What I Tell My Patients:
Faculty Physicians and Nurses Discuss Patient Education About New Treatments and Clinical Trials

Part 1 of a 3-Part Complimentary NCPD Webinar Series
in Partnership with the 2023 ONS Congress

Urothelial Bladder Cancer

Thursday, May 25, 2023
5:00 PM – 6:00 PM ET

Faculty

Brenda Martone, MSN, NP-BC, AOCNP
Jonathan E Rosenberg, MD

Moderator

Neil Love, MD

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Faculty

Brenda Martone, MSN, NP-BC, AOCNP
Northwestern Medicine
Northwestern Memorial Hospital
Chicago, Illinois

Moderator

Neil Love, MD
Research To Practice
Miami, Florida

Jonathan E Rosenberg, MD
Chief, Genitourinary Medical Oncology Service
Division of Solid Tumor Oncology
Enno W Ercklentz Chair
Memorial Sloan Kettering Cancer Center
New York, New York

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Commercial Support

This activity is supported by an educational grant from Astellas and Seagen Inc.

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Dr Love — Disclosures

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Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Ms Martone — Disclosures

No relevant conflicts of interest to disclose.

Dr Rosenberg — Disclosures

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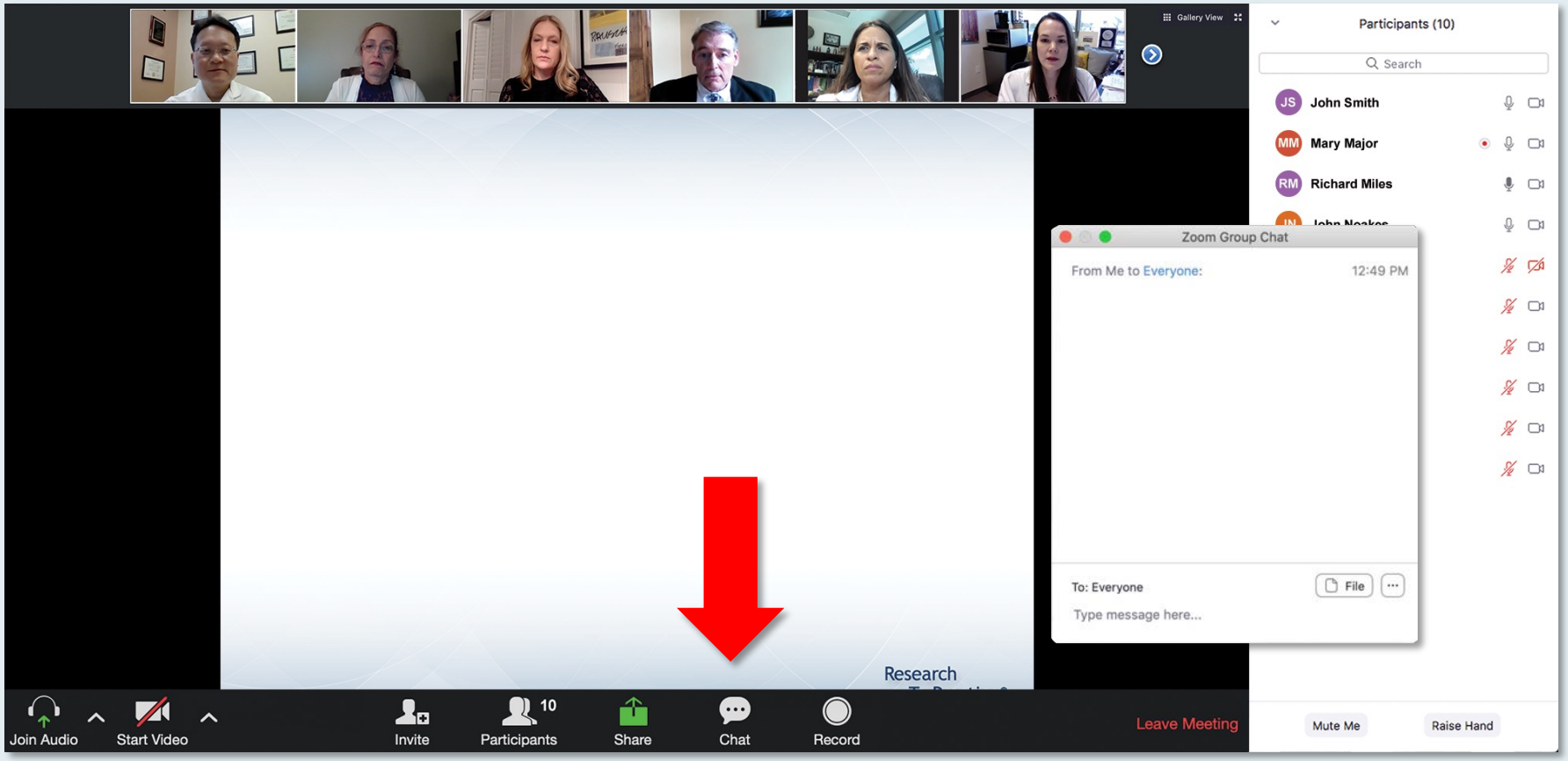

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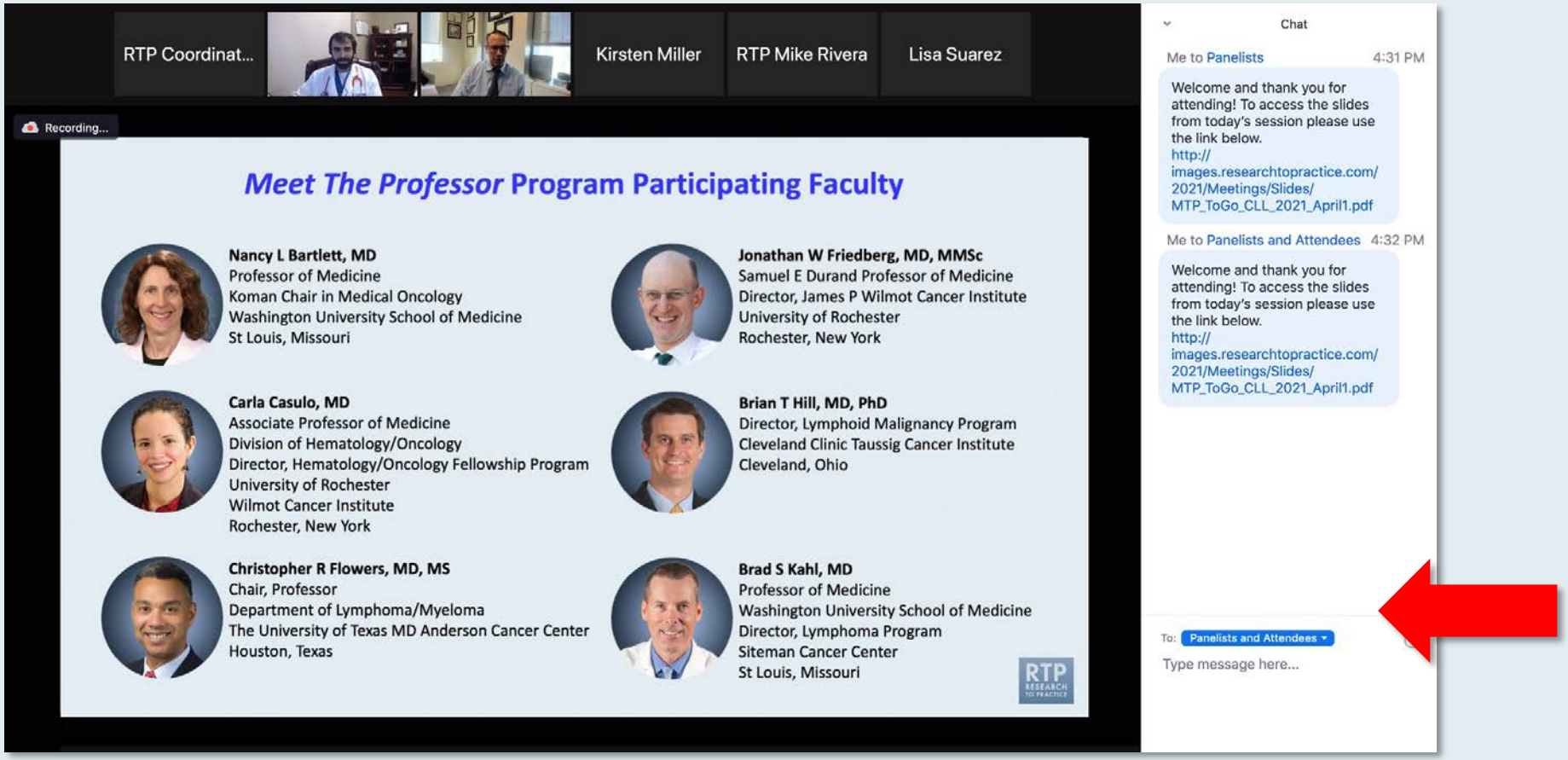
Expand chat submission box



Drag the white line above the submission box up to create more space for your message.

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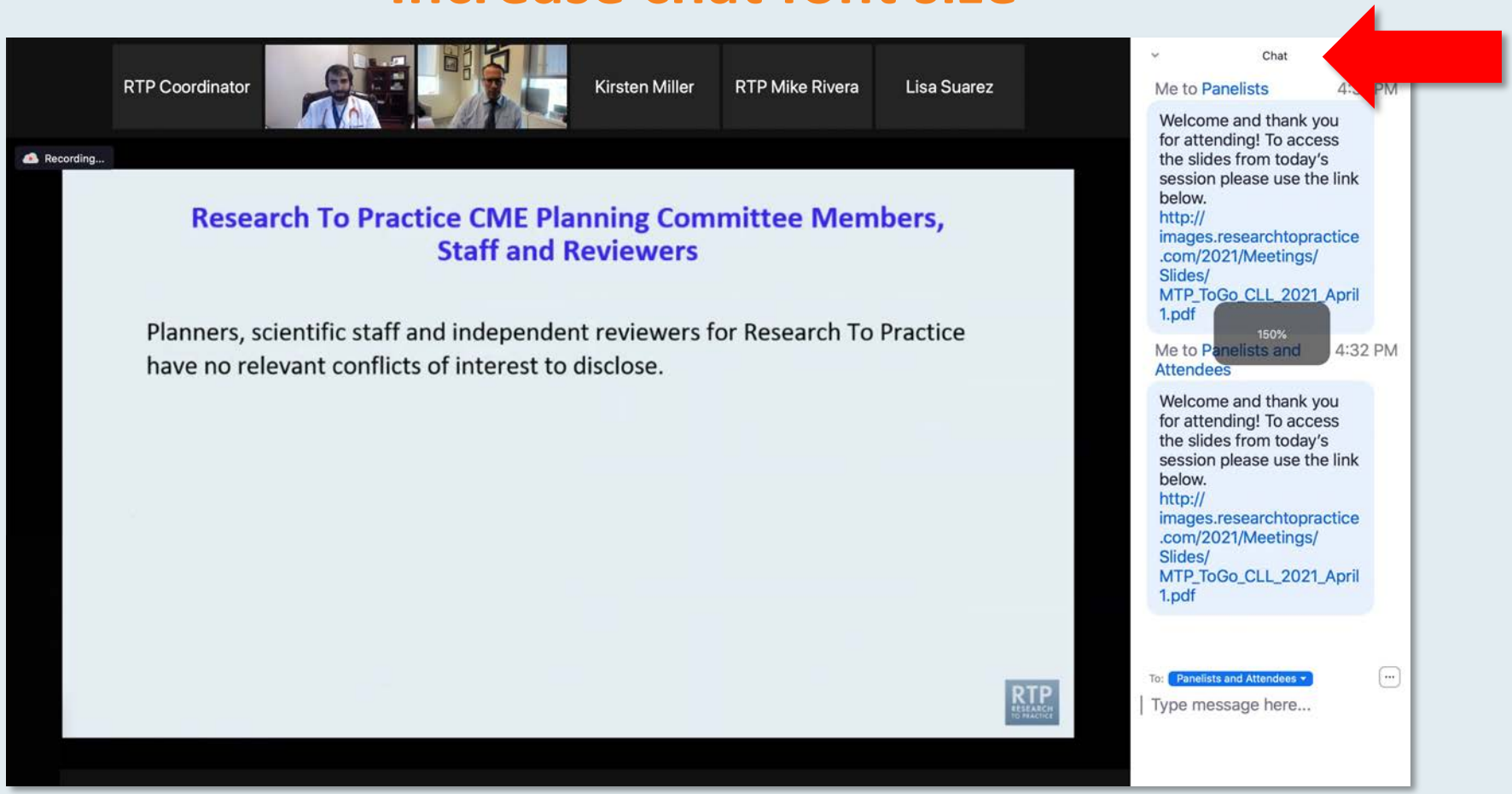

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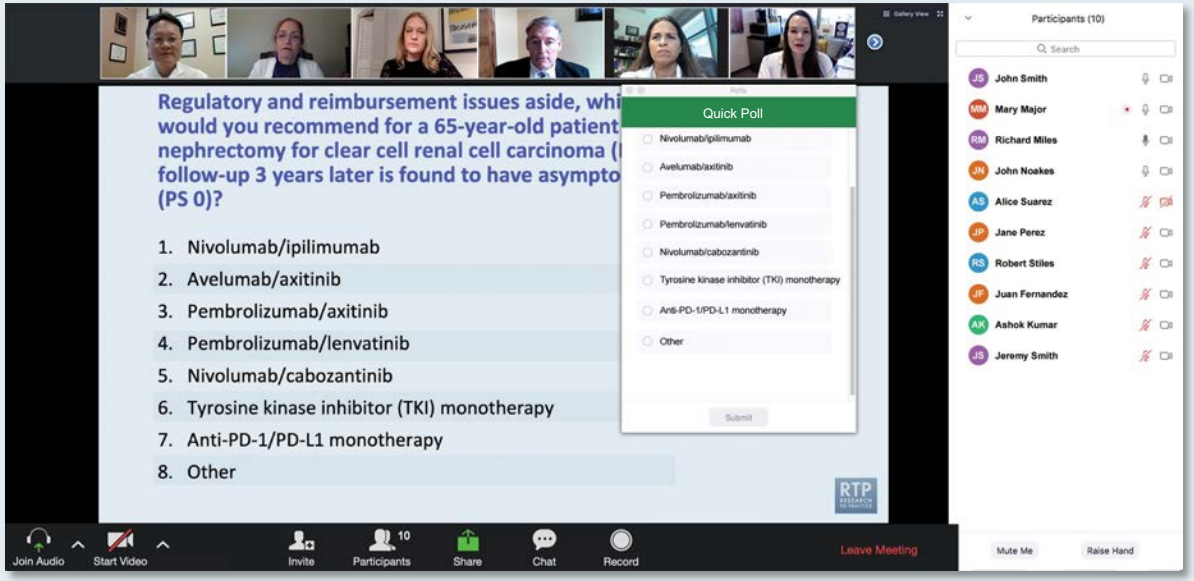

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ONCOLOGY TODAY

WITH DR NEIL LOVE

Managing Metastatic Urothelial Bladder Cancer

DR SCOTT TAGAWA

WEILL CORNELL MEDICINE

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Manish A Shah, MD

Harry H Yoon, MD, MHS

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Thank you for joining us!

