



**FDA-AACR Non-clinical Models for Safety Assessment of
Immuno-oncology Products Workshop
September 6, 2018 | Washington, DC**

Workshop Cochairs:

John K. Leighton, PhD, Director, Division of Hematology Oncology Toxicology, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Haleh Saber, PhD, Deputy Director, Division of Hematology Oncology Toxicology, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Julie Schneider, PhD, Regulatory Scientist, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

AGENDA

8:00 AM **Welcome and Workshop Objectives**
John K. Leighton, PhD, U.S. Food and Drug Administration

8:15 AM **Current Non-clinical Models for Immuno-oncology Products**
Marcela V. Maus, MD, PhD, Harvard Medical School, Massachusetts General Hospital

8:45 AM **Experience with Keytruda/MM and Use of Animal Models**
Sarah Javaid, PhD, Merck

9:15 AM **Humanized Mice**
Karolina Palucka, MD, PhD, The Jackson Laboratory for Genomic Medicine

10:00 AM **BREAK**

10:15 AM **Evaluating IO Toxicities in Syngeneic Immunocompetent Mouse Models: Lessons, Opportunities and Challenges**
Gregory L. Beatty, MD, PhD, University of Pennsylvania Perelman School of Medicine

11:00 AM **A Comparative Approach to Immuno-oncology Drug Development: Integration of Companion Canine Models**
Amy K. LeBlanc, DVM, National Cancer Institute

11:50 AM **LUNCH BREAK (ON YOUR OWN)**

1:00 PM **Challenges and Opportunities in Developing Non-clinical Models for Immuno-oncology**
Lei Zheng, MD, PhD, Johns Hopkins University School of Medicine, Sidney Kimmel Cancer Center

1:45 PM **PANEL DISCUSSION**

Moderator: **Haleh Saber, PhD**, FDA

Panelists: **Gregory L. Beatty, MD, PhD**, University of Pennsylvania Perelman School of Medicine

Sarah Javaid, PhD, Merck

Marcela V. Maus, MD, PhD, Harvard Medical School, Massachusetts General Hospital

Karolina Palucka, MD, PhD, The Jackson Laboratory for Genomic Medicine

Lei Zheng, MD, PhD, Johns Hopkins University School of Medicine, Sidney Kimmel Cancer Center



- 2:15 PM** **Animal Models in Immuno-oncology Drug Development**
Danuta Herzyk, PhD, Merck
- 2:50 PM** **Use of Antigen Challenge in Non-human Primate to Assess Pharmacodynamic Activity and Translation to Clinic**
Helen Haggerty, PhD, Bristol-Myers Squibb
- 3:15 PM** **BREAK**
- 3:25 PM** **A Case Study of Mitigating Safety Risk for Combination Therapy of IO Biologics and Small Molecules**
Robert Li, PhD, DABT, Genentech
- 3:40 PM** **NCI Funding Programs That Support Development of Cancer Models**
Mariam Eljanne, PhD, National Cancer Institute
- 3:55 PM** **PANEL DISCUSSION and AUDIENCE Q&A**
- Moderators:** **John K. Leighton, PhD, and Julie Schneider, PhD, FDA**
- Panelists:** **Mariam Eljanne, PhD, National Cancer Institute**
Helen Haggerty, PhD, Bristol-Myers Squibb
Danuta Herzyk, PhD, Merck
Alan Korman, PhD, Bristol-Myers Squibb
Robert Li, PhD, DABT, Genentech
- 4:40 PM** **ADJOURN**