

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

12-1:15pm	Session 1: Regulatory background for use of pathologic complete response (pCR) in bladder cancer	
<i>Objectives</i> <ul style="list-style-type: none"> • Define pCR • Introduce regulatory perspectives in the consideration of endpoints • Explore lessons learned from use of pCR in breast cancer • Distinguish between the evidence needed for individual level and trial level surrogates • Identify unanswered questions affecting the application of pCR in trials 		
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 in Neoadjuvant Bladder Cancer Trial Design	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
1:20-1:30	BREAK	



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1:30-3:05	Session 2: Pathologic, surgical, and other considerations, in the use of pCR	
<i>Objectives</i> <ul style="list-style-type: none"> Review lessons from discussions to harmonize adjuvant bladder cancer trial conduct Identify unique risk-benefit considerations for cisplatin-ineligible patients Assess the current landscape of evidence to support clinical restaging strategies Describe the role of transurethral resection of bladder tumor (TURBT) and pathology technique in the measurement of pCR 		
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
3:05-3:20	BREAK	

3:20-4:00	Session 3: Steps Forward	
<i>Objectives</i> <ul style="list-style-type: none"> Generalize workshop findings and priority areas needing additional evidence generation Discuss the operationalization of pCR as an endpoint 		
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

