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

MicroTek Training Center • Washington, DC
October 23 – 25, 2019

Wednesday, October 23, 2019

8:15 – 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 AM – 9:45 AM **Considerations for Clinical Trial Design and Endpoints Toward U.S. Drug Approval** ***1***
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 Review Procedures

9:45 – 10:05 AM ***Morning Break***

10:05 – 11:20 AM **Design and Analysis of Oncology Studies** ***2***
Malini Iyengar, PhD
Head of Clinical Pharmacology
TEVA Pharmaceuticals

Planned Topics
- Study Design
- Trials with Objective Response Rates
- Trials with PFS, OS

11:20 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Improved Strategies for Selecting Recommended Phase 2 Dosing: Moving Beyond Maximum Tolerated Dose** ***3***
Lanre Okusanya, PharmD, MS
Clinical Pharmacologist. Division of Clinical Pharmacology V
Office of Clinical Pharmacology
U.S. Food and Drug Administration

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

Wednesday, October 23, 2019 (continued)

12:30 PM – 1:30 PM ***Lunch Break***

1:30 – 2:30 PM **Breast Cancer Clinical Update** ***4***
Suparna Wedam, MD
Office of Hematology and Oncology Products
U.S. Food and Drug Administration

2:30 – 2:45 PM ***Afternoon Break***

2:45 – 4:00 PM **Emerging Concepts in Cancer Immunotherapy** ***5***
Julius Strauss, MD
Assistant Research Physician, Laboratory of Tumor Immunology and Biology
Co-Director, Clinical Trials Group
Center for Cancer Research
National Cancer Institute

Planned Topics

- Immune Checkpoint Inhibition
- Update on therapeutic cancer vaccines
- Biomarker development
- Developing immune combinations and the next generation of immunotherapy

4:00 – 5:00 PM **Prostate Cancer Clinical Update** ***6***
Marijo Bilusic, MD, PhD
Associate Research Physician, Genitourinary Malignancies Branch
Program Director, NIH Hematology Oncology Fellowship
National Cancer Institute

Planned Topics

- Current treatment landscape for metastatic prostate cancer
- Immunotherapy for prostate cancer
- Novel treatment options

5:00 PM **End of Day One**

Thursday, October 24, 2019

8:00 – 8:30 AM ***Continental Breakfast***

8:30 – 9:30 AM **Pediatric Regulations and New FDA Initiatives Supporting Development for Pediatrics** ***7***

Sonia Singh, MD
Pediatric Oncologist
Division of Oncology Products 2
Office of Hematology and Oncology Products
U.S. Food and Drug Administration

Planned Topics

- Challenges and Opportunities in Pediatric Oncology Trials
- Legislation Impacting Drug Development in Pediatric Oncology
- Pediatric Oncology at FDA

9:30 – 9:45 AM ***Morning Break***

9:45 – 11:00 AM **Regulatory Actions and Outcomes for NDAs and BLAs** ***8***

Florence Houn, MD, MPH, FACP
VP, Global Regulatory Science
Celgene Corporation

Planned Topics

- Refuse to file, filing over protest, withdrawal
- PDUFA VI Interactions
- Complete Response, Approval, Appeals
- PMR/PMC, REMS

11:00 AM – 12:00 PM **Gynecologic Malignancies** ***9***

Shaily Arora, PharmD
Clinical Reviewer, Gynecologic Malignancies Team
Division of Oncology Products 1
Office of Hematology and Oncology Products
U.S. Food and Drug Administration

Planned Topics

- Rare subsets
- Recent approvals
- Expanding the drug indication

12:00 – 1:00 PM ***Lunch Break***

Thursday, October 24, 2019 (continued)

1:00 – 2:00 PM **Lung Cancer Clinical Update** ***10***

Shakun Malik, MD
Head, Thoracic Cancer Therapeutics
Cancer Therapy Evaluation Program
National Cancer Institute

Planned Topics

- Overview of molecular pathogenesis of lung cancer
- Staging and treatment of lung cancer

2:00 – 2:15 PM ***Afternoon Break***

2:15 – 3:30 PM **Malignant Melanoma** ***11***

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

3:30– 3:40 PM ***Stretch Break***

3:40 – 4:45 PM **Brain and CNS Cancer: Primary Tumors** ***12***

Deepa S. Subramaniam, M.D., M.Sc.
Director, Oncology R&D, AstraZeneca Plc
Associate Professor, Georgetown University
Lombardi Comprehensive Cancer Center

Planned Topics

- Overview of classification of primary brain tumors
- Standard treatment options for high grade gliomas

4:45 – 5:00 PM **Course Wrap Up / End of Day Two**

Friday, October 25, 2019

8:00 – 8:30 AM ***Continental Breakfast***

8:30 – 9:30 AM **Colorectal Cancer Clinical Update** ***13***
Benjamin A. Weinberg, MD
Assistant Professor of Medicine, Division of Hematology and Oncology
Gastrointestinal Medical Oncologist, Lombardi Comprehensive Cancer Center
MedStar Georgetown University Hospital

Planned Topics
- Review IDEA data of 3 vs. 6 months of adjuvant chemotherapy
- Review current NCCN guidelines for metastatic disease
- Updates on BRAF-targeted therapy

9:30 – 9:45 AM ***Morning Break***

9:45 – 10:45 AM **Pancreatic Cancer Clinical Update** ***14***
Benjamin A. Weinberg, MD

Planned Topics
- Review current standards-of-care for adjuvant therapy and data on neoadjuvant therapy
- Review standards for advanced disease
- Discuss novel therapeutic options and ongoing clinical trials for patients with advanced disease

10:45 AM – 12:00 PM **Upper Gastrointestinal Malignancies: An Overview of Therapy** ***15***
Benjamin A. Weinberg, MD

Planned Topics
- Pancreatic cancer
- Stomach cancer
- Hepatocelluar carcinoma

12:00 PM **Course Adjournment**

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Course Description

Therapeutics for cancer are entering a new era, where precision approaches promise to revolutionize the way in this disease is treated. This comprehensive course reviews current and emerging drugs, immunotherapies, their application to specific cancer types, how to conduct clinical trials for oncologic therapies, and the drug development process for drug candidates leading to their approval. The US Food & and Drug Administration (FDA) regulatory considerations for Oncology drugs, registration endpoints, and accelerated and Breakthrough approval mechanisms are also covered.

Course Objectives

Upon completion of this course, participants should be able to:

- Discuss the scope, nature and epidemiology of many human cancers with an emphasis on principles of case management of common malignancies
- Describe specific applications of commonly used cancer treatments
- Evaluate the design and conduct of oncology Phase I, II, and III clinical trials
- Apply FDA requirements for oncology clinical trials and drug development programs to facilitate/expedite drug development