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
CONFIRMED
Julie Bullock, PharmD
Senior Director of Clinical Pharmacology & Regulatory Science
d3 Medicine

10:00 – 10:15 AM  Morning Break

10:15 – 11:30 AM  Statistical Considerations for Trials with Interim Analyses
CONFIRMED
Malini Iyengar, PhD
Director, Biostatistics
Adaptimmune US

Planned Topics
• Overview of Phase 2-3 Trial Designs
• Approaches without or with predictive biomarkers
• Clinically meaningful endpoints, PFS, OS, and the “ASCO Recommendations to Raise the Bar for Clinical Trials”
• Foreign data; Regional differences in standard care

11:30 AM – 12:30 PM  Considerations for Clinical Trial Design and Endpoints Toward U.S. Drug Approval
CONFIRMED
Lorraine Pelosiof, 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

1:30 – 2:30 PM  Upper Gastrointestinal Malignancies: An Overview of Therapy
CONFIRMED
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
Wednesday, October 25, 2017  continued

2:30 – 3:30 PM  **Brain and CNS Cancer: Primary Tumors**  
Deepta 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

3:30 – 3:45 PM  **Afternoon Break**

3:45 – 5:00 PM  **Clinical Pharmacology in Oncology Drug Development**  
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  **Invited Presentation: Clinical Development**

9:30 – 10:30 AM  **Invited Presentation: Clinical Development**

10:30 – 10:45 AM  **Morning Break**

10:45 – 11:45 AM  **Renal Cell Cancer**  
Chana Weinstock, MD  
RCC/Prostate Cancer Scientific Liaison  
Division of Oncology Products 1  
Office of Hematology and Oncology Products  
U.S. Food and Drug Administration

11:45 AM – 12:45 PM  **Malignant Melanoma**  
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

**Planned Topics**
- Background & Staging of disease
- Risk factors and screening
- Overview of Current treatment standard of care – pros/cons
- Recent approvals
- Overview of future treatment horizons

12:45 – 1:45 PM  **Lunch Break**
Thursday, October 26, 2017  (continued)

1:45 – 2:30 PM  Leukemias  11
CONFIRMED
Blanche H. Mavromatis, MD
Braddock Oncology Associates
Western Maryland Health System Regional Cancer Center

Planned Topics
• Acute leukemias
• Chronic leukemias

2:30 – 3:30 PM  Lymphoid Malignancies  12
CONFIRMED
Blanche H. Mavromatis, MD
Braddock Oncology Associates
Western Maryland Health System Regional Cancer Center

Planned Topics
• Lymphoid malignancies overview
• Hodgkin’s disease and non-Hodgkin’s lymphoma
• Burkitt’s lymphoma

3:30 – 3:45 PM  Afternoon Break

3:45 – 4:45 PM  Breast Cancer  13
CONFIRMED
Blanche H. Mavromatis, MD
Braddock Oncology Associates
Western Maryland Health System Regional 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

4:45 – 5:00 PM  End of Day Discussion

Friday, October 27, 2017

8:00 – 8:30 AM  Continental Breakfast

8:30– 9:30 AM  Prostate Cancer Clinical Update  14
CONFIRMED
Ravi Madan, MD
Clinical Director, Genitourinary Malignancies Branch
Center for Cancer Research
National Cancer Institute

9:30 – 9:45 AM  Morning Break

9:45 – 11:00 AM  Regulatory Actions and Outcomes for NDAs and BLAs  15
CONFIRMED
Florence Houn, PhD

Planned Topics
• Refuse to file, filing over protest, withdrawal
• PDUFA VI Interactions
• Complete Response, Approval, Appeals
• PMR/PMC, REMS
Friday, October 27, 2017 (continued)

11:00 AM – 12:15 PM  Emerging Concepts in Cancer Immunotherapy  
Ravi Madan, MD  
National Cancer Institute

CONFIRMED  
Planned Topics  
• Immune Checkpoint Inhibition  
• Update on therapeutic cancer vaccines  
• Biomarker development  
• Developing immune combinations and the next generation of immunotherapy

12:15 – 1:15 PM  Lunch Break

1:15 – 2:30 PM  Pediatric Regulations and FDASIA: Operational Approaches to New FDA Initiatives Supporting Development for Pediatrics  
Margaret Thompson, MD  
Medical Officer, Division of Oncology Products 2  
Office of Hematology and Oncology Products  
FDA

2:30 – 2:45 PM  Afternoon Break

2:45 – 3:45 PM  New era of Novel Diagnostics and Novel- Novel Therapies in Multiple Myeloma  
Dickran Kazandjian, MD  
FDA/NCI Clinical Investigator

CONFIRMED  
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