NCPD credit information will be emailed to each participant within 5 business days.

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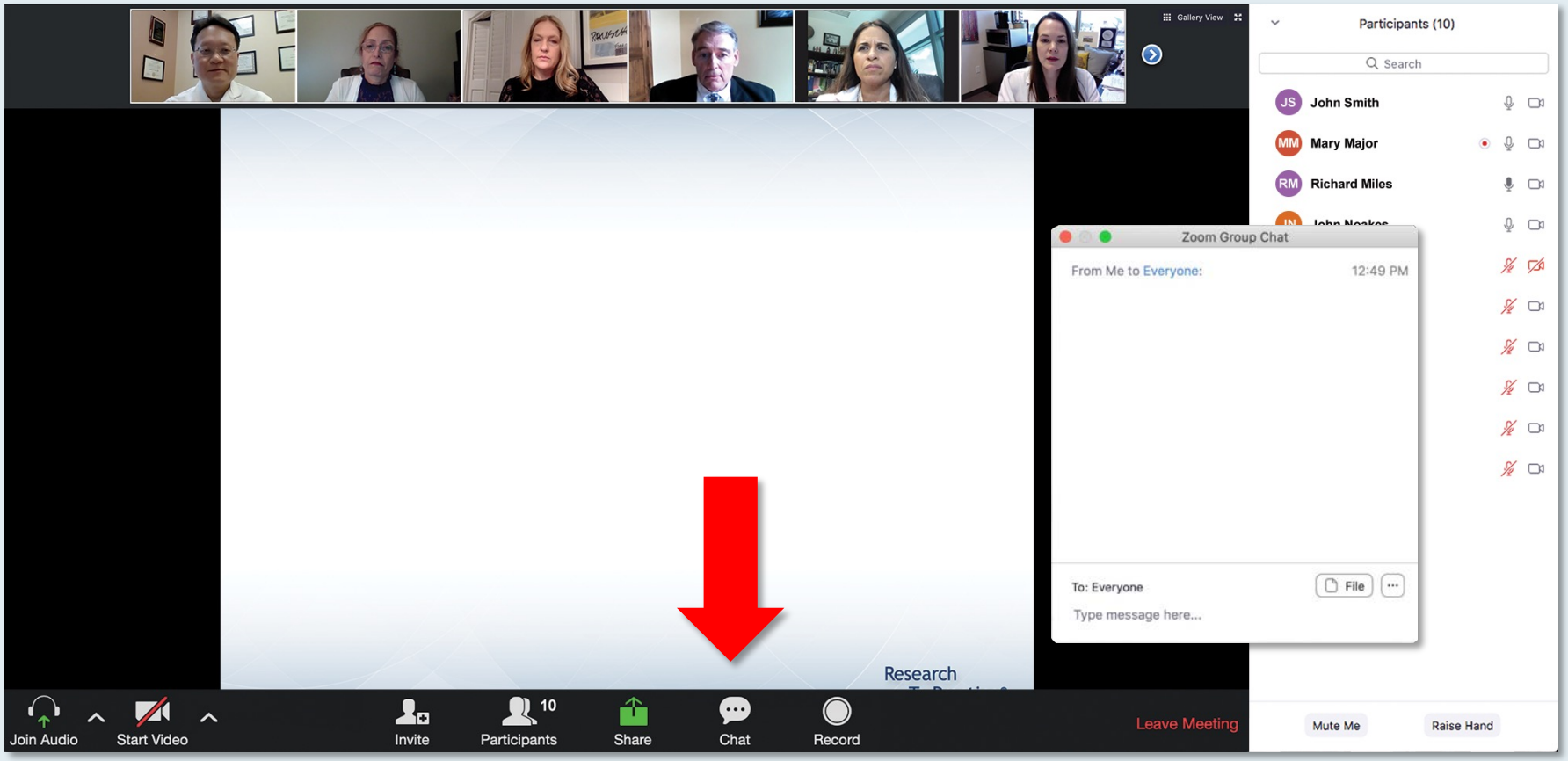

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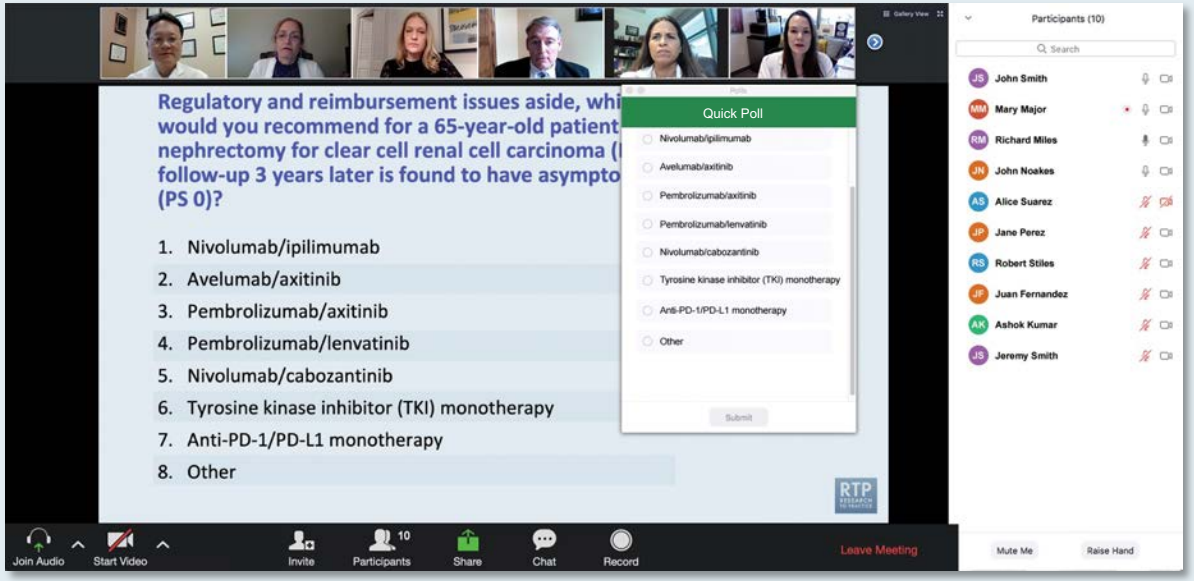

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“What I Tell My Patients”
Fifteenth Annual RTP-ONS NCPD Symposium Series
ONS Congress, San Antonio, Texas — April 26 to 29, 2023

Wednesday April 26	**Cervical and Endometrial Cancer** 11:15 AM – 12:45 PM CT (12:15 PM – 1:45 PM ET)
	Breast Cancer 6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)
Thursday April 27	**Diffuse Large B-Cell Lymphoma** 6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
	Chronic Lymphocytic Leukemia 12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)
	HER2-Targeted Antibody-Drug Conjugates 6:00 PM – 7:30 PM CT (7:00 PM – 8:30 PM ET)
Friday April 28	**Hepatobiliary Cancers** 6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
	Ovarian Cancer 12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)
	Lung Cancer 6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)
Saturday April 29	**Acute Myeloid Leukemia, Myelodysplastic Syndromes and Myelofibrosis** 6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
	Prostate Cancer 12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)

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What I Tell My Patients

2023 ONS Congress

San Antonio, Texas

Symposia Themes

- New agents and therapies; ongoing trials related to specific clinical scenarios
- Patient education: Preparing to receive new therapies
- The bond that heals
- THANKS! (Great job)

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How was it different to take care of this patient versus another patient in the same oncologic setting?

What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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Agenda

Module 1: Overview; localized urothelial bladder cancer (UBC)

Module 2: First-line treatment of metastatic disease

Module 3: Sequencing of therapy for metastatic UBC

Agenda

Module 1: Overview; localized urothelial bladder cancer (UBC)

Module 2: First-line treatment of metastatic disease

Module 3: Sequencing of therapy for metastatic UBC

Dr Rosenberg
New York, New York

Clinical Research Background

- **Overview of urothelial bladder cancer**
  - **Cystectomy-sparing approaches**
- **Non-muscle-invasive bladder cancer (NMIBC)**
  - **Pembrolizumab**
  - **TAR-200**
- **Nonmetastatic muscle-invasive bladder cancer (MIBC)**
  - **Adjuvant nivolumab**

Overview of Bladder Cancer

- Patient profile
  - Median age at diagnosis: 73 years
  - 76% male
  - Smoking is the most well-established risk factor (47% of all cases in the United States)
- Natural history
  - Non-muscle-invasive
  - Muscle-invasive
  - Metastatic
- Cystectomy and ileal conduit/stoma management
- Neoadjuvant and adjuvant chemotherapy

American Cancer Society Cancer Facts & Figures 2020. www.cancer.org.

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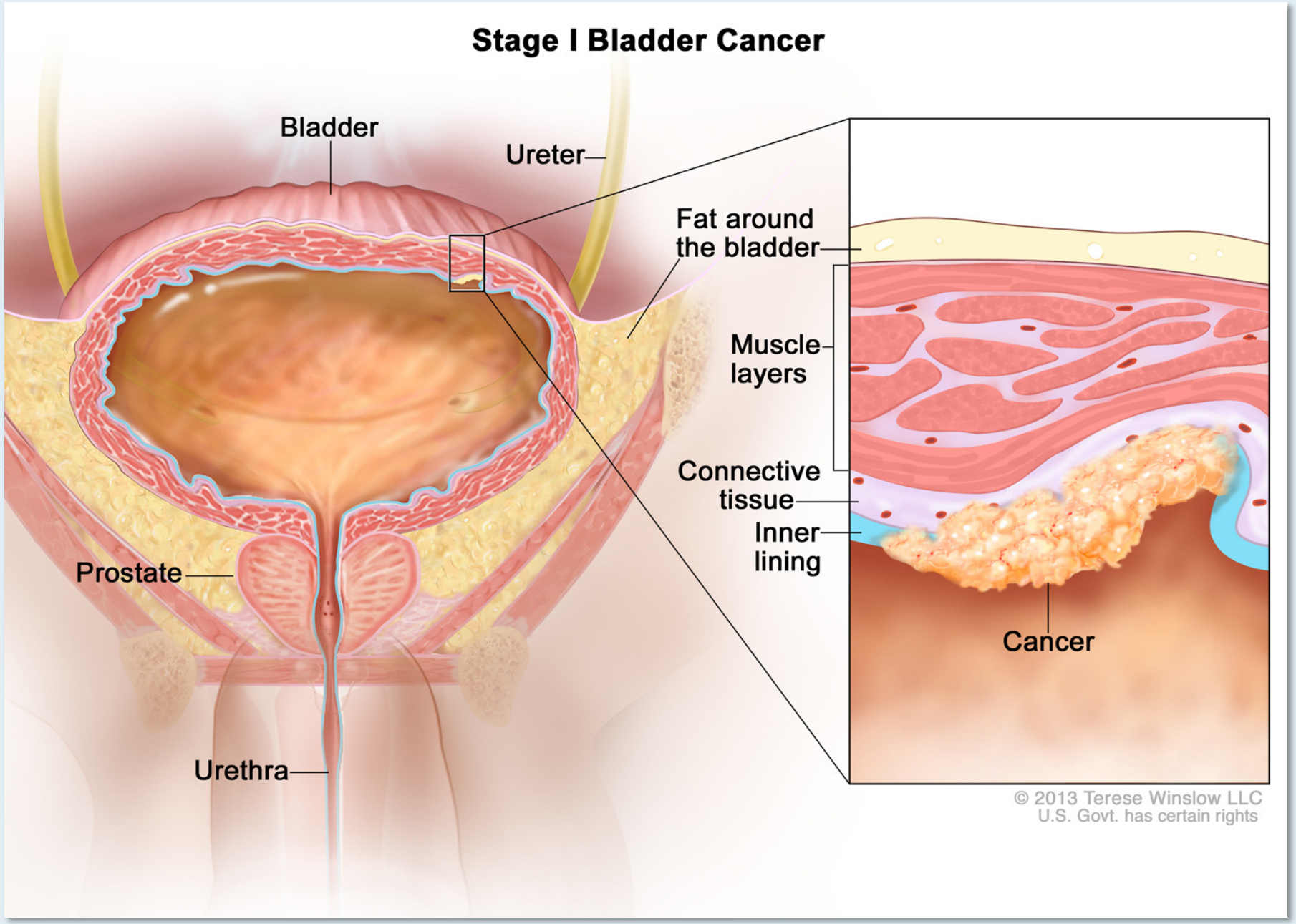
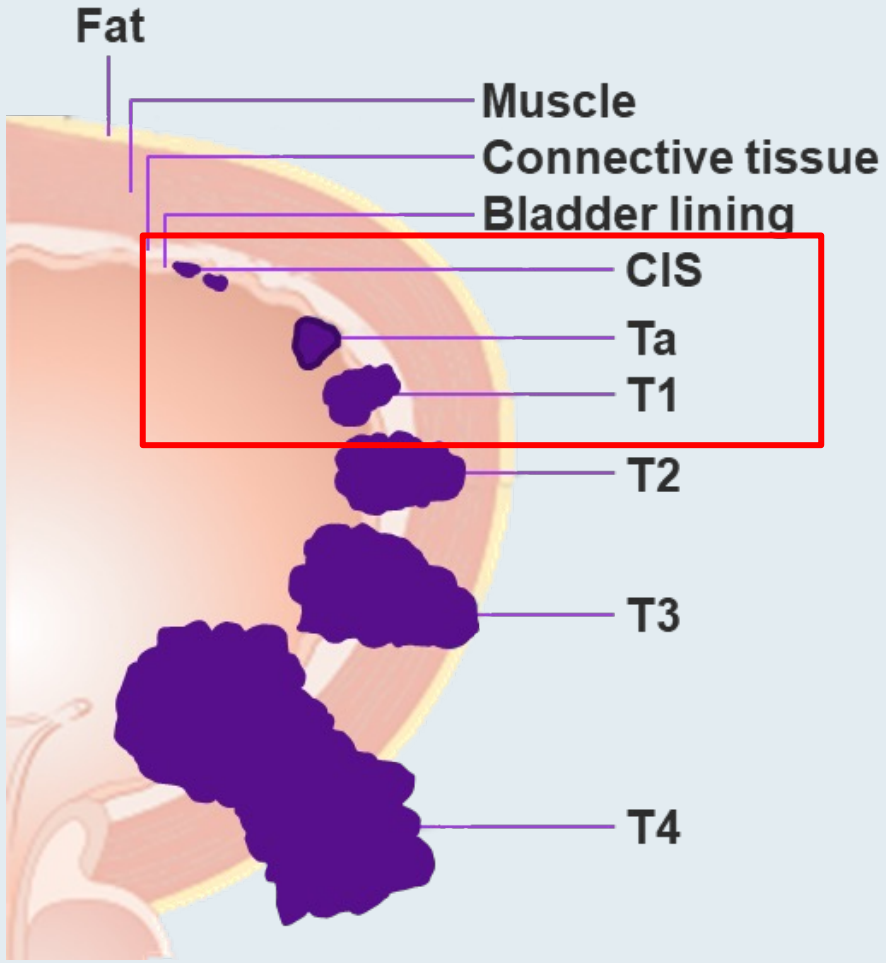


