NATIONAL CANCER POLICY FORUM

Advancing Progress in the Development of Combination Cancer Therapies with Immune Checkpoint Inhibitors

JULY 16 – 17, 2018

Keck Center of the National Academies
500 Fifth Street, NW
Washington, DC
Room 100

WORKSHOP AGENDA

July 16, 2018	
7:30 am	**Registration and Breakfast**
8:00 am	**Welcome from the National Cancer Policy Forum and Workshop Overview** Samir N. Khleif, Georgetown University Roger Dansey, Seattle Genetics, Inc. Planning Committee Co-Chairs

8:15 am	**Session 1: Overview of PD-1/PD-L1 Therapy and the Need for Combination Therapies**
	Moderator: Roger Dansey, Seattle Genetics, Inc.
	
	The State-of-the-Art of PD-1/PD-L1 Development and Clinical Use/Outcomes
	• Ramy Ibrahim, Parker Institute for Cancer Immunotherapy
	
	Limits of Monotherapy, and the State of PD-1 and PD-L1 Combination Therapies in Clinical Trials
	• Roy Herbst, Yale Cancer Center
	
	Criteria for Selecting Preclinical Combinations and Combination Prioritization Strategies in Early-Stage Drug Development
	• Academic Perspectives
	  ○ Samir N. Khleif, Georgetown University
	  ○ Dan Theodorescu, Samuel Oschin Comprehensive Cancer Institute
	• Industry Perspectives
	  ○ Emmett Schmidt, Merck
	  ○ Chris Boshoff, Pfizer
	
	Panel Discussion

10:30 am	**Break**
10:45 am	**Session 2: The Role of Biomarkers in Developing PD-1/PD-L1 Combinations** Moderator: David Rimm, Yale University School of Medicine **Overview of Biomarker Development for Immune PD-1/PD-L1 Checkpoint Blockade Combinations** • David Rimm, Yale University School of Medicine

	Perspectives on Biomarkers for PD-1/PD-L1 Combination Therapies • Naiyer Rizvi, Columbia University Medical Center • Benjamin Izar, Dana-Farber Cancer Institute • Margaret Shipp, Dana-Farber Cancer Institute **The Unique Challenges in Developing Biomarker-Driven Site-Agnostic Therapies** • Richard L. Schilsky, American Society of Clinical Oncology **The Microbiome in Cancer Immunotherapy** • Christian Jobin, University of Florida **Panel Discussion**
12:45 pm	**Lunch**
1:30 pm	**Session 3: Clinical Trial Design for PD-1/PD-L1 Combination Therapies** Moderator: George Weiner, University of Iowa Holden Comprehensive Cancer Center **Combination Trial Design Strategies** • Adil Daud, UCSF Helen Diller Family Comprehensive Cancer Center **Master Protocols for Immunotherapy Combinations** • Ahmad Tarhini, Cleveland Clinic and Case Comprehensive Cancer Center **Strategies for Incorporating Biomarkers in Clinical Trials for PD-1/PD-L1 Combination Therapies** • Lisa Butterfield, University of Pittsburgh and the Society for Immunotherapy of Cancer **Appropriate Endpoints for Evaluating the Efficacy of PD-1/PD-L1 Combination Therapies** • Elizabeth Jaffee, Johns Hopkins University School of Medicine **Panel Discussion** Include speakers and • Linda House, Cancer Support Community • Louise Perkins, Melanoma Research Alliance
3:25 pm	**Break**
3:35 pm	**Session 4: Regulatory Challenges with Developing PD-1/PD-L1 Combination Therapies** Moderator: Roy Herbst, Yale Cancer Center **Overview of Regulatory and Labeling Challenges with Developing Immune Checkpoint Blockade Combination Therapies** • Amy McKee, Food and Drug Administration **Regulatory Requirements for Site-Agnostic Indications** • Steven Lemery, Food and Drug Administration

	Industry Perspectives • Daniel Chen, Genentech/Roche • Katrin Rupalla, Bristol-Myers Squibb **Panel Discussion**
5:30 pm	**Adjourn Day 1**
5:35 pm	**Reception**
	July 17, 2018
7:30 am	**Registration and Breakfast**
8:00 am	**Session 5: Precompetitive Data Sharing and Collaboration to Develop PD-1/PD-L1 Combinations** Moderator: Martin Murphy, CEO Roundtable on Cancer **An Overview of How Real World Evidence, Data Sharing, and Precompetitive Collaboration May Influence the Development of PD-1/PDL-1 Combination Therapies** • Amy Abernethy, Flatiron Health **Sharing Data to Support Development, Validation, and Standardization of Biomarkers in Patient Selection Used in Immunotherapy Trials** • Gaurav Singal, Foundation Medicine **Precompetitive Use of Algorithms to Predict Adverse Events** • Sean Khozin, Food and Drug Administration **Panel Discussion**
10:00 am	**Break**
10:15 am	**Session 6: Stakeholder Perspectives on the Path Forward** Moderator: Ramy Ibrahim, Parker Institute for Cancer Immunotherapy • Roger Dansey, Seattle Genetics, Inc. • Roy Herbst, Yale Cancer Center • Una Hopkins, White Plains Hospital • Linda House, Cancer Support Community • Marc Theoret, Food and Drug Administration **Group Discussion**
11:30 am	**Workshop Wrap Up**
11:45 am	**Adjourn**