology
	Jose Pinheiro, PhD, Janssen
	Vivek Kadambi, PhD, Blueprint Medicines
	Sherry Ralston, PhD, AbbVie

	Pasi Jänne, MD, PhD, Dana Farber Cancer Institute
	Rajeshwari Sridhara, PhD, FDA
	Vikram Sinha, PhD, FDA
5:00 pm	**Wrap up and Adjourn**

DAY TWO

8:00 am	**Welcome and Workshop Objectives**
	Amy McKee, MD, FDA
	Pasi Jänne, MD, PhD, Dana Farber Cancer Institute
SESSION III:	**DOSE-EXPOSURE EXPLORATION**
8:05 am	**Oncology Drugs Dose Selection-What Have We Learned?**
	Qi Liu, PhD, FDA
8:15 am	**Dose Optimization: ceritinib**
	Dan Howard, PhD, Novartis
8:45 am	**Dose Optimization: Axitinib as a case example for Dose Titration**
	Yazdi Pithalva, PhD, Pfizer
9:15 am	**30-MINUTE BREAK**
9:45 am	**Dose Optimization: vandetanib**
	Eric Masson, PharmD, AstraZeneca
10:15 am	**Dose Optimization for Small Molecule Combinations in Oncology**
	Jin Jin, PhD, Genentech
10:45 am	**PANEL DISCUSSION**
Moderators	**Qi Liu, PhD, FDA and Julie Bullock, PharmD, d3 Medicine**
	Yazdi Pithavala, PhD, Pfizer
	Eric Masson, PharmD, AstraZeneca
	Dan Howard, PhD, Novartis
	Jin Jin, PhD, Genentech
	Akintunde Bello, PhD, Bristol-Myers Squibb
	Mark Ratain, MD, University of Chicago

	Eric Rubin, MD, Merck
	Vivek Kadambi, PhD, Blueprint Medicines
	Stuart Bailey, PhD, Novartis
	Nam Atiqur Rahman, PhD, FDA
11:45 am	**ONE-HOUR LUNCH (on your own)**
SESSION IV: INTEGRATING DOSE OPTIMIZATION IN CLINICAL DEVELOPMENT	
1:00 pm	**Integrative Approach to Dose Finding**
	Geoffrey Kim, MD, FDA
1:15 pm	**Feasibility of an integrative, adaptive dose finding trial**
	Rajeshwari Sridhara, PhD, FDA
1:45 pm	**Barriers to implementing integrative, adaptive dose finding trials**
	Lilli Petruzzelli, MD, PhD, Novartis
2:15 pm	**30-MINUTE BREAK**
2:45 pm	**Practical considerations of implementing dose optimization strategies in the clinic**
	Alice Shaw, MD, PhD, Massachusetts General Hospital
3:15 pm	**Approaches to integrative, adaptive dose-finding combination studies**
	Pasi Jänne, MD, PhD, Dana Farber Cancer Institute
3:45 pm	**Future considerations and moving forward**
Moderators	**Geoffrey Kim, MD, FDA and Alice Shaw, MD, PhD, Mass General**
	Pasi Jänne, MD, PhD, Dana Farber Cancer Institute
	Lilli Petruzzelli, MD, PhD, Novartis
	Amy McKee, MD, FDA
	Mark Ratain, MD, University of Chicago
	Jeffrey Barrett, PhD, Sanofi
	James Yates, PhD, AstraZeneca
	Jin Jin, PhD, Genentech
	Jose Pinheiro, PhD, Janssen
	Thomas Jones, PhD, Eli Lilly

Donna Dambach, VMD, PhD, Genentech

5:00 pm **Wrap up and Adjourn**

Amy McKee, MD, FDA and Pasi Jänne, MD, PhD, Dana Farber Cancer Institute