Wednesday, October 15, 2014

7:30 – 8:00 AM **Registration and Continental Breakfast**

8:00 – 8:15 AM **PERI Welcome and Course Overview**
Marian Selby, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

8:15 – 9:00 AM **Overview of Oncology Targets and Emerging Therapies**
Howard J. Fingert, MD, FACP - **Course Director**
Senior Medical Director, Clinical Intelligence, Takeda Pharmaceuticals
and Industry Representative to the FDA Oncology Drugs Advisory Committee (ODAC)

Planned Topics: Fundamentals of early drug development
• Molecular Underpinnings of Oncology
• Pathways to Clinical Development
• Emerging targets, platforms, immunotherapies, novel combinations

9:00 – 10:00 AM **Protocol Designs and Statistical Issues**
Nicole Blackman, PhD

10:00 – 10:15 AM **Morning Break**

10:15 – 11:15 PM **Overview of EMA Regulatory Guidance in Oncology Development**
Invited speaker from The European Medicines Agency via webcast

Planned Topics
• Overview of EU Regulatory Framework – EMA, CHMP, SAG-O etc.
• Overview of centralized procedure
• EU Cancer Guideline i.e. endpoints, lines of therapies, specific issues of interest to EU regulators
• EU mechanisms for expediting DD e.g. Conditional approval, exceptional circumstances etc.

11:15 AM – 12:15 PM **Overview of US FDA Regulatory Guidance in Oncology Development**
Dickran Kazandjian, MD
Reviewer, CDER, U.S. Food and Drug Administration

Planned Topics
• Safety and Efficacy requirements for approval
• Clinical Trial Endpoints, trial designs, types of approval
• Updates on Breakthrough Therapy
• Considerations with Foreign Data

12:15 – 1:15 PM **Lunch Break (on your own)**
Wednesday, October 15, 2014 … CONTINUED

1:15 – 2:00 PM
**Benefit-Risk Considerations by Industry, Regulators and the Clinical Community**
Laurie Smaldone, MD

SPEAKER INVITED

*Planned Topics*
- ASCO Guidance and minimally important clinical benefit
- Benefit-risk by regulators and Oncology Drugs Advisory Committee (ODAC)
- Preparing for an ODAC – operations, regulations, and medical science

2:00 – 3:00 PM
**Learnings from Oncology Drug Advisory Committees (ODAC)**
Howard Fingert, MD

SESSION CONFIRMED

- Perspectives on ODAC – past, present, future
- Optimizing strategic engagement with Industry Representative
- Common features of recent successes and failures

3:00 – 3:15 PM
Afternoon Break

3:15 – 4:15 PM
**Clinical Operations, CROs, and Multiregional Trials**
Dirk Reitsma, MD
VP, Global Product Development
Head, Oncology, PPD Incorporated

SESSION CONFIRMED

*Planned Topics*
- Realities and challenges of global trials
- Enrolment outside the US, including Emerging Markets (EM)
- Proactive strategies to support quality of foreign data
- Optimizing global team effectiveness & competency

4:15 – 5:00 PM
**Panel Discussion: Afternoon Sessions**
H. Fingert, L. Smaldone, D. Reitsma, D. Kazandjian

SESSION CONFIRMED

*Planned Topics*
- Managing quality, multi-regional trials, foreign data
- Success factors for development and submission of NDA/BLA
Thursday, October 16, 2014

7:30 – 8:00 AM  Continental Breakfast

8:00 – 9:00 AM  Prostate Cancer Clinical Update
Ravi Madan, MD
Assistant Clinical Investigator, Medical Oncology Branch
Center for Cancer Research, National Cancer Institute
US National Institutes of Health, USDHHS

Planned Topics
• Cancer detection and prognosis
• Local and systemic therapy
  o Androgen Deprivation
  o Chemotherapy
  o Diverse new Immunotherapies
• Future directions

9:00 – 9:15 AM  Morning Break

9:15 – 10:15 AM  Biologic Therapeutics
Ravi Madan, MD

Planned Topics
• PD-1 Checkpoint in lung and other cancers
• Update on therapeutic vaccines, antibody-drug conjugates
• Novel antibodies
• Combinations and design of protocols with PD1, other emerging immunotherapies

10:15 – 11:00 AM  Lung Cancer
Shakun M. Malik, MD,
Head, Thoracic and Head & Neck Cancer Therapeutics,
Clinical Investigational Branch, CTEP
National Cancer Institute
Former Medical Officer, CDER
U.S. Food and Drug Administration

Planned Topics
• Overview of molecular pathogenesis of lung cancer
• Staging and treatment of lung cancer
• Emerging targeted and checkpoint inhibitors

11:00 – 11:45 AM  Managing Radiologic Imaging for Oncology Phase II-III Studies
Robert Ford, MD
Former Chief Medical Officer, RadPharm, Inc.

