Liquid Biopsies in Oncology Drug and Device Development Part 2

October 10, 2017
Renaissance Downtown Hotel, Washington, DC
Room: Congressional A/B

Purpose: As a noninvasive method to detect genetic alterations in tumors, analysis of tumor-derived cell-free DNA (cfDNA) in plasma holds much promise for improving cancer diagnosis and monitoring as well as drug development. This technology is advancing quickly, being incorporated into numerous drug development programs, and likely to be rapidly incorporated into clinical care.

Theme: Technology has evolved to enable the development of tests that can detect signs of cancer in blood and other bio-fluids. Although liquid biopsies are an exciting development, this technology presents with a set of unique regulatory concerns, particularly in establishing analytic and clinical validity. This session will build upon a July 2016 U.S. Food and Drug Administration-AACR co-sponsored workshop on liquid biopsies and will examine the regulatory challenges in adopting this technology for early detection, disease monitoring, and the potential use as surrogate endpoint markers for drug development.

AGENDA

8:30 AM **Welcome and Workshop Objectives - Workshop Cochairs**
Julia A. Beaver, MD, Director (acting), Division of Oncology Products I, Office of Hematology and Oncology Products (OHOP), Center for Drug Evaluation and Research (CDER), FDA

Gideon M. Blumenthal, MD, Deputy Director (acting), Office of Hematology and Oncology Products (OHOP), Center for Drug Evaluation and Research (CDER), FDA

Reena Philip, PhD, Director, Division of Molecular Genetics and Pathology (DMGP), Office of In Vitro Diagnostics and Radiological Health (OIR), Center for Devices and Radiological Health (CDRH), FDA

Carlos L. Arteaga, MD, AACR President, 2014-2015; Director, Harold C. Simmons Comprehensive Cancer Ctr., UT Southwestern Medical Ctr.

Pasi Jänne, MD, PhD, Director, Lowe Center for Thoracic Oncology; Scientific Director, Belfer Institute for Applied Cancer Science; Senior Physician, Dana-Farber Cancer Institute; and Professor of Medicine, Harvard Medical School

SESSION I: CANCER LIQUID BIOPSIES: STATE OF THE SCIENCE
Session Chair: Julia A. Beaver, MD

8:40 AM	**Session Overview** **Julia A. Beaver, MD,** FDA
8:45 AM	**New Developments in Analysis of Circulating Tumor DNA** **Maximilian Diehn, MD, PhD,** Stanford Univ.
9:10 AM	**Strategies to Exploit the Biology of Exosomes for Diagnosis and Treatment of Cancer** **Raghu Kalluri, MD, PhD,** UT MD Anderson Cancer Ctr.
9:35 AM	**New Strategies for Quantification of Circulating Tumor Cells** **Daniel A. Haber, MD, PhD,** Massachusetts General Hospital
10:00 AM	**BREAK**

SESSION II: LIQUID BIOPSIES FOR EARLY DIAGNOSIS
Session Chair: Carlos L. Arteaga, MD

10:15 AM	**Session Overview** **Carlos L. Arteaga, MD,** UT Southwestern Medical Ctr.
10:20 AM	**Circulating Cell-free Nucleic Acids for Early Cancer Diagnosis** **Anne-Renee Hartman, MD,** GRAIL, Inc.
10:40 AM	**Minimal Residual Disease Detection in Multiple Myeloma: Outcomes and Implications** **C. Ola Landgren, MD, PhD,** Memorial Sloan Kettering Cancer Ctr.
11:00 AM	**Residual Disease Detection in Breast Cancer: Implications for Solid Tumors** **Nicholas C. Turner, MD, PhD,** Royal Marsden Hospital Inst. of Cancer Res.
11:20 AM	**PANEL DISCUSSION and AUDIENCE Q&A**
12:00 PM	**LUNCH BREAK (ON YOUR OWN)**

SESSION III: LIQUID BIOPSIES IN CANCER DRUG DEVELOPMENT AND CLINICAL USE
Session Cochairs: Gideon M. Blumenthal, MD, & Pasi Jänne, MD, PhD

1:00 PM	**Session Overview & "State of the Art" for Lung Cancer** **Pasi Jänne, MD, PhD,** Dana-Farber Cancer Inst., Harvard Medical School
1:15 PM	**Optimizing Biomarkers for Oncology Drug Development** **Gideon M. Blumenthal, MD,** FDA
1:35 PM	**Clinical Trial Enrollment Based on cfDNA; Are We Ready for Liquid-MATCH?** **David Hyman, MD,** Memorial Sloan Kettering Cancer Ctr.
1:55 PM	**Clinical Care Based on cfDNA; What are the Opportunities and Needs?** **Scott Kopetz, MD, PhD,** UT MD Anderson Cancer Ctr.
2:15 PM	**PANEL DISCUSSION and AUDIENCE Q&A**
2:55 PM	**BREAK**

SESSION IV: LIQUID BIOPSY TEST DEVELOPMENT
Session Chair: Reena Philip, PhD

3:10 PM	**Session Overview** **Reena Philip, PhD,** FDA
3:15 PM	**Regulatory Perspective on Liquid Biopsy Diagnostics for Oncology Applications** **Eunice Lee, PhD,** FDA
3:25 PM	**Examination of Analytical Factors Impacting Concordance of Plasma vs Tumor Testing By Next Generation Sequencing: When Can the LB Replace the Tumor Biopsy?** **J. Carl Barrett, PhD,** AstraZeneca
3:45 PM	**A Precompetitive Effort to Deliver Reference/Control Materials for ctDNA Assays** **P. Mickey Williams, PhD,** for the FNIH ctDNA Reference Material Working Group
4:05 PM	**Study Designs for Early Detection** **Meijuan Li, PhD,** FDA
4:20 PM	**PANEL DISCUSSION and AUDIENCE Q&A**
5:00 PM	**ADJOURN**