FDA-American Society of Clinical Oncology-Friends of Cancer Research
Workshop on Development of Tissue-Agnostic, Biomarker-Based Indications

Co-Sponsored by the:
U.S. Food & Drug Administration (FDA), American Society of Clinical Oncology (ASCO), and Friends of Cancer Research (Friends)
Twitter: #FDATissueAgnostic19

FDA White Oak Campus, Building 31, Room 1503 - Great Room
10903 New Hampshire Avenue, Silver Spring, MD 20993

April 26, 2019 – 8:30 am – 4:00 pm (Eastern)

1. **Welcome and Introductions – 8:30-8:40**
   Suanna Steeby Bruinooge, MPH (ASCO)

2. **State of the Science and Clinical Care for Tissue-Agnostic, Biomarker-Based Indications – 8:40-9:50**
   a. Moderator – Steven Lemery, MD (FDA)
   b. Funda Meric-Bernstam, MD (MD Anderson Cancer Center)
   c. Michael Berger, MD (Memorial Sloan-Kettering Cancer Center)
   d. Stacie C. Lindsey (Cholangiocarcinoma Foundation)
   e. Martha Donoghue, MD (FDA)
   f. Discussion with Audience – 20 mins

3. **Complexities/Key Lessons Learned from Case Examples – 9:50-10:20**
   a. Eric Rubin, MD (Merck Research Laboratories) – 15 minutes
      i. Pembrolizumab (Keytruda, Merck & Co.), May 2017
   b. Josh Bilenker, MD (Loxo Oncology) – 15 minutes
      i. Larotrectinib (Vitrakvi, Loxo Oncology Inc. and Bayer), November 2018

10-minute break – 10:20-10:30

4. **Multi-Stakeholder Panel – Early Research and Development Considerations – 10:30-12:10**
   a. Moderator – Gideon Blumenthal, MD (FDA)
   b. Presentations – 40 minutes
      i. Haleh Saber, PhD (FDA)
      ii. Alexia Iasonos, PhD (Memorial Sloan-Kettering Cancer Center)
      iii. Julie Bullock, PhD (Certara)
      iv. Reena Philip, PhD (FDA)
   c. Moderated Panel Discussion – 40 minutes
      i. Ann Ramer, Patient Advocate
      ii. Katherine A. Janeway, MD (Boston Children's Hospital and Dana-Farber Cancer Institute)
      iii. Shivaani Kummar, MD, FACP (Stanford University)
      iv. Antoine Yver, MD, MSc (Daiichi Sankyo)
      v. John Simmons, PhD (PGDx)
      vi. P. “Mickey” Williams, PhD (National Cancer Institute)
      vii. Adnan Jaigirdar, MD (FDA)

d. Open Q&A with Audience – 20 minutes

Lunch Break – 12:10-12:40

5. **Multi-Stakeholder Panel – Registration Research and Development Considerations – 12:40-2:10**
    a. Moderator – Tatiana Prowell, MD (FDA)
    b. Presentations – 30 minutes
        i. Leigh Marcus, MD (FDA)
        ii. Vivian Yuan, PhD (FDA)
        iii. Pierre Demolis, PhD (European Medicines Agency)
    c. Moderated Panel Discussion – 40 minutes
        i. Josh Mailman (Northern California CarciNET Community)
        ii. Vivek Subbiah, MD (MD Anderson Cancer Center)
        iii. Theodore Laetsch, MD (University of Texas Southwestern Medical Center)
        iv. Howard A. Burris, MD, FACP, FASCO (Sarah Cannon)
        v. Joon Rhee, PhD (AstraZeneca)
        vi. David Fabrizio, MD (Foundation Medicine, Inc.)
        vii. Reena Philip, PhD (FDA)
    d. Open Q&A with Audience – 20 minutes

10-minute stretch break to reset for next speakers – 2:10-2:20

6. **Multi-Stakeholder Panel – Post-Market Research and Development Considerations – 2:20-3:50**
    a. Moderator – Julia Beaver, MD (FDA)
    b. Presentations – 40 minutes
        i. Ashley Ward, MD (FDA)
        ii. Deb Schrag, MD (Dana-Farber Cancer Institute)
        iii. Meg Mooney, MD, MBA, (Cancer Therapy Evaluation Program, National Cancer Institute)
        iv. Monica M. Bertagnolli, MD, FACS, FASCO (The Alliance for Clinical Trials in Oncology)
    c. Moderated Panel Discussion – 40 minutes
        i. Richard L. Schilsky, MD, FACP, FSCT, FASCO (ASCO)
        ii. Suparna Wedam, MD (FDA)
        iii. Alex Spira, MD, PhD, FACP (Virginia Cancer Specialists)
        iv. Mary Beattie, MD (Genentech)
        v. Dana Deighton (Esophageal Cancer Action Network)
        vi. Rajeshwari Sridhara, PhD (FDA)
    d. Open Q&A with Audience – 20 minutes

7. **Workshop Wrap-up – 3:50-4:00**
    Mark Stewart, PhD (Friends)