Planned Topics
• Imaging Endpoints and RECIST
• Challenges for imaging with emerging therapies
• Global Registration Trials

11:45 AM – 12:00 PM  Featured Panel Discussion
R. Madan, S. Malik, R. Ford

Planned Topics
• Strategic Design and Conduct of next-generation protocols with new checkpoint inhibitors, targeted, and immuno-therapies

12:00 – 1:00 PM  Lunch Break (on your own)
Thursday, October 16, 2014 ... CONTINUED

1:00 – 1:45 PM  Leukemias
Blanche H. Mavromatis, MD
Braddock Oncology Associates
Western Maryland Health System Regional Cancer Center

*Planned Topics*
- Acute leukemias
- Chronic leukemias

1:45 – 2:00 PM  Afternoon Break

2:00 – 3:15 PM  Lymphoid Malignancies
Blanche H. Mavromatis, MD

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

3:15 – 4:15 PM  Breast Cancer
Blanche H. Mavromatis, MD

*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

4:15 – 4:30 PM  End of Day Discussion Workshop
Friday, October 17, 2014

7:30 – 8:00 AM  Continental Breakfast

8:00 – 9:15 AM  New Perspectives in Colorectal Cancer
John L. Marshall, MD
Chief, Division of Hematology/Oncology & Associate Director for Clinical Research
Director, Reusch Center for the Cure of GI Cancers
Lombardi Comprehensive Cancer Center, Georgetown University Medical Center

Planned Topics
- General trends in gastrointestinal cancer
- Etiology
- Current effective treatment modalities
- Experimental horizons

9:15 – 9:30 AM  Morning Break

9:30 – 10:45 AM  Upper Gastrointestinal Malignancies: An Overview of Therapy
Jimmy J. Hwang, MD
Associate Professor of Medicine, Division of Hematology/Oncology
Lombardi Comprehensive Cancer Center
Georgetown University Medical Center

Planned Topics
- Esophageal cancer
- Pancreatic cancer
- Stomach cancer
- Hepatocellular carcinoma

10:45 AM – 12:00 PM  Melanoma
Sekwon Jang, MD
Melanoma/Dermatologic Oncology
Washington Hospital Center

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
- Questions and Answers

12:00 – 1:00 PM  Lunch Break (on your own)

1:00 – 2:15 PM  Pediatric Regulations and FDASIA: Operational Approaches to New FDA Initiatives Supporting Development for Pediatrics
Greg Reamon, MD or Melissa S. Tassinari, PhD
Pediatric and Maternal Health Staff
Office of New Drugs, CDER
U.S. Food and Drug Administration

2:15 – 2:30 PM  Afternoon Break
Friday, October 17, 2014 … CONTINUED

2:30 – 3:30 PM                      Ovarian and Renal Cancers
                                        Howard Fingert, MD
PLANNED SESSION

Planed Topics
• Background & Risk factors
• Emerging therapeutics
• Learnings from recent registration programs

3:30 – 4:00 PM                      Summation Workshop: How to Apply the Information Learned
                                        Guided Open Discussion Format
PLANNED SESSION

4:00 PM                           Adjournment

PERI reserves the right to change agenda items and instructors without notice to accommodate situations beyond its control.

CONTINUING EDUCATION CREDIT
Pharmaceutical Education & Research Institute, Inc. (PERI) is pleased to make continuing education credit available to you for attendance at this program. To receive credit, you must attend the entire program and submit both the Continuing Education Application form and the program evaluation directly to a PERI on-site coordinator. A continuing education certificate or Statement of Credit will be distributed to you within three weeks of this program.

Pharmaceutical
Pharmaceutical Education & Research Institute, Inc. (PERI) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ACPE Universal Activity Number is 0708-0000-14-007-L01-P 2.05 continuing education units (CEUs) are available for this program. Initial Release Date: 10/15/2014. This is a knowledge based CPE Activity.

Continuing Medical Education
PERI, Inc. is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. PERI, Inc. designates this live activity for a maximum of 20.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.