

# 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

## AGENDA

<b>12-1:15pm</b>	<b>Session 1: Regulatory background for use of pathologic complete response (pCR) in bladder cancer</b>	
<p><i>Objectives</i></p> <ul style="list-style-type: none"> <li>• <i>Define pCR</i></li> <li>• <i>Introduce regulatory perspectives in the consideration of endpoints</i></li> <li>• <i>Explore lessons learned from use of pCR in breast cancer</i></li> <li>• <i>Distinguish between the evidence needed for individual level and trial level surrogates</i></li> <li>• <i>Identify unanswered questions affecting the application of pCR in trials</i></li> </ul>		
12:00-12:10	Welcome; Regulatory Considerations	Elaine Chang
12:10-12:20	pCR in Breast Cancer	Tatiana Prowell
12:20-12:40	pCR & Survival: Individual Level Surrogate, Trial Level Surrogate, Both, or Neither?	Matt Galsky
12:40-12:50	Identifying Unanswered Questions Through the Estimand Framework	Elaine Chang
12:50-1:20	Panel discussion <u>Moderators:</u> Seth Lerner & Chana Weinstock	Tatiana Prowell Matt Galsky Rick Bangs Elizabeth Plimack Hui Zhang
<b>1:20-1:30</b>	<b>BREAK</b>	

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<b>1:30-3:05</b>	<b>Session 2: Pathologic, surgical, and other considerations, in the use of pCR</b>	
<p><i>Objectives</i></p> <ul style="list-style-type: none"> <li>• Review lessons from discussions to harmonize adjuvant bladder cancer trial conduct</li> <li>• Identify unique risk-benefit considerations for cisplatin-ineligible patients</li> <li>• Assess the current landscape of evidence to support clinical restaging strategies</li> <li>• Describe the role of transurethral resection of bladder tumor (TURBT) and pathology technique in the measurement of pCR</li> </ul>		
1:30-1:45	Trial Designs and Endpoints for Development of Perioperative Systemic Therapy in Cisplatin-Ineligible Patients	Andrea Apolo
1:45-2:00	Clinical Restaging in MIBC: How Do We Do It And What Does It Mean?	Evan Yu
2:00-2:15	Impact of TURBT	Ashish Kamat
2:15-2:35	Reliability & Reproducibility of pCR and Other Pathologic Measurements of Treatment Effect	Donna Hansel
2:35-3:05	Panel Discussion <u>Moderators:</u> Harpreet Singh & Elizabeth Plimack	Evan Yu Ashish Kamat Donna Hansel Vinay Duddalwar Jason Efstathiou
<b>3:05-3:20</b>	<b>BREAK</b>	

<b>3:20-4:00</b>	<b>Session 3: Steps Forward</b>	
<p><i>Objectives</i></p> <ul style="list-style-type: none"> <li>• Generalize workshop findings and priority areas needing additional evidence generation</li> <li>• Discuss the operationalization of pCR as an endpoint</li> </ul>		
3:20-3:50	Panel Discussion <u>Moderators:</u> Matt Galsky & Dan Suzman	Paul Kluetz Rick Bangs Andrea Apolo Seth Lerner Evan Yu
3:50-4:00	Closing	Chana Weinstock