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
         TBD

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, Jackson Laboratory for Genomics Medicine
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<th>Time</th>
<th>Session</th>
<th>Speaker/s</th>
<th>Affiliation</th>
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<tr>
<td>2:15 PM</td>
<td>Animal models in immuno-oncology drug development</td>
<td>Danuta Herzyk, PhD, Merck</td>
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<td>2:45 PM</td>
<td>Using the NHP to understand pharmacodynamic activity and translation to humans</td>
<td>Helen Haggerty, PhD, Bristol-Myers Squibb</td>
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<td>3:05 PM</td>
<td>A case study of mitigating safety risk for combination therapy of IO biologics and small molecules</td>
<td>Robert Li, PhD, Genentech</td>
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<td>3:15 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>
<td>Mariam Eljanne, PhD, National Cancer Institute</td>
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<td>Moderator(s): John Leighton, PhD, and Julie Schneider, PhD, FDA</td>
<td>Helen Haggerty, PhD, Bristol-Myers Squibb</td>
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<td>Panelists: Danuta Herzyk, PhD, Merck</td>
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<td>Robert Li, PhD, Genentech</td>
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