

# FDA-BCAN Workshop: Endpoints for the Development of Neoadjuvant Systemic Therapy Regimens for Muscle-Invasive Bladder Cancer (MIBC)

August 8, 2019

Capital Hilton – Washington, DC

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## Preliminary AGENDA

Time	Title/Activity	Speakers/panelists
<b>12-1:10pm</b>	<b>Session 1: Regulatory background for use of pathologic complete response (pathCR) in bladder cancer</b>	
12:00-12:10	Welcome; Regulatory Considerations	Elaine Chang
12:10-12:20	PathCR in Breast Cancer	Tatiana Prowell
12:20-12:40	PathCR & Survival: Individual Level Surrogate, Trial Level Surrogate, Both, or Neither?	Matt Galsky
12:40-1:10	Panel discussion	Tatiana Prowell, Matt Galsky, Rick Bangs, Elizabeth Plimack, Hui Zhang; Seth Lerner and Chana Weinstock as moderators
<b>1:10 -1:25</b>	<b>BREAK</b>	
<b>1:25-3:00</b>	<b>Session 2: Pathologic, surgical, and other considerations, in the use of path CR</b>	
1:25-1:40	Cisplatin-Ineligible	Andrea Apolo
1:40-1:55	Clinical Restaging	Evan Yu
1:55-2:10	TURBT	Ashish Kamat
2:10-2:30	Reliability & Reproducibility of PathCR and Other Pathologic Measurements of Treatment Effect	Donna Hansel
2:30-3:00	Panel Discussion	Evan Yu, Ashish Kamat, Donna Hansel, Vinay Duddalwar and Jason Efstathiou; Harpreet Singh and Elizabeth Plimack as moderators
<b>3:00-3:15</b>	<b>BREAK</b>	
<b>3:15-4 pm</b>	<b>Session 3: Steps Forward</b>	
3:15-3:25	Defining the Key Issues and Questions	Dan Suzman
3:25-3:55	Panel Discussion	Paul Kluetz, Rick Bangs, Donna Hansel, Andrea Apolo, Seth Lerner; Matt Galsky as moderator
3:55-4:00	Wrap-Up	Elaine Chang

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