Approaches to Neoadjuvant Treatment in Melanoma:
A Public Workshop Organized by the FDA and MRA

Date: Wednesday, November 6, 2019, 7:00AM – 2:00PM
Location: The Westin National Harbor, Potomac Ballroom,
171 Waterfront Street, Oxon Hill, MD, 20745

Workshop Co-Chairs:

Ashley Ward, MD, *U.S. Food and Drug Administration (FDA)*
Marc Hurlbert, PhD, *Melanoma Research Alliance (MRA)*
Suzanne Topalian, MD, *Johns Hopkins Bloomberg-Kimmel Institute for Cancer Immunotherapy* (JHU)

AGENDA

7:00 – 8:00 AM	Registration and Continental Breakfast
8:00 – 8:10 AM	**Introduction and Welcome** – *Ashley Ward, MD (FDA) and Michael Kaplan (MRA)*
8:10 – 8:40 AM	**Keynote Lecture:** A role and rationale for neoadjuvant therapy in the melanoma treatment landscape – *Suzanne Topalian, MD (JHU)*
8:40 – 10:05 AM	**Session 1:** Foundational Experience from Other Areas in Oncology – *Moderator: Ashley Ward, MD (FDA)*
8:40 – 8:55 AM	Neoadjuvant/adjuvant Standards of Care and Experimental Approaches in Breast Cancer – *Angela DeMichele, MD, University of Pennsylvania (Penn)*
8:55 – 9:10 AM	Neoadjuvant Immunotherapy in Lung Cancer – *Patrick Forde, MD (JHU)*
9:10 – 9:25 AM	Regulatory Perspective on Neoadjuvant Approvals and Trials – *Laleh Amiri-Kordestani, MD (FDA)*
9:25 – 9:40 AM	Surrogate Endpoints and Statistical Considerations – *Donald Berry, PhD, University of Texas MD Anderson Cancer Center (MDACC)*
9:40 – 9:55 AM	Q&A – Clarifying questions or comments
9:55 – 10:05 AM	Break
10:05 – 11:00 AM	**Session 2:** Current Melanoma Neoadjuvant Experience – *Moderator: Marc Theoret, MD (FDA)*
10:05 – 10:20 AM	Melanoma Neoadjuvant Clinical Trials with Immunotherapy – *Caroline Robert, MD, PhD, Institut Gustave Roussy*
10:20 – 10:35 AM	Melanoma Neoadjuvant Therapy with Kinase Inhibitors – *Jennifer Wargo, MD, MMSc, (MDACC)*
10:35 – 10:50 AM	Pathologic Response Criteria – *Janis Taube, MD, MSc (JHU)*
10:50 – 11:00 AM	Q&A – Clarifying questions or comments

11:00 – 2:00 PM	**Session 3:** Optimal Clinical Trial Design and Patient Selection – *Moderator: Steven Lemery, MD, MPH (FDA)*
11:00– 11:15 AM	Patient Selection and Risk:Benefit Considerations: A Surgeon's Perspective – *Charlotte Ariyan, MD, PhD, Memorial Sloan Kettering Cancer Center (MSKCC)*
11:15 – 11:30 AM	Patient Selection and Risk:Benefit Considerations: An Oncologist's Perspective – *Michael Atkins, MD, Georgetown University*
11:30 – 11:45 AM	Patient Selection and Risk:Benefit Considerations: A Patient's Perspective – *To Be Named*
11:45 AM – 12:00 PM	Neoadjuvant Melanoma Trials Data Collection and Endpoint Selection – *Christian Blank, MD, PhD, Netherlands Cancer Institute*
12:00 – 12:15 PM	Trial Design / Analysis Method Considerations – *Rajeshwari Sridhara, PhD (FDA)*
12:15 – 12:20 PM	Q&A – Clarifying questions or comments
12:20 – 12:40 PM	Lunch: Select box lunch and return to Workshop
12:40 – 1:50 PM	**Panel Discussion with Audience Q&A** – Working Together to Develop Neoadjuvant Therapies in Melanoma *Chair: Keith Flaherty, MD, Massachusetts General Hospital* Topics to be discussed include: • Actionable, cross-sector collaborations • Consistency across multiple centers in patient selection, surgical approach, and specimen and data collection • Innovative biomarkers
	Panel members: *Charlotte Ariyan, MD, PhD (MSKCC); Nageatte Ibrahim, MD, Merck; Patricia Keegan, MD (FDA); Tara Mitchell, MD (Penn); Rebecca Moss, MD, Bristol-Myers Squibb; Michael Tetzlaff, MD, PhD (MDACC)*
1:50 – 2:00 PM	**Summary and Closing Remarks** – *Marc Hurlbert, PhD (MRA)*

Workshop Planning Committee:

Steven Lemery, MD, MPH, Marc Theoret, MD, and Ashley Ward, MD *(FDA)*

Marc Hurlbert, PhD, Kristen Mueller, PhD *(MRA)*

Suzanne Topalian, MD (JHU)