



## Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development

One Washington Circle Hotel, Washington, DC 20037  
October 25-27, 2017

### Wednesday, October 25, 2017

7:30 – 8:30 AM

**Registration and Continental Breakfast**

8:30 – 8:45 AM

**PERI Welcome and Course Overview**

Lauren Kirk, Course Manager

The Pharmaceutical Education and Research Institute, Inc.

8:45 – 10:00 AM

**Improved Strategies for Selecting Recommended Phase 2 Dosing: Moving Beyond Maximum Tolerated Dose**

**1**

Julie Bullock, PharmD

Senior Director of Clinical Pharmacology & Regulatory Science

Certara USA

*Planned Topics*

- Learnings from “toxic” examples
- Clinical Pharmacology driven decision making
  - Dose-response and exposure-response
- Non-oncology learnings
- Dose Selection
  - Importance and process
  - Alternatives to toxicity driving RP2D
  - Pharmacodynamic endpoints in early drug development

10:00 – 10:15 AM

**Morning Break**

10:15 – 11:30 AM

**Analysis of Time to Event Data**

**2**

Malini Iyengar, PhD

Director, Biostatistics & Programming

Adaptimmune US

*Planned Topics*

- Define Time to event data
- Methods used to analyze these data
- Designing studies with TTE data

11:30 AM – 12:30 PM

**Considerations for Clinical Trial Design and Endpoints Toward U.S. Drug Approval**

**3**

Lorraine Pelosof, MD PhD

Medical Officer, Gastrointestinal Oncology Team

Office of Hematology and Oncology Products

U.S. Food and Drug Administration

*Planned Topics*

- Safety and Efficacy requirements for approval
- Clinical Trial Endpoints, trial designs, types of approval
- Expedited Trials

12:30 PM – 1:30 PM

**Lunch Break**

**Wednesday, October 25, 2017 continued**

- 1:30 – 2:30 PM **Brain and CNS Cancer: Primary Tumors** **4**  
 Deepa Subramaniam, MD, MSc  
 Director, Multi-Disciplinary Thoracic Oncology Clinic  
 Director, Brain Tumor Center  
 Member, Clinical & Experimental Therapeutics Program  
 Lombardi Comprehensive Cancer Center, Georgetown University Medical Center
- Planned Topics*
- Overview of classification of primary brain tumors
  - Standard treatment options for high grade gliomas
- 2:30 – 3:30 PM **Upper Gastrointestinal Malignancies: An Overview of Therapy** **5**  
 M. Naomi Horiba, MD, MPH  
 Medical Officer, GI team  
 Scientific Liaison for Gastroesophageal Cancers  
 CDER/OND/OHOP/DOP2  
 US Food and Drug Administration
- Planned Topics*
- Pancreatic cancer
  - Stomach cancer
  - Hepatocellular carcinoma
- 3:30 – 3:45 PM ***Afternoon Break***
- 3:45 – 5:00 PM **Clinical Pharmacology in Oncology Drug Development** **6**  
 Neeraj Gupta, Ph.D., FCP  
 Quantitative Clinical Pharmacology  
 Oncology Therapeutic Area Unit  
 Takeda Pharmaceuticals International Co.

**Thursday, October 26, 2017**

- 8:00 – 8:30 AM ***Continental Breakfast***
- 8:30 – 9:30 AM **Lymphoid Malignancies** **7**  
 Blanche H. Mavromatis, MDd  
 Medical Oncologist  
 Western Maryland Health System Schwab Family Cancer Center
- Planned Topics*
- Lymphoid malignancies overview
  - Hodgkin's disease and non-Hodgkin's lymphoma
  - Burkitt's lymphoma
- 9:30 – 10:30 AM **Breast Cancer** **8**  
 Blanche H. Mavromatis, MD  
 Medical Oncologist  
 Western Maryland Health System Schwab Family Cancer Center
- Planned Topics*
- Risk factors and screening
  - Local treatment options for adjuvant therapies
  - Hormonal therapy options for early stage breast cancer
  - Adjuvant chemotherapy options
  - Goals of treatment
  - Therapies: supportive, endocrine, chemotherapy

Thursday, October 26, 2017 (continued)

