

**Second Annual Workshop on Getting the Dose Right:
Optimizing Dose Selection Strategies in Combination Anticancer Therapies**

An FDA-ASCO Virtual Workshop

September 6-7, 2023

	Day 1: September 6, 2023
1:00	<p>Introduction to the Workshop</p> <ul style="list-style-type: none"> • R. Donald Harvey, American Society of Clinical Oncology (ASCO) Co-Chair, Emory School of Medicine • Mirat Shah, FDA Co-chair, U.S. Food and Drug Administration
1:20	<p>Opening Remarks</p> <ul style="list-style-type: none"> • Richard Pazdur, U.S. Food and Drug Administration
1:30	<p>Session 1: Current State of Dosage Optimization in Combination Anticancer Therapies</p> <p>Moderator: Mirat Shah, U.S. Food and Drug Administration</p> <p>Keynote Presentation: Challenges and Opportunities to Developing Combination Anticancer Therapies in Oncology</p> <ul style="list-style-type: none"> • Pat LoRusso, Yale School of Medicine <p>Lessons from Anesthesiology</p> <ul style="list-style-type: none"> • Steven Shafer, Stanford University <p>Panelists:</p> <ul style="list-style-type: none"> • Janice Cowden, Patient-Centered Dosing Initiative • Nicole Gormley, U.S. Food and Drug Administration • Alice Tseng, University Health Network • Jennifer Lauchle, Genentech <p>Panel Discussion</p>
2:45	Break

3:00	Session 2: The Nuts and Bolts of Combination Dosage Optimization Moderator: Julie Bullock, Certara Presenters: <ul style="list-style-type: none">• Mallika Singh, REVOLUTION Medicines• Giovanni Abbadessa, Sanofi• J. Jack Lee, MD Anderson Cancer Center Panelists: <ul style="list-style-type: none">• Percy Ivy, National Cancer Institute• Joyce Cheng, U.S. Food and Drug Administration• Atik Rahman, U.S. Food and Drug Administration Panel Discussion
4:30	Wrap-up and Adjourn

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	Day 2 September 7
1:00	Welcome to the Workshop <ul style="list-style-type: none"> • R. Donald Harvey, ASCO Co-Chair, Emory School of Medicine • Mirat Shah, FDA Co-chair, U.S. Food and Drug Administration
1:05	Session 3: Case Studies for Developing Combination Therapies Moderator: Michael Maitland, Intellia Therapeutics, Inc. Case Study 1: Nivolumab and relatlimab <ul style="list-style-type: none"> • Jamie Brewer, U.S. Food and Drug Administration • Akintunde Bello, Bristol Myers Squibb Case Study 2: Dabrafenib and trametinib <ul style="list-style-type: none"> • Ruby Leong, U.S. Food and Drug Administration • Shefali Kakar, Novartis Pharmaceuticals Corporation Case Study 3: Venetoclax + decitabine/azacytidine/cytarabine <ul style="list-style-type: none"> • Lori Ehrlich, U.S. Food and Drug Administration • Ahmed Salem, AbbVie Inc. (discussant) • Jalaja Potluri, AbbVie Inc. (presenter + discussant) Panelists: <ul style="list-style-type: none"> • Chris Takimoto, IGM Biosciences • Lanre Okusanya, U.S. Food and Drug Administration • Lesley Seymour, Queens University • Glenn Sykes, patient advocate Panel Discussion After Each Case Study
3:15	Break

3:30	<p>Session 4: The Path Forward: Optimizing Dose Selection in Combination Anticancer Therapies</p> <p>Moderator: R. Donald Harvey, ASCO Workshop Co-Chair, Emory School of Medicine</p> <p>Panelists:</p> <ul style="list-style-type: none">• Dean Ho, National University of Singapore• Funda Meric-Bernstem, MD Anderson Cancer Center• Debbie Pickworth, American Lung Association’s Lung Cancer Patient Advisory Group• Eric Rubin, Merck• Stacy Shord, U.S. Food and Drug Administration• Garth Strohbehn, University of Michigan <p>Panel Discussion</p>
4:30	Wrap-up and Adjourn