With permission from Terese Winslow LLC

High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)

- High-risk (HR) NMIBC is defined as any carcinoma in situ (CIS), T1 tumor, and/or high-grade Ta tumor
- Standard-of-care therapy for HR NMIBC is TURBT and intravesical Bacillus Calmette-Guérin (BCG)
  - Although there is a high rate of complete response (70%) to initial therapy, most patients with high-risk disease do not maintain response
    - 30% of patients experience recurrence within 1 year
    - 40% of patients at high risk progress to muscle-invasive disease
    - 20% - 30% of patients progress to metastatic disease
- BCG unresponsive disease – standard of care is cystectomy
- With the lack of a suitable comparator, single-arm designs testing novel agents are thought to be acceptable in the BCG-unresponsive population
- World-wide BCG shortage



Cumberbatch MGK et al. *Eur Urol.* 2018;74:784-795. NCCN guidelines: bladder cancer (Version 1.2019). Hemdan T et al. *J Urol*. 2014;191:1244. Herr HW et al. *Urol Oncol.* 2015;33:108.e1-4. Anastasiadis A et al. *Ther Adv Urol.* 2012;4:13-32. FDA. https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm529600.pdf. Babjuk M et al. *Eur Urol.* 2017;71:447-461.

Courtesy of Arjun Balar, MD

Pembrolizumab for NMIBC

Mechanism of action

- **Anti-PD-L1 antibody**

Indication

- **For patients with BCG-unresponsive, high-risk NMIBC with carcinoma in situ with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy**

Recommended dose

- **200 mg every 3 weeks or 400 mg every 6 weeks**

Pembrolizumab package insert, 4/2023

TAR-200

Mechanism of action

- **An intravesical drug delivery system that provides sustained local release of gemcitabine into the bladder**

Indication

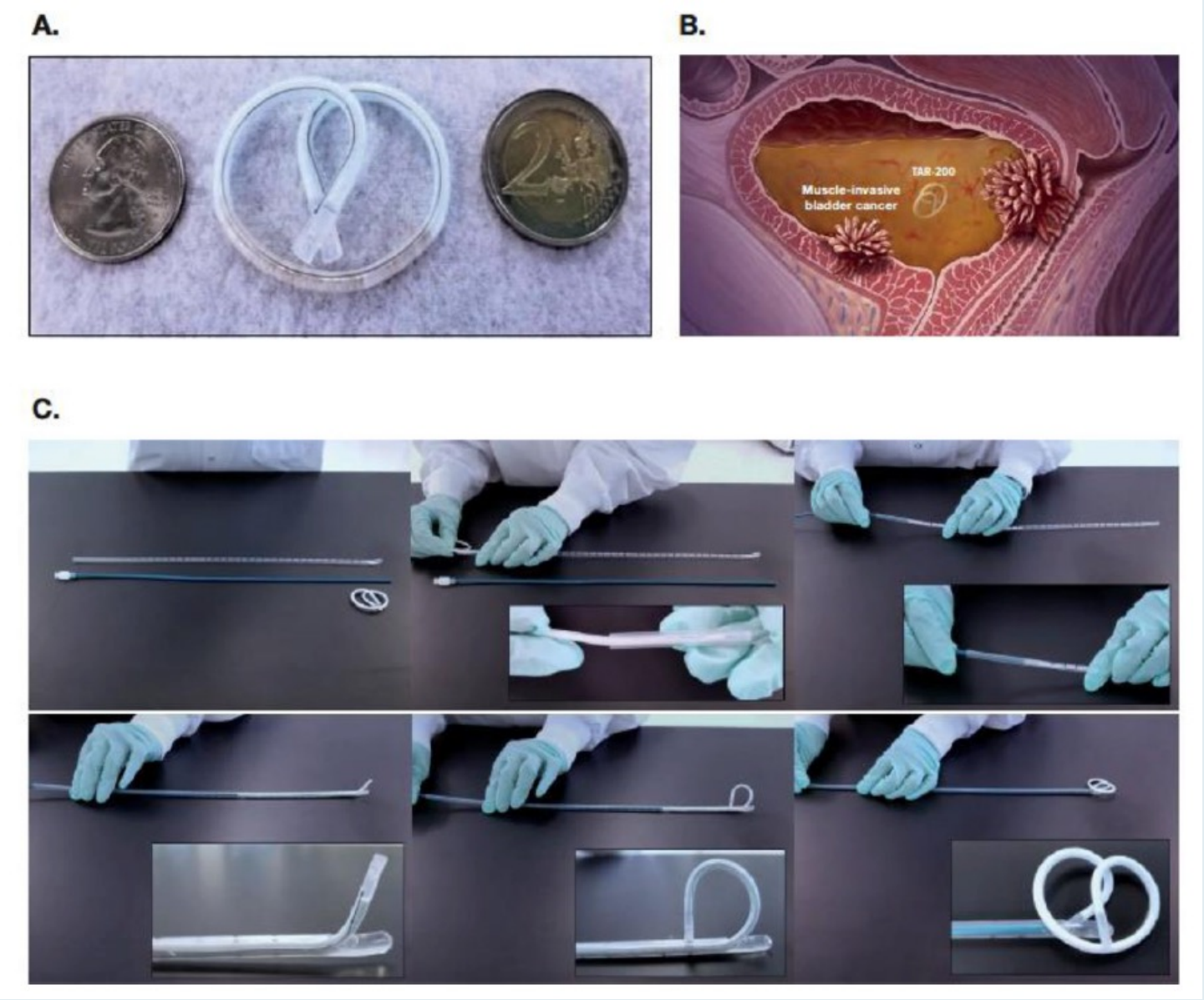
- **Investigational**

Pivotal clinical data

- **Phase II SunRISe-1 study evaluating the efficacy and safety of TAR-200 and cetrelimab either in combination or alone for patients with BCG-unresponsive high-risk NMIBC who are ineligible for or decline radical cystectomy**

www.clinicaltrials.gov. NCT04640623. Accessed May 2023.

Components of TAR-200



TAR-200, a gemcitabine-releasing intravesical system, is formed into a "pretzel"-like configuration within the bladder.

TAR-200:

- A. Consists of a small, flexible silicone tube filled with gemcitabine
- B. Is designed to release drug directly inside the bladder over the indwelling period
- C. Is inserted using a TARIS urinary placement catheter

Daneshmand S et al. *Urol Oncol* 2022;[Online ahead of print].

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Adjuvant Nivolumab

Mechanism of action

- **Anti-PD-L1 antibody**

Indication

- **For the adjuvant treatment of urothelial carcinoma in adult patients who are at high risk of recurrence after undergoing radical resection**

