



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 <ul style="list-style-type: none"> • Ramy Ibrahim, Parker Institute for Cancer Immunotherapy Limits of Monotherapy, and the State of PD-1 and PD-L1 Combination Therapies in Clinical Trials <ul style="list-style-type: none"> • Roy Herbst, Yale Cancer Center Criteria for Selecting Preclinical Combinations and Combination Prioritization Strategies in Early-Stage Drug Development <ul style="list-style-type: none"> • Academic Perspectives <ul style="list-style-type: none"> ○ Samir N. Khleif, Georgetown University ○ Dan Theodorescu, Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai • Industry Perspectives <ul style="list-style-type: none"> ○ 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 <ul style="list-style-type: none"> • David Rimm, Yale University School of Medicine

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	<p>Perspectives on Biomarkers for PD-1/PD-L1 Combination Therapies</p> <ul style="list-style-type: none"> • Naiyer Rizvi, Columbia University Medical Center • Benjamin Izar, Dana-Farber Cancer Institute • Margaret Shipp, Dana-Farber Cancer Institute <p>The Unique Challenges in Developing Biomarker-Driven Site-Agnostic Therapies</p> <ul style="list-style-type: none"> • Richard L. Schilsky, American Society of Clinical Oncology <p>The Microbiome in Cancer Immunotherapy</p> <ul style="list-style-type: none"> • Christian Jobin, University of Florida <p>Panel Discussion</p>
12:45 pm	Lunch
1:30 pm	<p>Session 3: Clinical Trial Design for PD-1/PD-L1 Combination Therapies Moderator: George Weiner, University of Iowa Holden Comprehensive Cancer Center</p> <p>Combination Trial Design Strategies</p> <ul style="list-style-type: none"> • Adil Daud, UCSF Helen Diller Family Comprehensive Cancer Center <p>Master Protocols for Immunotherapy Combinations</p> <ul style="list-style-type: none"> • Ahmad Tarhini, Cleveland Clinic and Case Comprehensive Cancer Center <p>Strategies for Incorporating Biomarkers in Clinical Trials for PD-1/PD-L1 Combination Therapies</p> <ul style="list-style-type: none"> • Lisa Butterfield, University of Pittsburgh and the Society for Immunotherapy of Cancer <p>Appropriate Endpoints for Evaluating the Efficacy of PD-1/PD-L1 Combination Therapies</p> <ul style="list-style-type: none"> • Elizabeth Jaffee, Johns Hopkins University School of Medicine <p>Panel Discussion Include speakers and</p> <ul style="list-style-type: none"> • Linda House, Cancer Support Community • Louise Perkins, Melanoma Research Alliance
3:25 pm	Break
3:35 pm	<p>Session 4: Regulatory Challenges with Developing PD-1/PD-L1 Combination Therapies Moderator: Roy Herbst, Yale Cancer Center</p> <p>Overview of Regulatory and Labeling Challenges with Developing Immune Checkpoint Blockade Combination Therapies</p> <ul style="list-style-type: none"> • Amy McKee, Food and Drug Administration <p>Regulatory Requirements for Site-Agnostic Indications</p> <ul style="list-style-type: none"> • Steven Lemery, Food and Drug Administration

	<p>Industry Perspectives</p> <ul style="list-style-type: none"> • Daniel Chen, Genentech/Roche • Katrin Rupalla, Bristol-Myers Squibb <p>Panel Discussion</p>
5:30 pm	Adjourn Day 1
5:35 pm	Reception
July 17, 2018	
7:30 am	Registration and Breakfast
8:00 am	<p>Session 5: Precompetitive Data Sharing and Collaboration to Develop PD-1/PD-L1 Combinations Moderator: Martin Murphy, CEO Roundtable on Cancer</p> <p>An Overview of How Real World Evidence, Data Sharing, and Precompetitive Collaboration May Influence the Development of PD-1/PDL-1 Combination Therapies</p> <ul style="list-style-type: none"> • Amy Abernethy, Flatiron Health <p>Mechanisms to Enable Data Sharing</p> <ul style="list-style-type: none"> • Mia Levy, Vanderbilt-Ingram Cancer Center <p>Sharing Data to Support Development, Validation, and Standardization of Biomarkers in Patient Selection Used in Immunotherapy Trials</p> <ul style="list-style-type: none"> • Gaurav Singal, Foundation Medicine <p>Precompetitive Use of Algorithms to Predict Adverse Events</p> <ul style="list-style-type: none"> • Sean Khozin, Food and Drug Administration <p>Panel Discussion</p>
10:00 am	Break
10:15 am	<p>Session 6: Stakeholder Perspectives on the Path Forward Moderator: Samir N. Khleif, Georgetown University</p> <ul style="list-style-type: none"> • 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 <p>Group Discussion</p>
11:30 am	<p>Workshop Wrap Up Samir N. Khleif, Georgetown University</p>
11:45 am	Adjourn