FDA-AACR Workshop on
How Much is Enough? Trial Designs for Treatment Regimens with Multiple Phases
Bethesda Marriott Pooks Hill
May 9 | 9:00 AM – 4:00 PM

Workshop Co-chairs:
Harpreet Singh, MD, Director, Division of Oncology 2, U.S. Food and Drug Administration
Elizabeth Jaffee, MD, FAACR, FCP, Deputy Director, Sidney Kimmel Comprehensive Cancer Center

AGENDA

9:00 AM INTRODUCTION
9:00 AM Welcome & Introduction:
Elizabeth Jaffee, MD, Sidney Kimmel Comprehensive Cancer Center
9:05 AM Overview of Workshop:
Harpreet Singh, MD, U.S. Food and Drug Administration

9:15 AM SESSION 1: CURRENT LANDSCAPE FOR PERIOPERATIVE TRIAL DESIGNS
9:15 AM Moderator Introduction:
Erin Larkins, MD, U.S. Food and Drug Administration
9:20 AM Current Therapeutic Landscape for Early-Stage Solid Tumors:
Oladimeji Akinboro, MD, U.S. Food and Drug Administration
9:30 AM Biomarker-Guided Perioperative Clinical Trials:
Valsamo Anagnostou, MD, PhD, Sidney Kimmel Comprehensive Cancer Center
9:40 AM Implementing Sequential, Multiple, Randomized (SMART) Trial Designs:
Kelley Kidwell, PhD, University of Michigan School of Public Health

9:50 AM PANEL DISCUSSION
- Anup Amatya, PhD, U.S. Food and Drug Administration
- Paz Vellanki, MD, U.S. Food and Drug Administration
- Thelma Brown, Translational Breast Cancer Research Consortium
- Roy Herbst, MD, PhD, Yale University
- Mark Kris, MD, Memorial Sloan Kettering Cancer Center
- Aarón Sosa Mejia, MD, European Medicines Agency
- Craig Tendler, MD, Johnson & Johnson Innovative Medicine

10:45 AM BREAK
### SESSION 2A: OPTIMIZING PERIOPERATIVE TREATMENT REGIMENS

#### 10:55 AM
**Moderator Introduction:**
Elizabeth Jaffee, MD, Sidney Kimmel Comprehensive Cancer Center

#### 11:00 AM
**Optimizing the Regimen: Cooperative Group Perspective:**
Jhanelle Gray, MD, Moffitt Cancer Center

#### 11:10 AM
**Cumulative and Long-Term Toxicity with Immunotherapy:**
Mark Yarchoan, MD, Sidney Kimmel Comprehensive Cancer Center

#### 11:20 AM
**PANEL DISCUSSION**
- Vishal Bhatnagar, MD, U.S. Food and Drug Administration
- Tatiana Prowell, MD, U.S. Food and Drug Administration
- Michael Axelson, MD, Loxo@Lilly
- Fred Hirsch, MD, PhD, The Tisch Cancer Institute at Mount Sinai
- Jane Perlmutter, PhD, MBA, Gemini Group
- Sara Tolaney, MD, MPH, Dana-Farber Cancer Institute

#### 12:20 PM
**LUNCH BREAK**

#### 12:50 PM
**Fireside Chat with FDA Division Directors**
- Angelo de Claro, MD, Hematologic Malignancies I
- Nicole Gormley, MD, Hematologic Malignancies II
- Laleh Amiri-Kordestani, MD, Oncology I
- Steven Lemery, MD, Oncology III
- Harpreet Singh, MD, Oncology II
### 1:20 PM SESSION 2B: THE FUTURE OF REGISTRATIONAL TRIALS WITH MULTIPLE ARMS

**1:20 PM**
Moderator Introduction:
Bernardo Haddock Lobo Goulart, MD, U.S. Food and Drug Administration

**1:25 PM**
Statistical Considerations for Future Perioperative Trials:
Chi Song, PhD, U.S. Food and Drug Administration

**1:35 PM**
Industry Perspective on Future Perioperative Trials:
Minghua Shan, PhD, Bayer Pharmaceuticals

**1:45 PM PANEL DISCUSSION**
- Nicole Gormley, MD, U.S. Food and Drug Administration
- Pallavi Mishra-Kalyani, PhD, U.S. Food and Drug Administration
- Patrick Forde, MD, Johns Hopkins Medicine
- Giuseppe Giaccone, MD, PhD, Weill Cornell Medical College
- Joshua Reuss, MD, MedStar Georgetown
- Kathleen Winson, MS, Genentech, Inc.

**2:45 PM BREAK**

**2:55 PM Session 3: Considerations in Other Therapeutic Areas**

**2:55 PM**
Moderator Introduction:
Mirat Shah, MD, U.S. Food and Drug Administration

**3:00 PM**
Where Do We Go from Here? Considerations for NSCLC & Other Therapeutic Areas:
Harpreet Singh, MD, U.S. Food and Drug Administration

**3:10 PM PANEL DISCUSSION**
- Stephanie Wethington, MD, U.S. Food and Drug Administration
- Naomi Horiba, MD, MPH, U.S. Food and Drug Administration
- Christine Gause, PhD, Merck
- Manju George, PhD, MVSc, Colontown
- Cristina Migali, MD, PhD, European Medicines Agency
- Thomas Powles, MD, Barts-Cancer Institute, London

**3:55PM**
Concluding Remarks
Harpreet Singh, MD, U.S. Food and Drug Administration

**4:00 PM** ADJOURN