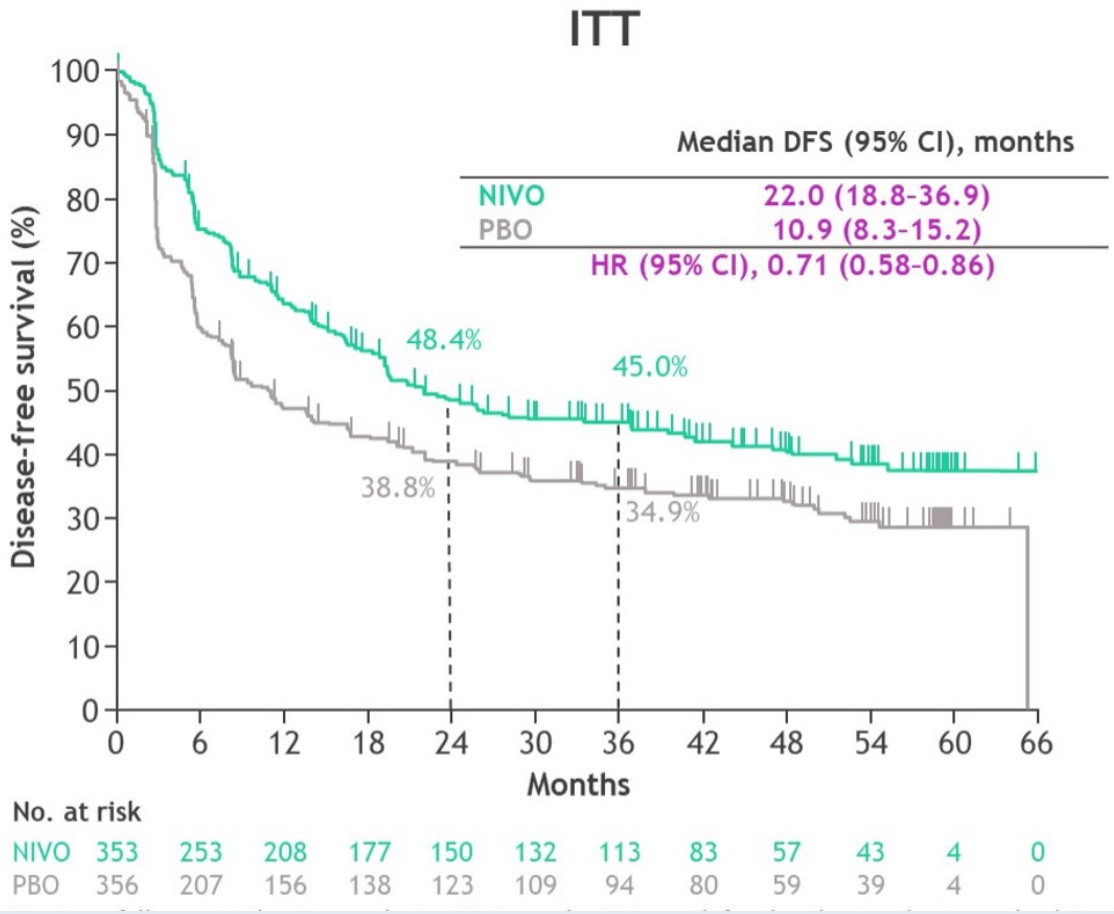
Recommended dose

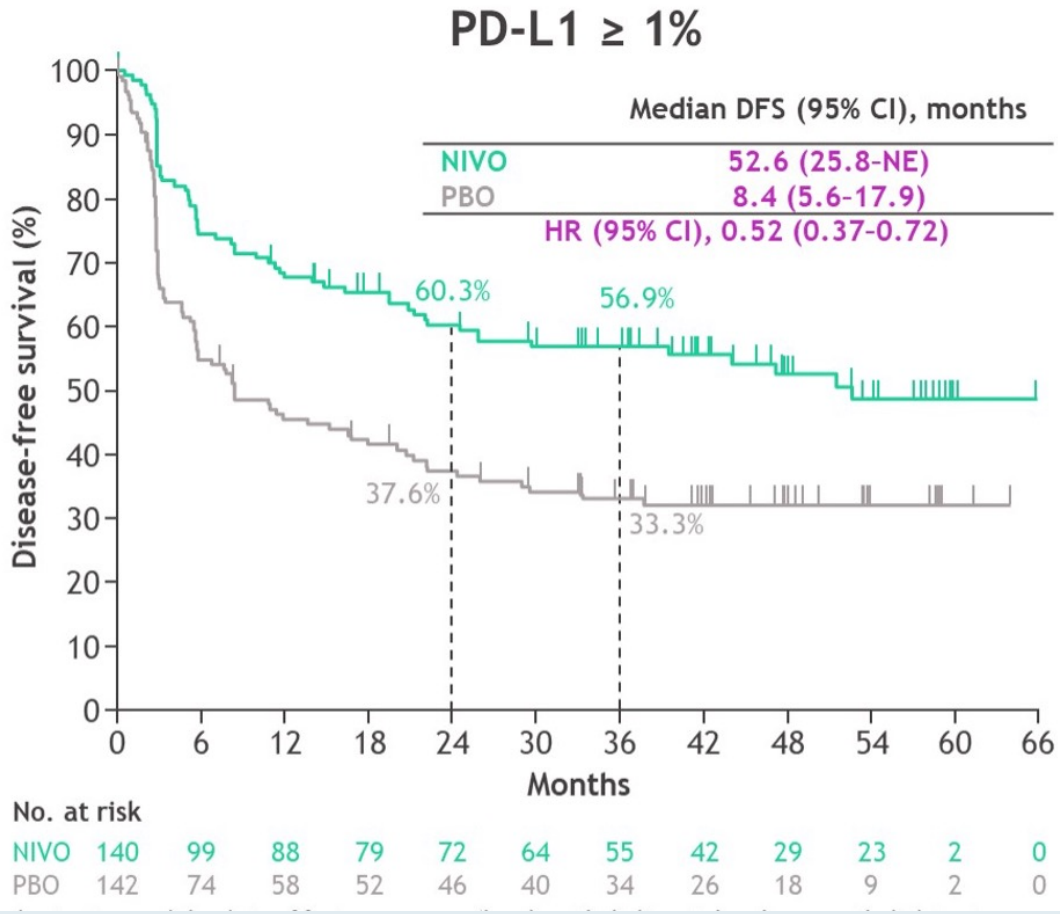
- **240 mg IV infusion every 2 weeks or 480 mg IV infusion every 4 weeks up to 1 year**

Nivolumab package insert, March 2022

CheckMate 274 Extended Follow-Up: Disease-Free Survival (Primary Endpoint)

- Continued DFS benefit was observed with NIVO versus PBO both in the ITT and tumor PD-L1 expression ≥ 1% populations





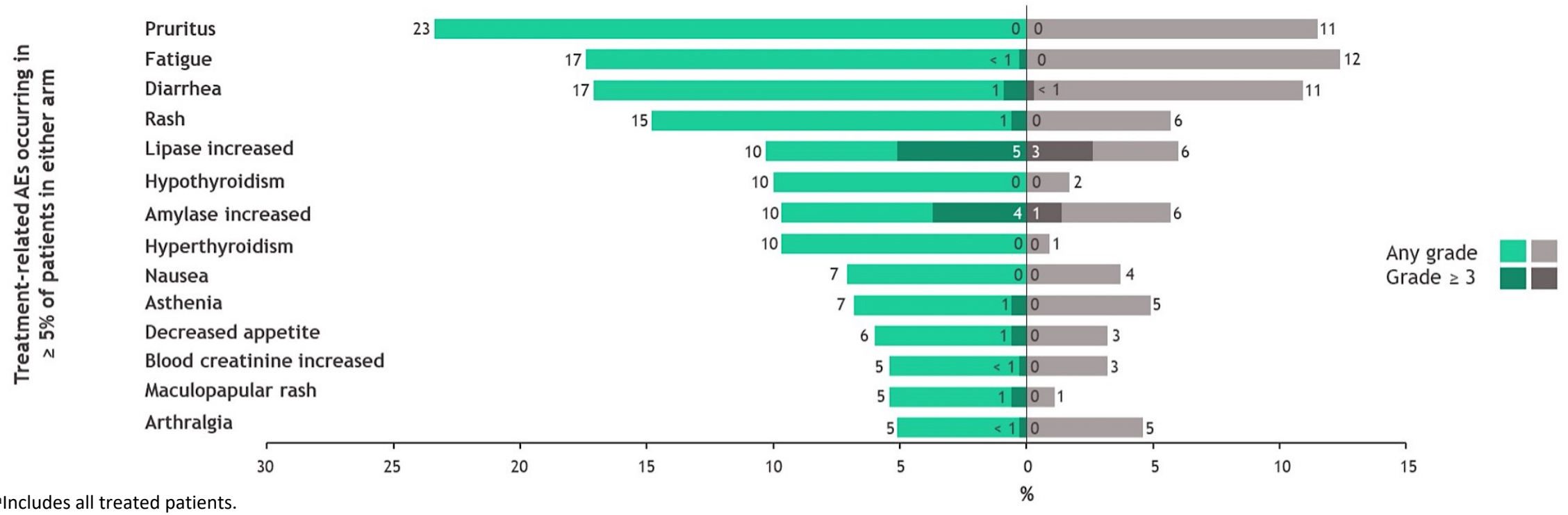
DFS = disease-free survival; NIVO = nivolumab; PBO = placebo; ITT = intent to treat

Galsky MD et al. Genitourinary Cancers Symposium 2023;Abstract LBA443.

RTP RESEARCH TO PRACTICE

CheckMate 274 Extended Follow-Up: Safety Summary

	NIVO (n = 351)[a]		PBO (n = 348)[a]	
	Any grade	Grade ≥ 3	Any grade	Grade ≥ 3
Treatment-related AEs, %	79	18	56	7
Treatment-related AEs leading to discontinuation, %	14	7	2	1



[a]Includes all treated patients.

AE = adverse event

Galsky MD et al. Genitourinary Cancers Symposium 2023;Abstract LBA443.

Brenda Martone, MSN, NP-BC, AOCNP

77-year-old man s/p radical cystectomy who discontinued carboplatin/gemcitabine due to neutropenia is started on adjuvant nivolumab

RTP
RESEARCH
TO PRACTICE

Agenda

Module 1: Overview; localized urothelial bladder cancer (UBC)

Module 2: First-line treatment of metastatic disease

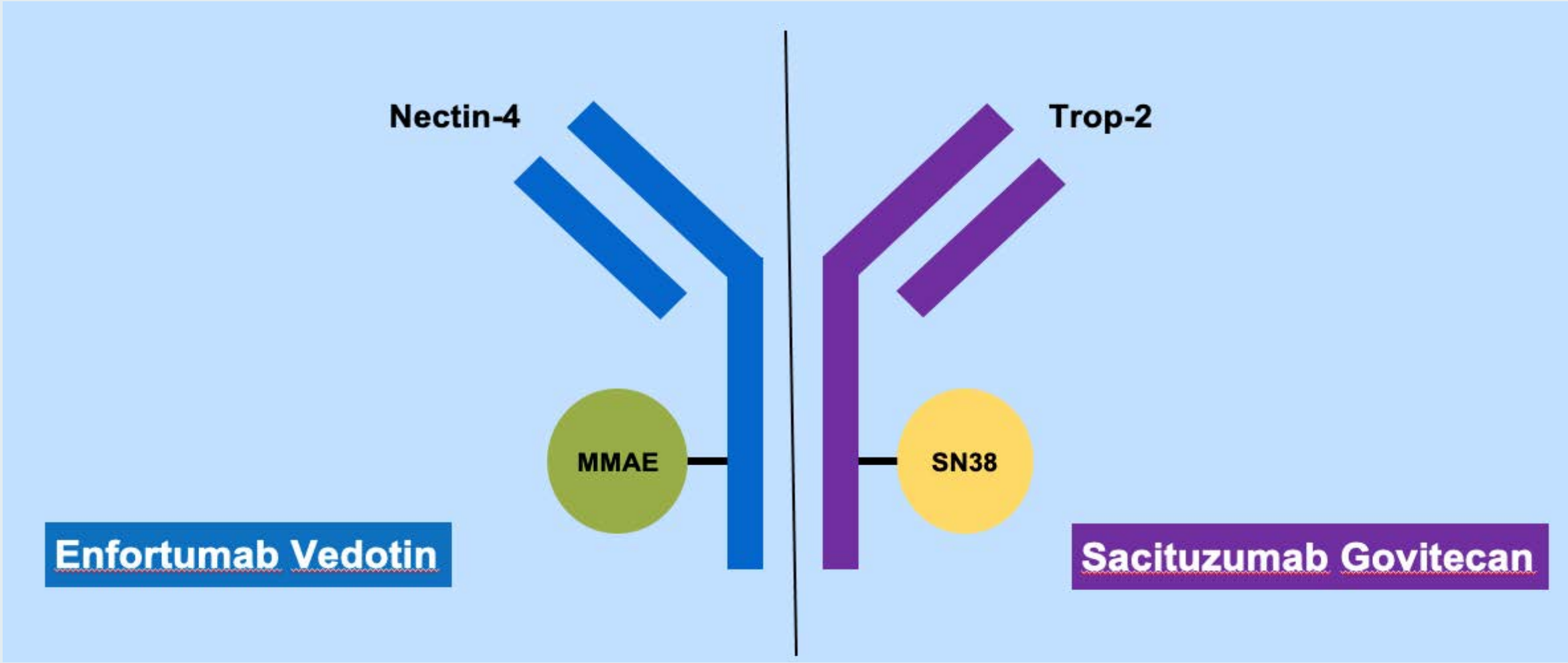
Module 3: Sequencing of therapy for metastatic UBC

Dr Rosenberg
New York, New York

Clinical Research Background

- **First-line treatment of metastatic UBC**
  - **Platinum-based chemotherapy → maintenance avelumab**
  - **Enfortumab vedotin in combination with pembrolizumab**

Antibody-Drug Conjugates for UBC



Courtesy of Matthew D Galsky, MD

Enfortumab Vedotin

Mechanism of action

- **Antibody-drug conjugate targeting nectin-4**

Indications

As monotherapy:

- **For adult patients with locally advanced or metastatic urothelial cancer who have previously received an anti-PD-1/PD-L1 antibody and platinum-containing chemotherapy or who are ineligible for cisplatin-containing chemotherapy and have received 1 or more prior lines of therapy**

In combination with pembrolizumab:

- **For adult patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy**

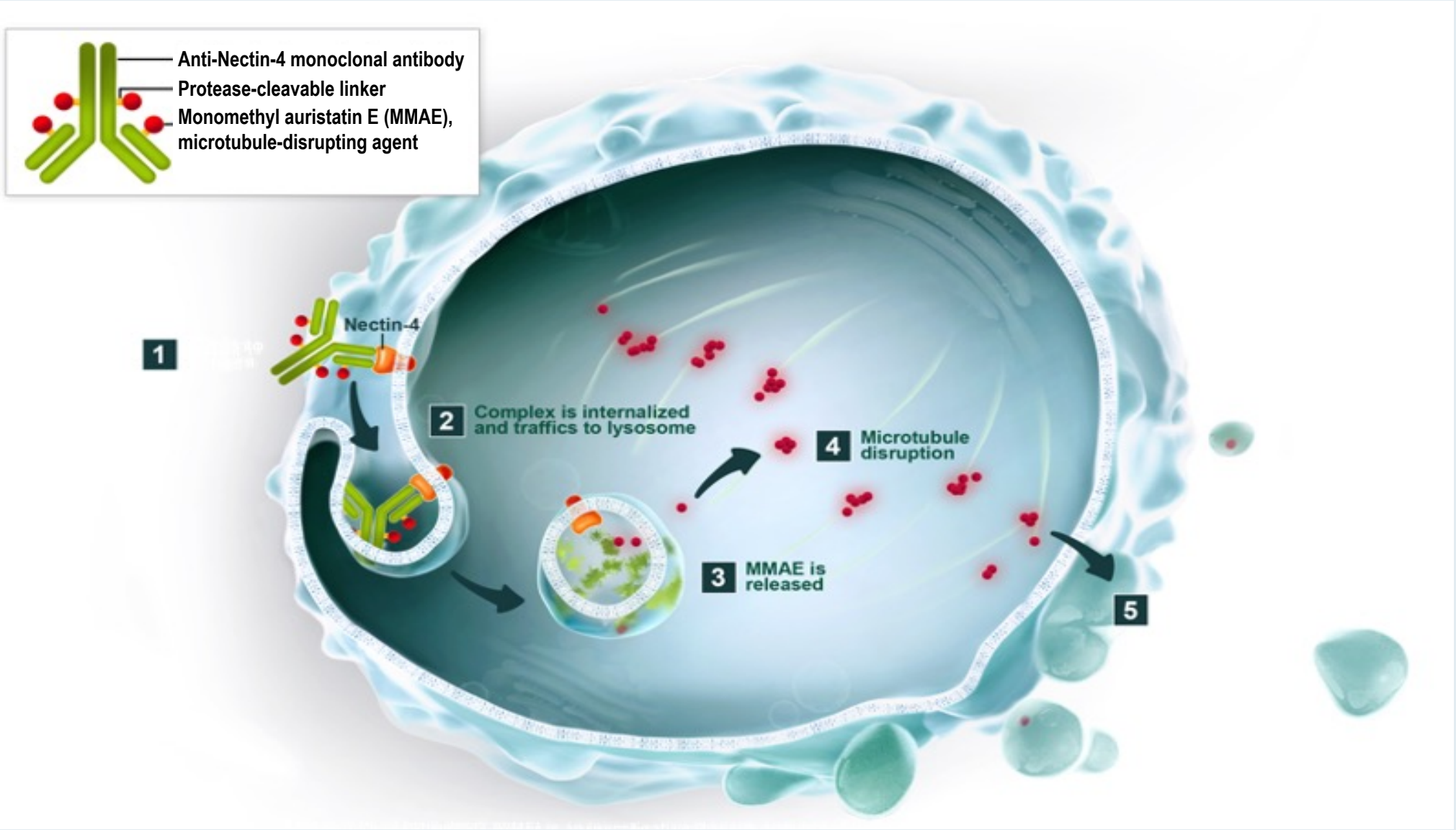
Recommended dose

- **1.25 mg/kg (up to maximum dose of 125 mg) IV infusion**

Enfortumab vedotin package insert, April 2023.