10:30 – 10:45 AM	<b>Morning Break</b>	
10:45 – 11:45 AM	<p><b>Renal Cell Cancer</b>            Chana Weinstock, MD            Medical Officer, Genitourinary Group            Division of Oncology Products 1            Office of Hematology and Oncology Products            U.S. Food and Drug Administration</p> <p><i>Planned Topics:</i></p> <ul style="list-style-type: none"> <li>• Background</li> <li>• Current treatment landscape</li> <li>• Ongoing trials and future directions</li> </ul>	<b>9</b>
11:45 AM – 12:30 PM	<p><b>Leukemias</b>            Blanche H. Mavromatis, MD            Medical Oncologist            Western Maryland Health System Schwab Family Cancer Center</p> <p><i>Planned Topics</i></p> <ul style="list-style-type: none"> <li>• Acute leukemias</li> <li>• Chronic leukemias</li> </ul>	<b>10</b>
12:30 – 1:30 PM	<b>Lunch Break</b>	
1:30 – 2:30 PM	<p><b>Malignant Melanoma</b>            Sekwon Jang, MD            Hematology Oncology, Inova Medical Group            Director, Melanoma and Cutaneous Oncology Therapeutics and Research            Inova Melanoma and Skin Cancer Center, Inova Schar Cancer Institute            Associate Professor of Medicine, Virginia Commonwealth University</p> <p><i>Planned Topics</i></p> <ul style="list-style-type: none"> <li>• Background &amp; Staging of disease</li> <li>• Risk factors and screening</li> <li>• Overview of Current treatment standard of care – pros/cons</li> <li>• Recent approvals</li> <li>• Overview of future treatment horizons</li> </ul>	<b>11</b>
2:30 – 3:30 PM	<p><b>Clinical Overview</b>            Jeffrey Raizer, MD            Executive Medical Director, Clinical Science            Celldex Therapeutics</p> <p><i>Planned Topics</i></p> <ul style="list-style-type: none"> <li>• Evolution of Targets</li> <li>• Development Phases</li> <li>• Companion Diagnostic Development Timeline</li> <li>• Clinical Team Members</li> </ul>	<b>12</b>
3:30 – 3:45 PM	<b>Afternoon Break</b>	

**Thursday, October 26, 2017 (continued)**

3:45 – 4:45 PM	<b><u>Oncologic Imaging in Drug Development: Past, Present and Future</u></b> Paul Garrett, MD Independent Imaging Contractor  <i>Planned Topics</i> <ul style="list-style-type: none"> <li>• Trial Mechanics</li> <li>• Imaging Modalities</li> <li>• Regulatory Issues</li> </ul>	<b>13</b>
4:45 – 5:00 PM	<b><u>End of Day Discussion</u></b>	

**Friday, October 27, 2017**

8:00 – 8:30 AM	<b><i>Continental Breakfast</i></b>	
8:30 – 9:30 AM	<b><u>Prostate Cancer Clinical Update</u></b> Ravi Madan, MD Clinical Director, Genitourinary Malignancies Branch Center for Cancer Research National Cancer Institute	<b>14</b>
9:30 – 9:45 AM	<b><i>Morning Break</i></b>	
9:45 – 11:00 AM	<b><u>Regulatory Actions and Outcomes for NDAs and BLAs</u></b> Florence Houn, MD, MPH, FACP VP, Global Regulatory Science Celgene Corporation  <i>Planned Topics</i> <ul style="list-style-type: none"> <li>• Refuse to file, filing over protest, withdrawal</li> <li>• PDUFA VI Interactions</li> <li>• Complete Response, Approval, Appeals</li> <li>• PMR/PMC, REMS</li> </ul>	<b>15</b>
11:00 AM – 12:15 PM	<b><u>Emerging Concepts in Cancer Immunotherapy</u></b> Ravi Madan, MD National Cancer Institute  <i>Planned Topics</i> <ul style="list-style-type: none"> <li>• Immune Checkpoint Inhibition</li> <li>• Update on therapeutic cancer vaccines</li> <li>• Biomarker development</li> <li>• Developing immune combinations and the next generation of immunotherapy</li> </ul>	<b>16</b>
12:15 – 1:15 PM	<b><i>Lunch Break</i></b>	
1:15 – 2:30 PM	<b><u>Pediatric Regulations and FDASIA: Operational Approaches to New FDA Initiatives Supporting Development for Pediatrics</u></b> Margaret Thompson, MD Medical Officer, Division of Oncology Products 2 Office of Hematology and Oncology Products FDA	<b>17</b>

Friday, October 27, 2017 (continued)

2:30 – 2:45 PM

**Afternoon Break**

2:45 – 3:45 PM

**New era of Novel Diagnostics and Novel-Novel Therapies in Multiple Myeloma****18**Dickran Kazandjian, MD  
FDA-NCI Clinical Investigator*Planned Topics*

- Progressive improvements in myeloma with progressive decades
- New treatments in treatment of myeloma
- Depth of response marker of long-term benefit
- Minimal Residual Disease and sensitivity of assays

3:45 – 4:00 PM

**Course Wrap-Up**

4:00 PM

**Adjournment****Continuing Education Credit**

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