Non-Clinical Models for Safety Assessment of Immuno-Oncology Products
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, focus on IO antibodies
          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  DISCUSSION

12:00 PM  LUNCH BREAK  (ON YOUR OWN)

1:00 PM   Challenges in developing nonclinical models for immuno-oncology
          Tbd

1:45 PM   Industry Perspective: Practical challenges/realities of using animal models in immuno-oncology drug development
          Danuta Herzyk, PhD, Merck
          Robert Li, PhD, Genentech

2:15 PM   BREAK
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<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
<th>Affiliation</th>
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<tr>
<td>2:30 PM</td>
<td>Use of NHP model to aid in defining the pharmacodynamic range and biology</td>
<td>Helen Haggerty, PhD, Bristol-Myers Squibb</td>
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<td>3:00 PM</td>
<td>Overview of NCI funding programs that support work in this area</td>
<td>Mariam Eljanne, PhD, National Cancer Institute</td>
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<td>3:30 PM</td>
<td>PANEL DISCUSSION and AUDIENCE Q&amp;A</td>
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<td>Panelists:</td>
<td>Alan Korman, PhD, Bristol-Myers Squibb</td>
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