RTP RESEARCH TO PRACTICE

Enfortumab Vedotin: Nectin-4 Targeted Therapy



Courtesy of Jonathan E Rosenberg, MD

FDA Grants Accelerated Approval for Enfortumab Vedotin-Ejfv with Pembrolizumab for Locally Advanced or Metastatic Urothelial Cancer in Patients Not Eligible for Cisplatin-Containing Chemotherapy

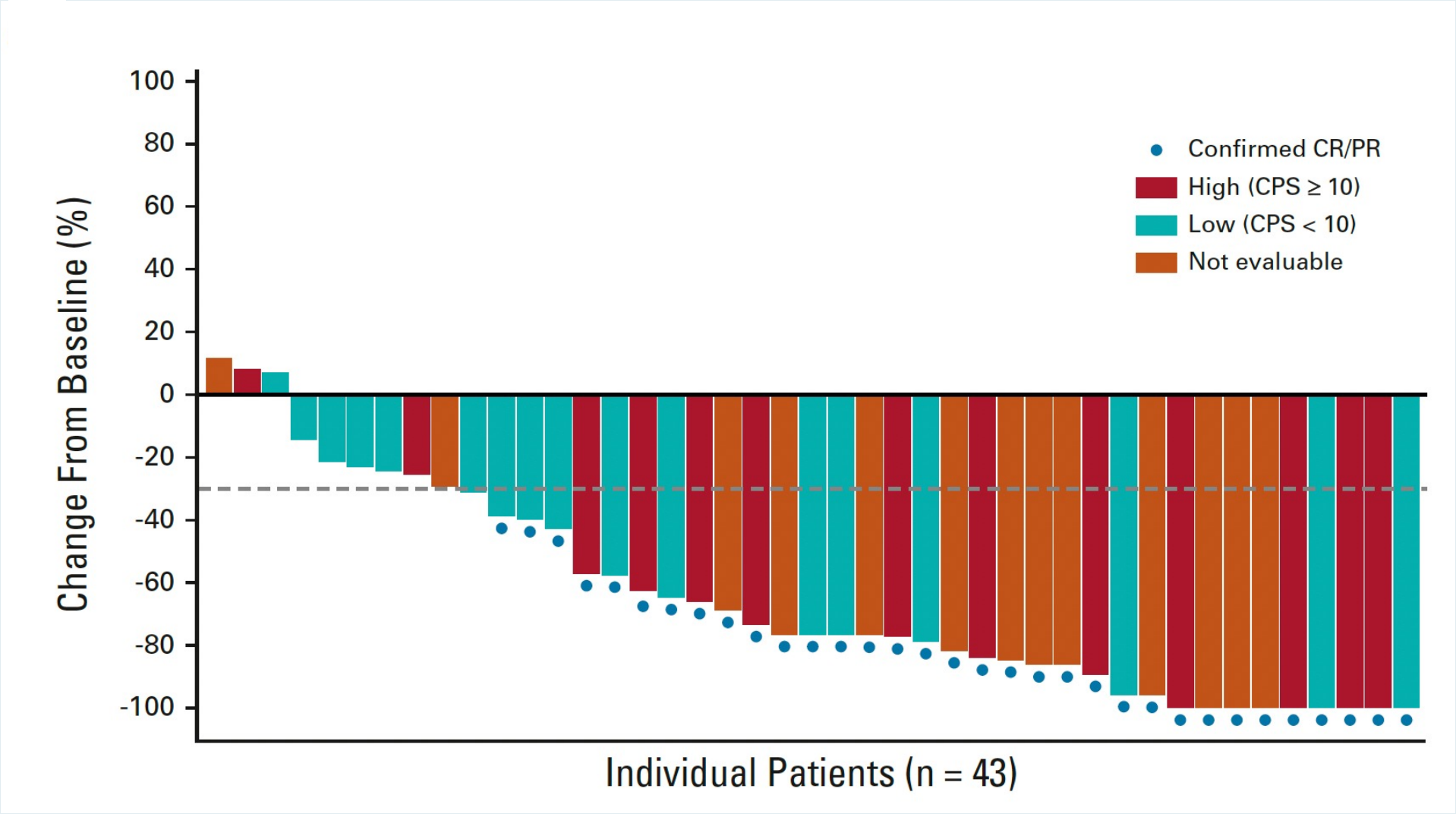
Press Release: April 3, 2023

"The approval is based on data from the KEYNOTE-869 trial (also known as EV-103) dose escalation cohort, Cohort A and Cohort K. The median follow-up time for the dose escalation cohort + Cohort A was 44.7 months (range, 0.7 to 52.4 months) and for Cohort K was 14.8 months (range, 0.6 to 26.2 months). In the combined efficacy analysis of the dose escalation cohort, Cohort A and Cohort K (n = 121), pembrolizumab in combination with enfortumab vedotin demonstrated an objective response rate (ORR) of 68% (95% CI: 58.7, 76.0), with complete and partial response rates of 12% and 55%, respectively.

The median duration of response (DOR) for the dose escalation cohort + Cohort A was 22.1 months (range, 1.0+ to 46.3+ months) and for Cohort K was not reached (range, 1.2 to 24.1+ months)."

https://www.merck.com/news/fda-approves-mercks-keytruda-pembrolizumab-in-combination-with-padcev-enfortumab-vedotin-ejfv-for-first-line-treatment-of-certain-patients-with-locally-advanced-or-metastatic/

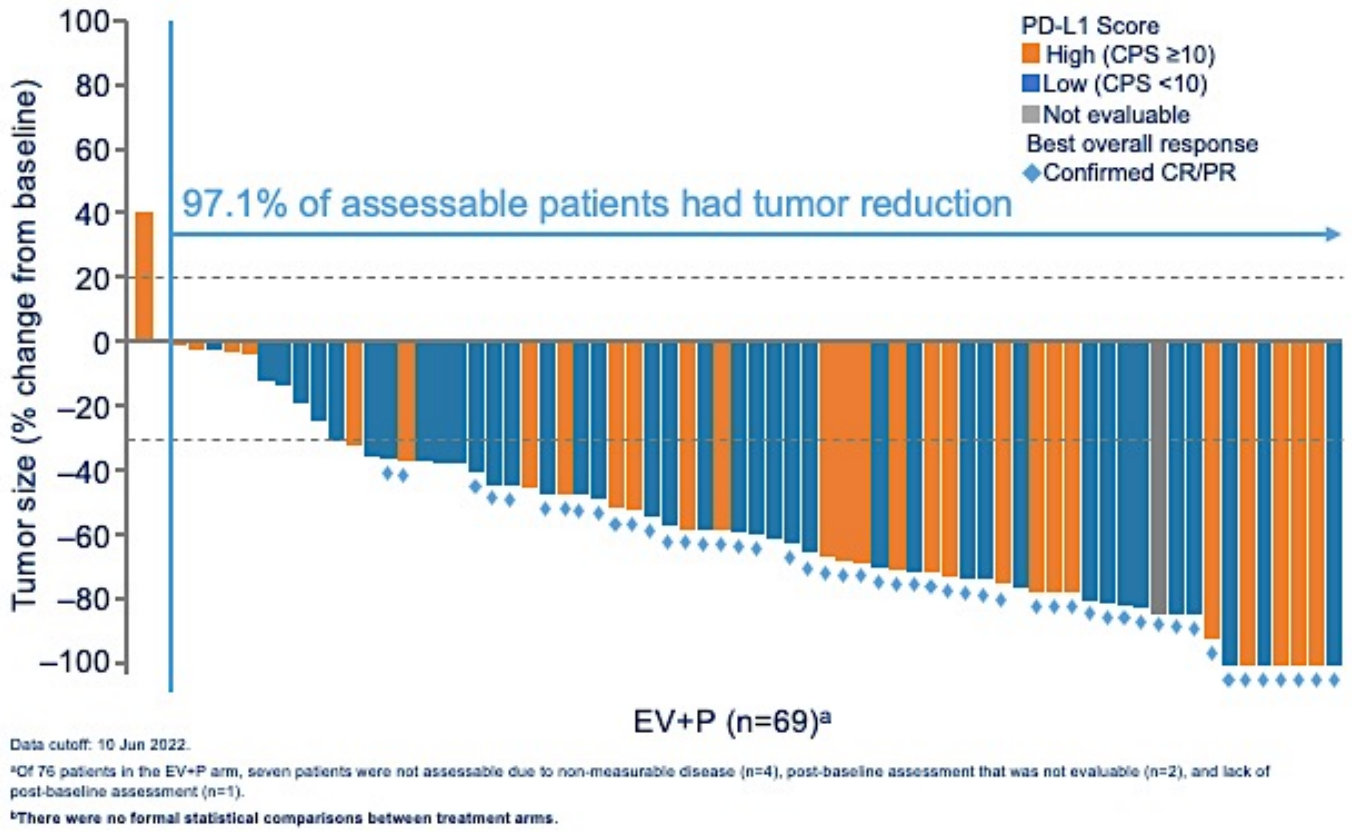
EV-103 Cohort A: Enfortumab Vedotin with Pembrolizumab for Previously Untreated Advanced Urothelial Cancer



Hoimes CJ et al. *J Clin Oncol* 2023:41:22-31.

RTP RESEARCH TO PRACTICE

EV-103 Cohort K: Efficacy and Safety



Data cutoff: 10 Jun 2022.

[a]Of 76 patients in the EV+P arm, seven patients were not assessable due to non-measurable disease (n=4), post-baseline assessment that was not evaluable (n=2), and lack of post-baseline assessment (n=1).

[b]There were no formal statistical comparisons between treatment arms.

	EV+P[b] (n=76)	EV mono[b] (n=73)
cORR, n (%) (95% CI)	49 (64.5) (52.7-75.1)	33 (45.2) (33.5-57.3)
Median time to objective response (range), mo	2.07 (1.1-6.6)	2.07 (1.9-15.4)
Median number of treatment cycles (range)	11.0 (1-29)	8.0 (1-33)

EV+P

- 42/49 (85.7%) of responses observed at first assessment (week 9±1 week)
- Most common AEs were fatigue, peripheral sensory neuropathy, alopecia, and maculopapular rash

EV mono

- Activity is consistent with prior results in 2L+ la/mUC
- Safety profile consistent with previous studies

Rosenberg JE et al. ESMO 2022;Abstract LBA73.

EV-103 Cohort K: Treatment-Related Adverse Events of Special Interest

The majority of treatment-related AESIs were grade ≤2

	EV+P (N=76)		EV Mono (N=73)	
	Any Grade n (%)	**Grade ≥3 n (%)**	**Any Grade n (%)**	**Grade ≥3 n (%)**
Skin reactions	51 (67.1)	16 (21.1)	33 (45.2)	6 (8.2)
Peripheral neuropathy	46 (60.5)	2 (2.6)	40 (54.8)	2 (2.7)
Ocular disorders	20 (26.3)	0	21 (28.8)	0
Dry eye	18 (23.7)	0	9 (12.3)	0
Blurred vision	9 (11.8)	0	10 (13.7)	0
Corneal disorders	0	0	4 (5.5)	0
Hyperglycemia	11 (14.5)	5 (6.6)	8 (11.0)	7 (9.6)
Infusion-related reactions	3 (3.9)	0	4 (5.5)	0

- Skin reactions were observed more frequently with EV+P
  - No serious skin reactions occurred with EV+P
- Peripheral neuropathy remains the most common reason for treatment-related discontinuations

*There are differences in the rates of skin reactions reported for EV treatment-related AESIs and pembro TEAEs of special interest because these adverse events were reported via different methodologies developed for EV and pembro monotherapies, respectively

Rosenberg JE et al. ESMO 2022;Abstract LBA73.

