Non-clinical Models for Safety Assessment of Immuno-oncology Products Workshop
September 6th, 2018
Marriott Wardman Park, 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 nonclinical 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, Jackson Laboratory for Genomics Medicine

10:00 AM BREAK

10:15 AM Syngeneic and transgenic models
          Gregory L. Beatty, MD, PhD, University of Pennsylvania Perelman School of Medicine

11:00 AM Comparative oncology models
          Amy K. LeBlanc, DVM, National Cancer Institute

11:45 AM AUDIENCE Q&A

11:50 AM LUNCH BREAK (ON YOUR OWN)

1:00 PM Challenges in developing nonclinical models for immuno-oncology
        Lei Zheng, MD, PhD, Johns Hopkins University School of Medicine

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, Jackson Laboratory for Genomics Medicine
          Lei Zheng, MD, PhD, Johns Hopkins University School of Medicine

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Join the conversation with #OCEIONonClinModels
2:15 PM  Animal models in immuno-oncology drug development
Danuta Herzyk, PhD, Merck

2:50 PM  Using the NHP to understand pharmacodynamic activity and translation to humans
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, Genentech

3:40 PM  Overview of NCI funding programs that support work in this area
Mariam Eljanne, PhD, National Cancer Institute

3:55 PM  PANEL DISCUSSION and AUDIENCE Q&A
Moderators: John 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, Genentech

4:40 PM  ADJOURN