Brenda Martone, MSN, NP-BC, AOCNP

77-year-old man with metastatic UBC develops Grade 2 peripheral neuropathy while receiving pembrolizumab/enfortumab vedotin as first-line treatment

RTP
RESEARCH
TO PRACTICE

Agenda

Module 1: Overview; localized urothelial bladder cancer (UBC)

Module 2: First-line treatment of metastatic disease

Module 3: Sequencing of therapy for metastatic UBC

Dr Rosenberg
New York, New York

Clinical Research Background

- **Enfortumab vedotin**
- **Sacituzumab govitecan**
- **Erdafitinib**
- **What's next?**

Sacituzumab Govitecan

Mechanism of action

- **Antibody-drug conjugate targeting TROP2**

Indication

- **For adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor**

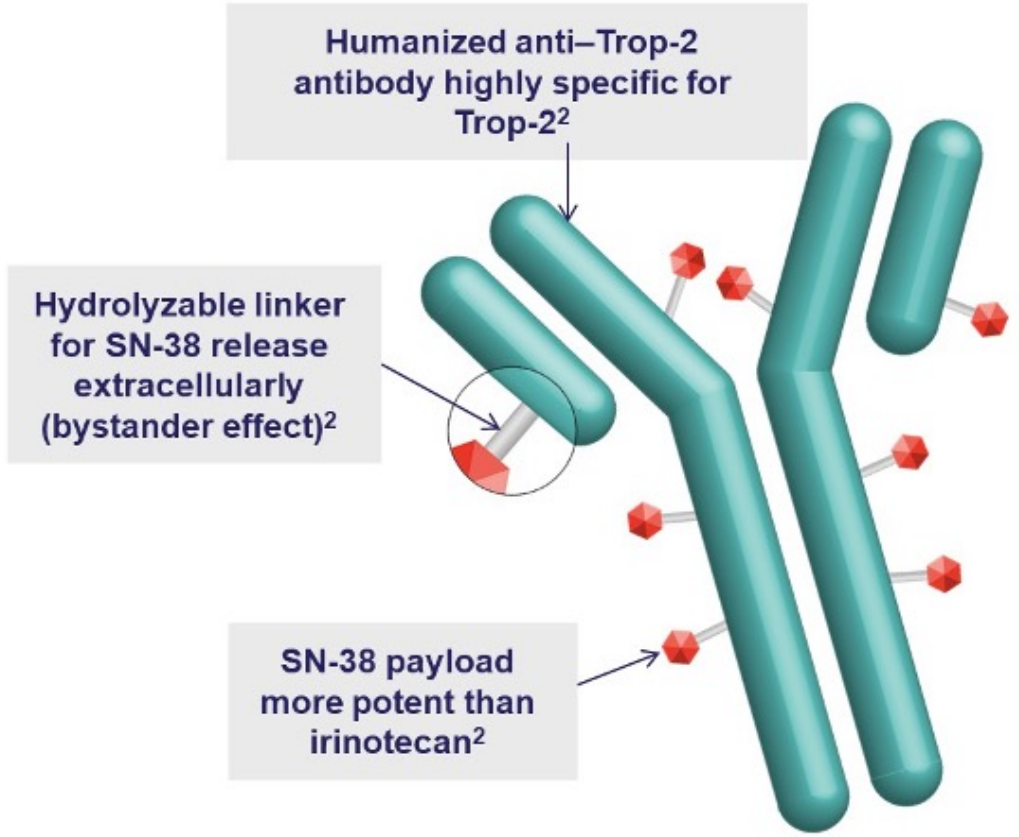
Recommended dose

- **10 mg/kg IV infusion**

Sacituzumab govitecan package insert, February 2023.

Sacituzumab Govitecan (SG): A First-in-Class TROP2-Directed Antibody-Drug Conjugate

- Trop-2 is an epithelial cell surface antigen highly expressed in many solid tumors including invasive bladder cancer[1]
- SG is distinct from other ADCs[2-6]
  - High drug-to-antibody ratio (7.6:1)
  - Internalization and enzymatic cleavage by tumor cell not required for SN-38 (active metabolite of irinotecan) liberation from antibody
- SG is FDA approved for the following:
  - Treatment of patients with mTNBC who received ≥2 prior chemotherapies (≥1 in metastatic setting)[7]
  - Treatment of patients with locally advanced or mUC who have previously received platinum-containing chemotherapy & PD-1/L1 inhibitor[a,7]



Grivas P et al. Genitourinary Cancers Symposium 2022;Abstract 434.

RTP RESEARCH TO PRACTICE

Erdafitinib

Mechanism of action

- Orally bioavailable and selective pan-FGFR tyrosine kinase inhibitor

Indication

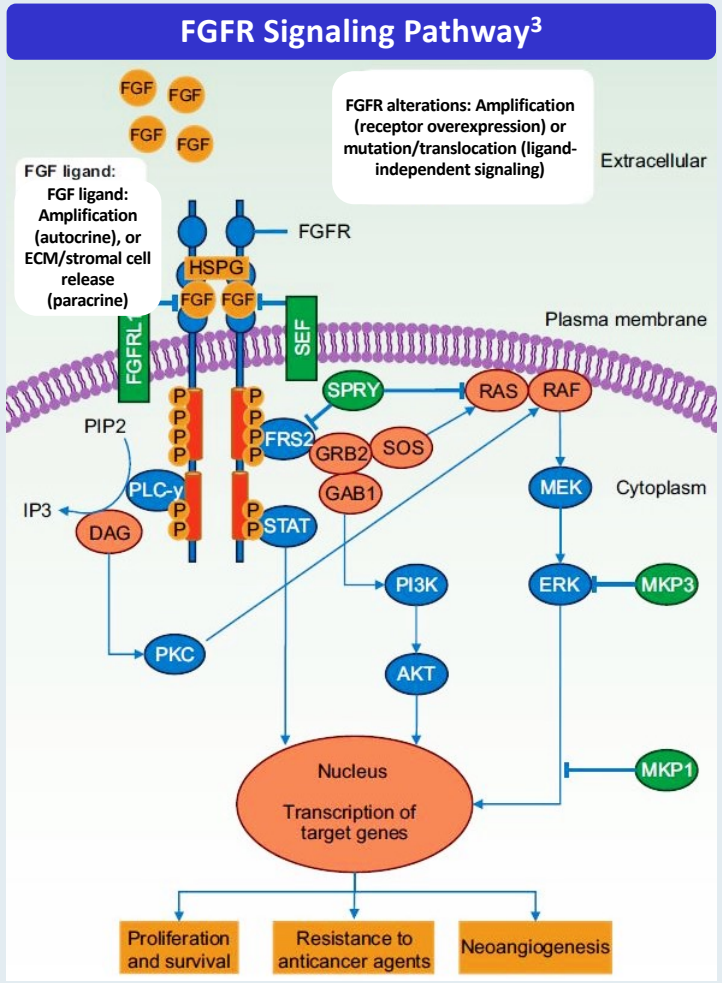
- For adult patients with locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations and disease progression during or after at least 1 prior line of platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy

Recommended dose

- Starting dose of 8 mg orally once daily with a dose increase to 9 mg once daily based on serum phosphate levels and tolerability

Erdafitinib package insert, 2019.

Rationale for Targeting FGFR in Urothelial Carcinoma (UC)[1,2]



- *FGFR* is altered in 15%-20% of advanced UC[4]
  - Mutated *FGFR3* is present in 37% of upper-tract UC[5]

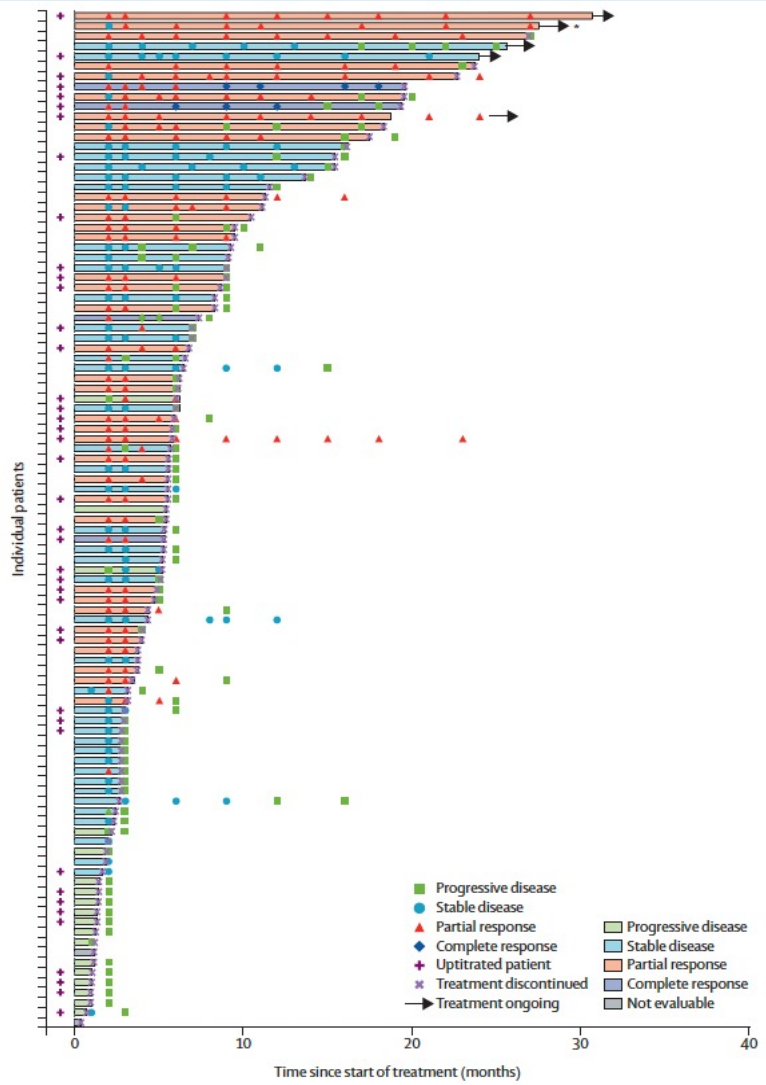
Cancer Type	Frequency of FGFR Alterations[1]
Metastatic UC	15%-20%
NMIBC	40%-70%
Cholangiocarcinoma	14%-22%
NSCLC	4%
HCC (FGF19 amp by FISH)	21%
Glioblastoma	23%
Breast cancer	3%-5%
Ovarian cancer	7%
Head and neck cancer	9%-17%

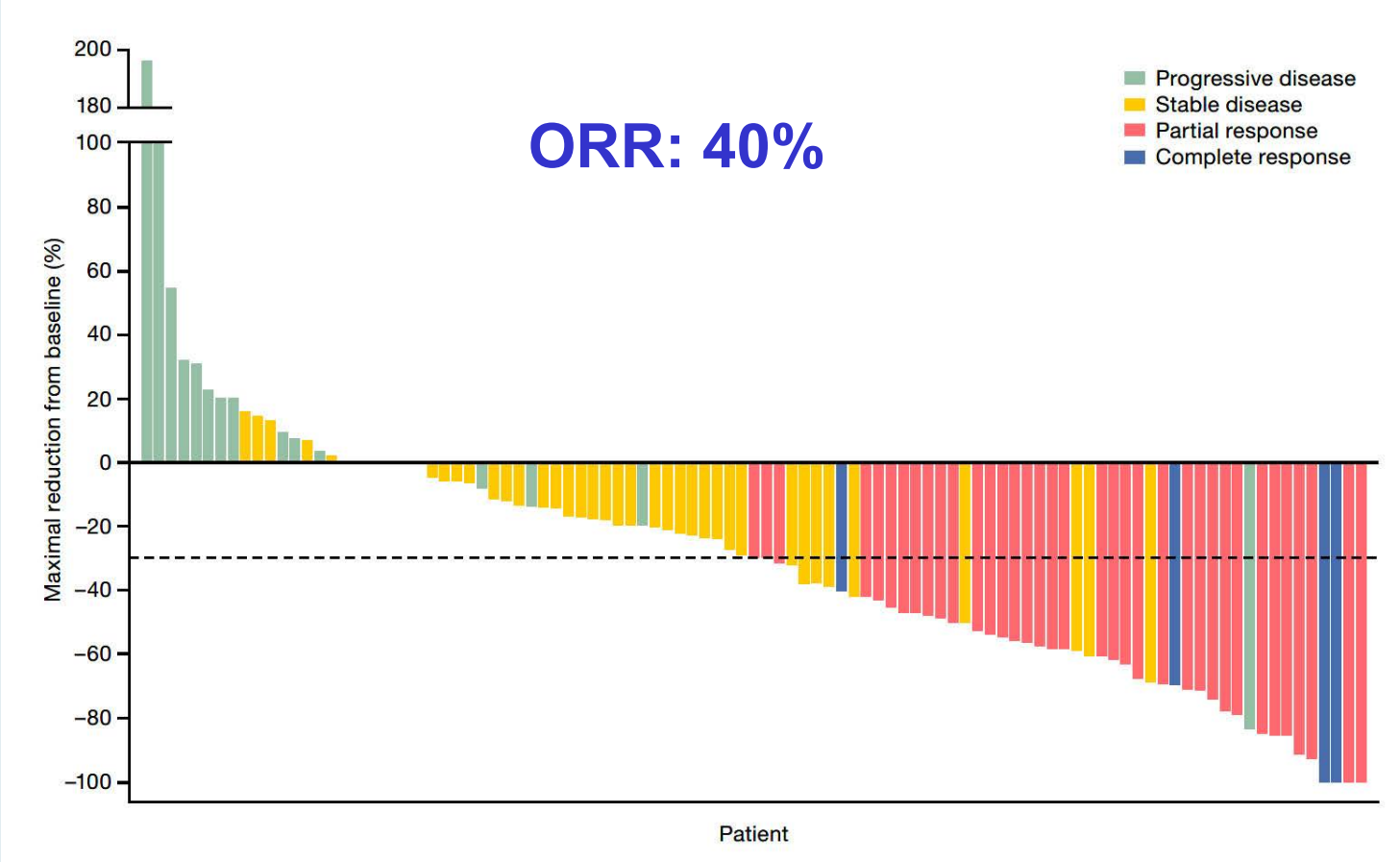
1. The Cancer Genome Atlas (TCGA) genomic alteration database: https://tcga-data.nci.nih.gov/docs/publications/tcga/. Accessed February 6, 2020.
2. Genomics Evidence Neoplasia Information Exchange (GENIE) genomic alteration database: https://www.aacr.org/Research/Research/pages/aacr-project-genie.aspx. Accessed February 6, 2020. 3. Touat M et al. *Clin Cancer Res*. 2015;21:2684-2694. 4. Rodriguez-Vida A et al. *J Hematol Oncol*. 2015;8:119. 5. Li Q et al. *Curr Urol Rep*. 2016;17:12.

Courtesy of Arjun Balar, MD

BLC2001: Erdafitinib for Locally Advanced or Metastatic UBC

Responses in Patients Who Received the Selected 8 mg/day Erdafitinib UpT* Regimen



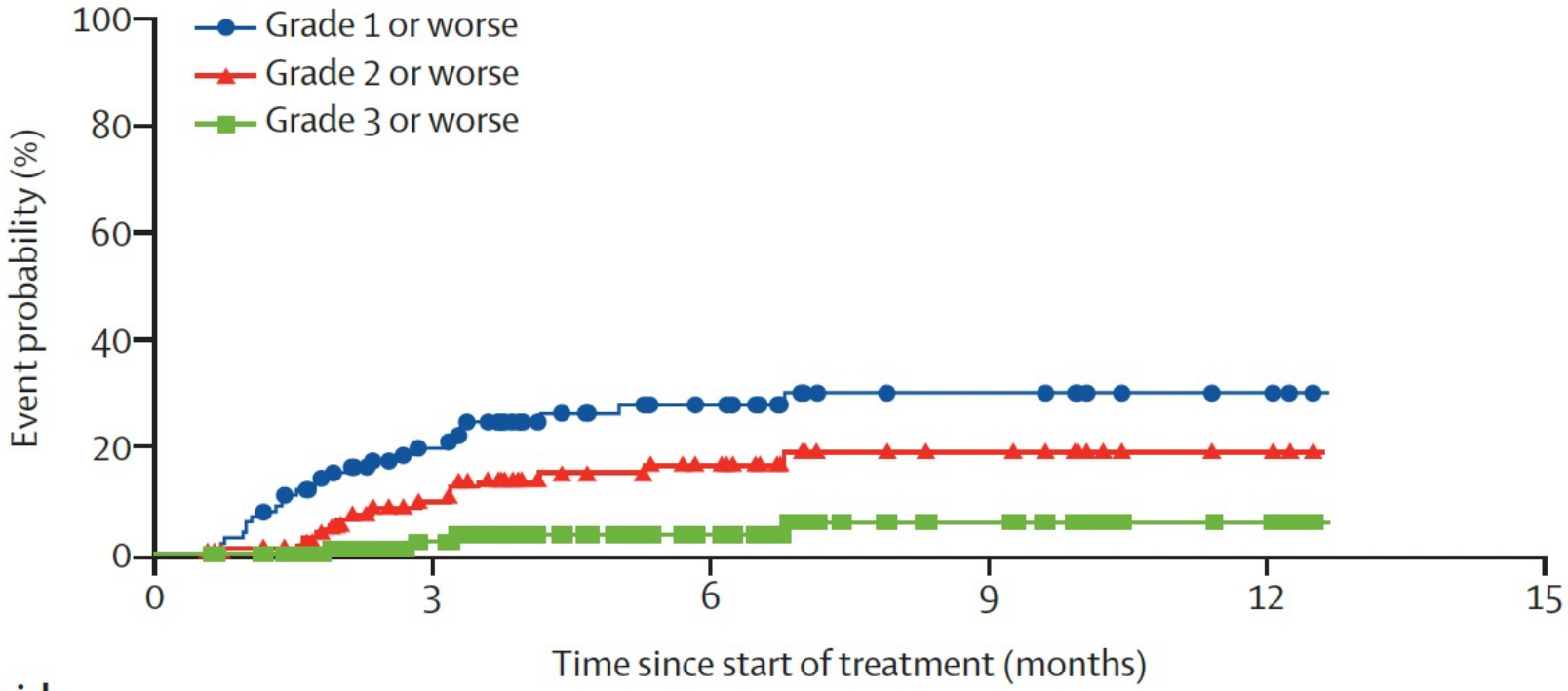


* Continuous once-daily 8 mg/day oral erdafitinib in 28-day cycles, with provision for pharmacodynamically guided uptitration to 9 mg/day

Siefker-Radtke A et al. *Lancet Oncol* 2022;23(2):248-58.

RTP RESEARCH TO PRACTICE

BLC2001: Post Hoc Analysis of the Cumulative Incidence of First-Onset Central Serous Retinopathy Events by Grade



Number at risk (number censored)						
Grade 1 or worse	101 (0)	67 (15)	41 (35)	26 (49)	19 (56)	..
Grade 2 or worse	101 (0)	74 (18)	47 (49)	29 (57)	19 (67)	..
Grade 3 or worse	101 (0)	80 (19)	53 (45)	30 (67)	20 (77)	..

Siefker-Radtke A et al. *Lancet Oncol* 2022;23(2):248-58.

BLC2001: Select Treatment-Emergent Adverse Events

	Grade 1–2	Grade 3	Grade 4	Grade 5*
All treatment-emergent adverse events	29 (29%)	58 (57%)	6 (6%)	8 (8%)
Hyperphosphataemia†	77 (76%)	2 (2%)	0	0
Stomatitis	46 (21%)	14 (14%)	0	0
Diarrhoea	51 (50%)	4 (4%)	0	0
Dry mouth	45 (45%)	1 (1%)	0	0
Decreased appetite	40 (40%)	1 (1%)	0	0
Dysgeusia	39 (39%)	2 (2%)	0	0
Alopecia	34 (34%)	0	0	0
Dry skin	34 (34%)	0	0	0
Fatigue	31 (31%)	2 (2%)	0	0
Constipation	28 (28%)	1 (1%)	0	0
Dry eye	27 (27%)	1 (1%)	0	0
Palmar-plantar erythrodysaesthesia syndrome	20 (20%)	5 (5%)	0	0

Siefker-Radtke A et al. *Lancet Oncol* 2022;23(2):248-58.

Disitamab Vedotin

Mechanism of action

- Antibody-drug conjugate targeting HER2

Indication

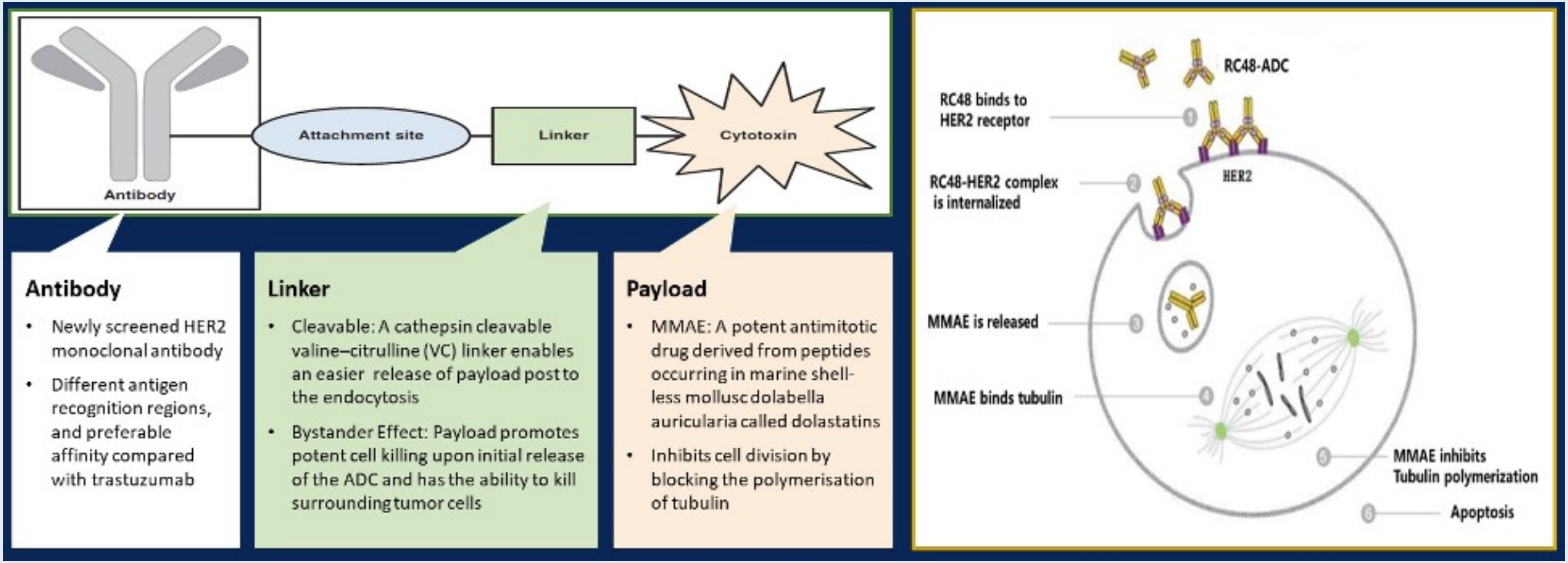
- Investigational

Pivotal clinical data

- Phase II studies evaluating disitamab vedotin in patients with HER2-positive (IHC 2+, IHC 3+)[1] and HER2-negative (IHC 0 or 1+)[2] metastatic urothelial cancer

1. Sheng X et al. ASCO 2022;Abstract 4520; 2. Xu H et al. ASCO 2022;Abstract 4519.

Disitamab Vedotin (RC48): A HER2-Directed Antibody-Drug Conjugate



Sheng X et al. ASCO 2022;Abstract 4520.

Brenda Martone, MSN, NP-BC, AOCNP

79-year-old man with metastatic UBC and a history of Wegener granulomatosis who previously received gemcitabine/carboplatin followed by pembrolizumab on progression is now receiving enfortumab vedotin

RTP
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APPENDIX

Non-muscle-invasive bladder cancer

ASCO Genitourinary Cancers Symposium

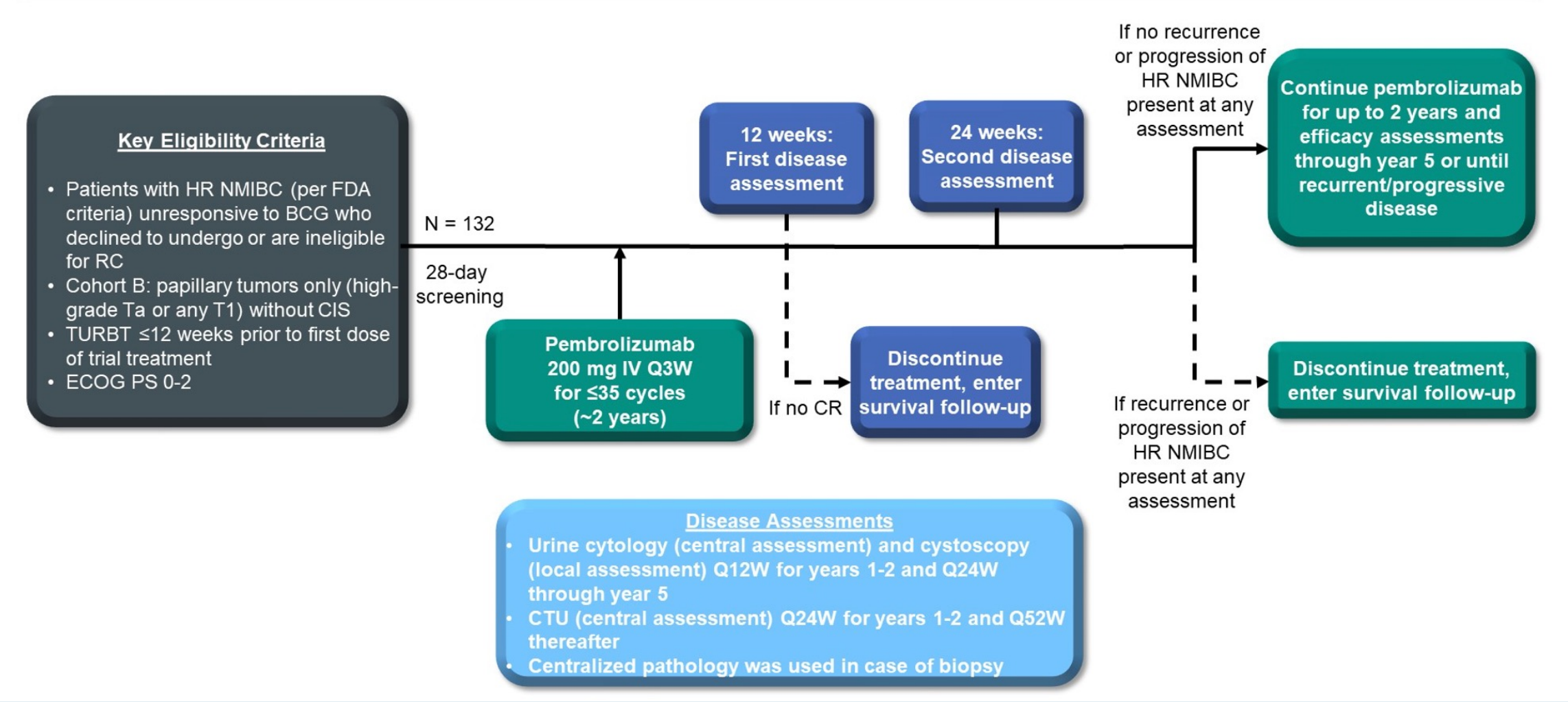
2023;Abstract LBA442.

Pembrolizumab Monotherapy for Patients With High-Risk Non–Muscle-Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guérin: Results From Cohort B of the Phase 2 KEYNOTE-057 Trial

Andrea Necchi[1]; Mathieu Roumiguié[2]; Ahmet Adil Esen[3]; Thierry Lebret[4]; Ronald de Wit[5]; Neal D. Shore[6]; Dean F. Bajorin[7]; Laurence E. M. Krieger[8]; Shuya Kandori[9]; Edward M. Uchio[10]; Ho Kyung Seo[11]; Joost Boormans[5] ; Ashish M. Kamat[12]; Eric A. Singer[13]; Petros Grivas[14]; Hiroyuki Nishiyama[9]; Kijoeng Nam[15]; Ekta Kapadia[15]; Margot Van den Sigtenhorst-Fijlstra[16]; Girish S. Kulkarni[17]

[1]Vita-Salute San Raffaele University, IRCCS San Raffaele Hospital and Scientific Institute, Milan, Italy; [2]Institut Universitaire du Cancer Toulouse–Oncopole CHU, Toulouse, France; [3]Dokuz Eylül University, Izmir, Turkey; [4]Hôpital Foch, Université Paris-Saclay, Université Versailles Saint-Quentin-en-Yvelines, Suresnes, France; [5]Erasmus MC Cancer Institute, Erasmus University Medical Center, Rotterdam, Netherlands; [6]Carolina Urologic Research Center, Myrtle Beach, SC, USA; [7]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [8]GenesisCare and Royal North Shore Hospital, Sydney, NSW, Australia; [9]University of Tsukuba, Tsukuba, Japan; [10]UCI Health, Orange, CA, USA; [11]National Cancer Center, Goyang, South Korea; [12]The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [13]Rutgers Cancer Institute of New Jersey, New Brunswick, NJ, USA; [14]University of Washington and Fred Hutchinson Cancer Center, Seattle, WA, USA; [15]Merck & Co., Inc., Rahway, NJ, USA; [16]MSD Netherlands, Haarlem, Netherlands; [17]University Health Network, UHN Princess Margaret Cancer Centre, University of Toronto, Toronto, ON, Canada

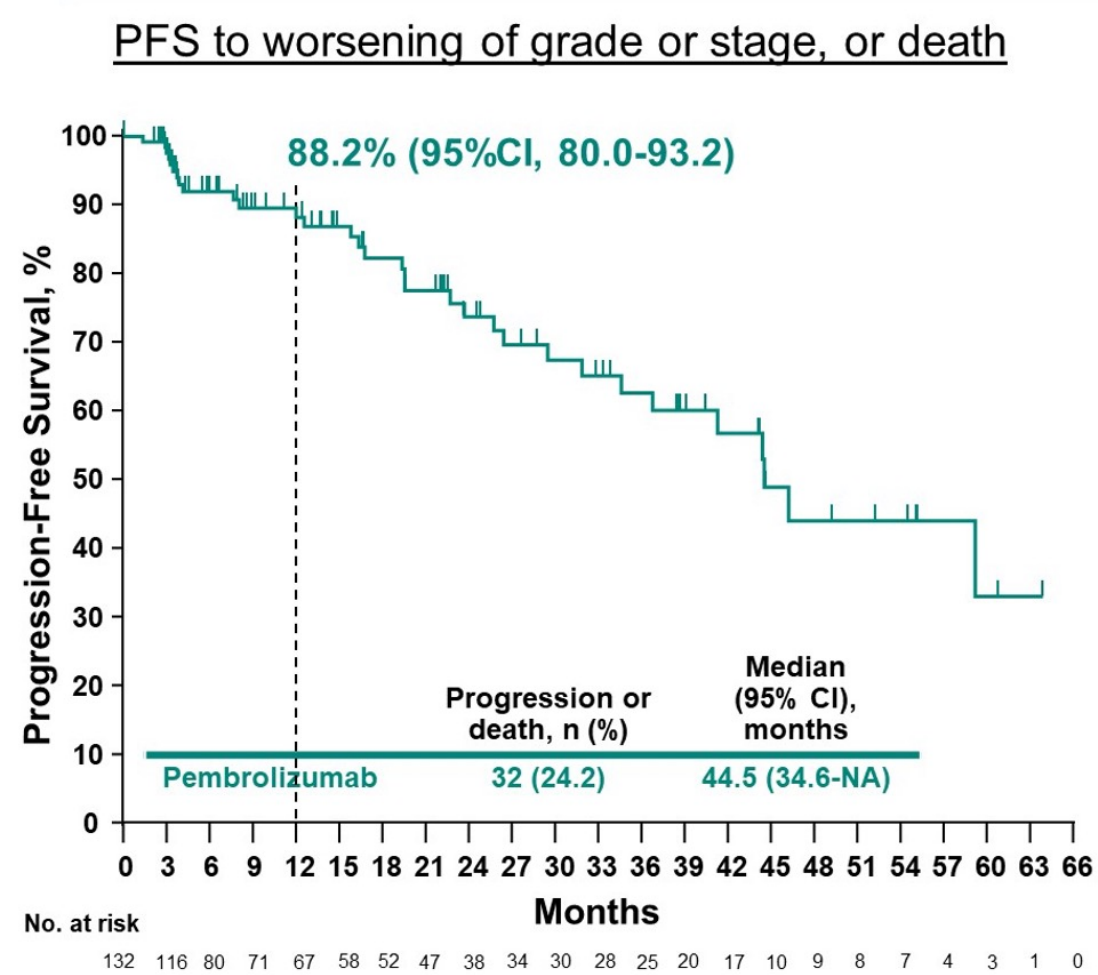
KEYNOTE-057 (Cohort B) Phase II Study Design

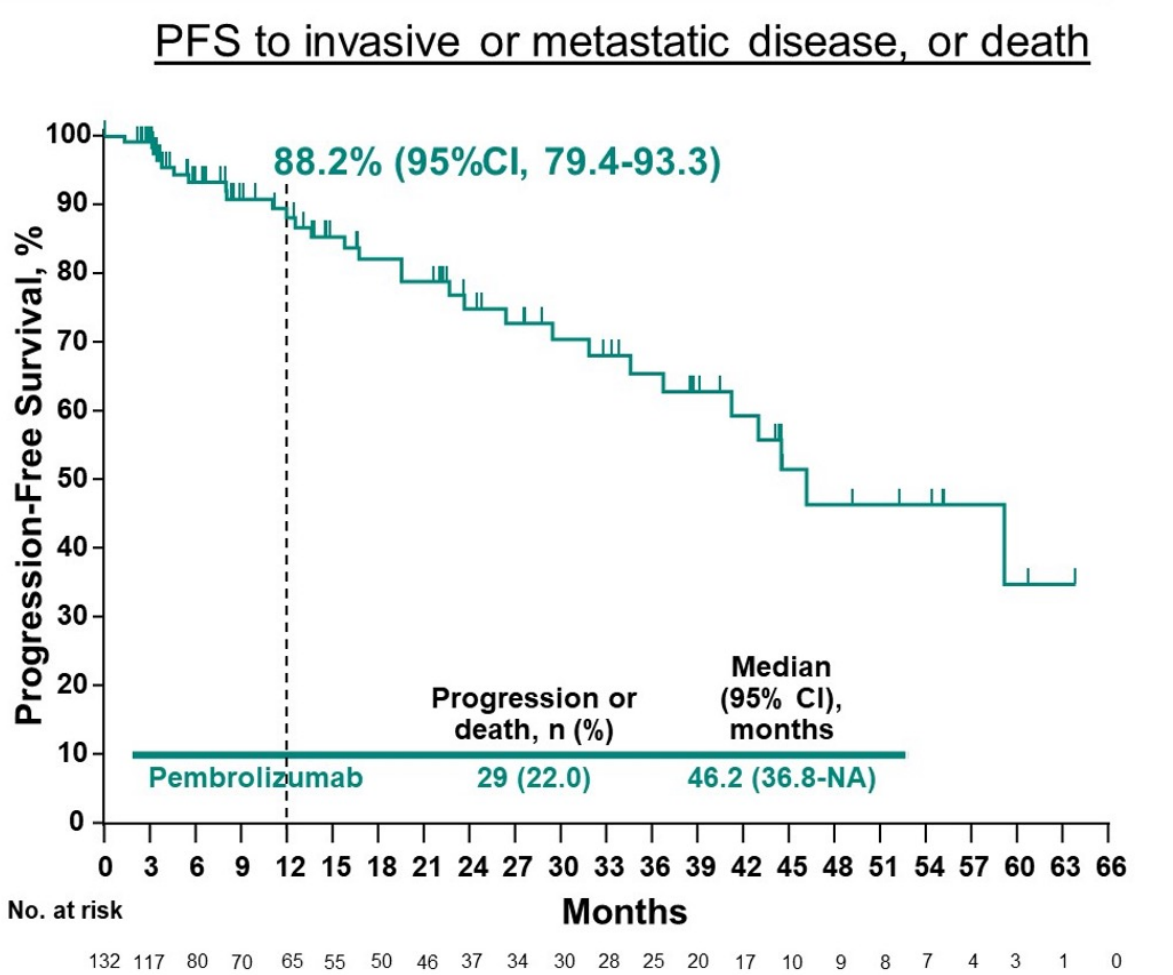


HR = high risk; RC = radical systectomy; CIS = carcinoma in situ

Necchi A et al. Genitourinary Cancers Symposium 2023;Abstract LBA442.

KEYNOTE-057 (Cohort B): Progression-Free Survival





Necchi A et al. Genitourinary Cancers Symposium 2023;Abstract LBA442.

Safety, Tolerability, and Preliminary Efficacy of TAR-200 in Intermediate-Risk Non–Muscle-Invasive Bladder Cancer Patients: a Phase 1 Study

F. Johannes P. van Valenberg,[1] Antoine G. van der Heijden,[1] Christopher J. Cutie,[2] Sumeet Bhanvadia,[2] Kirk A. Keegan,[2] Shalaka Hampras,[3] Hussein Sweiti,[4] John C. Maffeo,[2] Shu Jin,[2] Albert Chau,[5] Donald L. Reynolds,[2] Crysti Iarossi,[2] April Kelley,[3] Xiang Li,[3] Katharine Stromberg,[3] Michiel Sedelaar,[1] Jessica J.O. Steenbruggen,[6] Diederik M. Somford,[6] J. Alfred Witjes[1]

Genitourinary Cancers Symposium 2023;Abstract 505.

RTP RESEARCH TO PRACTICE

Phase Ib Study of TAR-200 for Intermediate-Risk NMIBC: Methods and Safety

- In this phase 1b open-label, prospective study, patients with papillary recurrence after prior histologically proven IR NMIBC received two 1-week TAR-200 dosing cycles over a 4- to 6-week period (Figure 2)
- The study used a marker lesion/ablation design with cystoscopy to assess for recurrent papillary disease and for complete transurethral resection of the residual bladder tumor (TURBT) after treatment
- The primary outcome was TAR-200 safety; secondary outcomes were tolerability, pharmacokinetics, preliminary efficacy, and immunohistochemistry

FIGURE 2: TAR-200 dosing schedule[a]

[a]Dosing schedule shown for Arm 1 of the study (n=11 patients). Arm 2 was initiated to evaluate a longer TAR-200 dwell time (n=1 patient). Arm 2 was terminated early for nonclinical reasons at the sponsor's discretion.

Overview of treatment-emergent adverse events (TEAEs)

Patients with events, n (%)	N=12
TEAE (any grade)	11 (92)
Grade ≥3 TEAE	0
Serious TEAE	0
TEAE leading to study discontinuation	0
TEAE leading to death	0
TEAE related to TAR-200 (any grade)	9 (75)

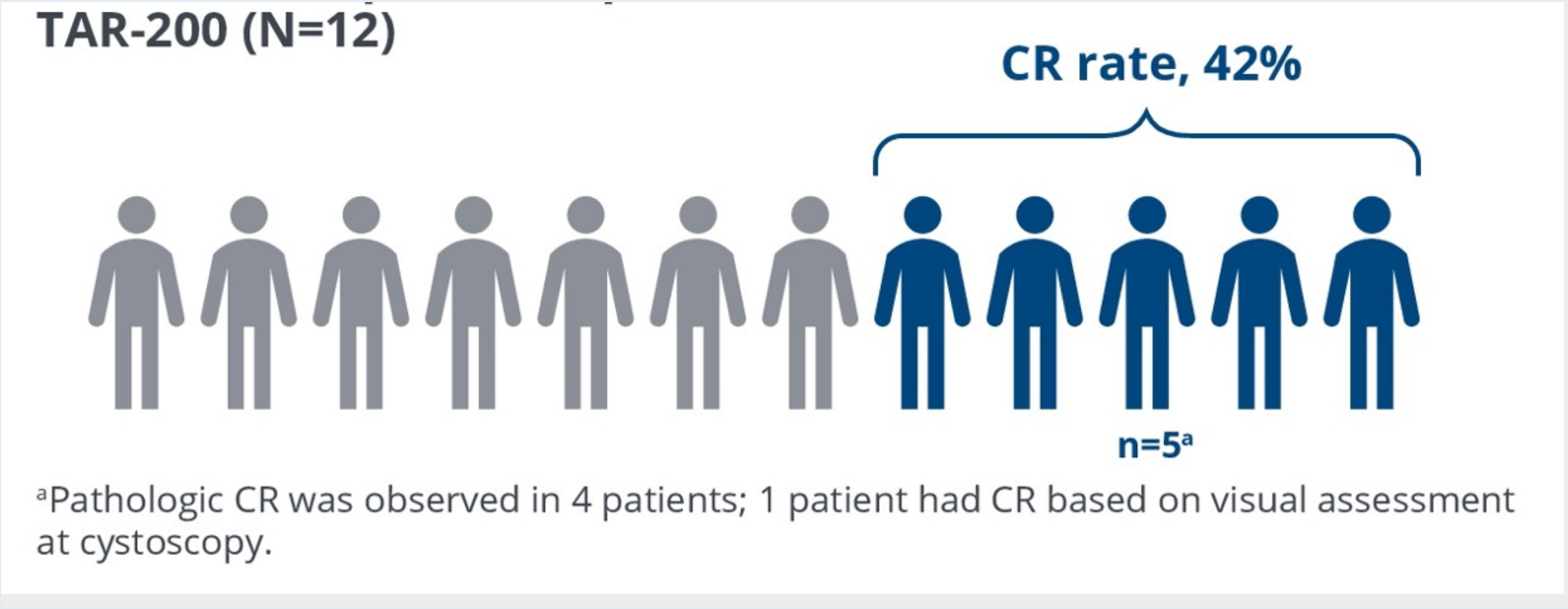
TABLE 2: Most frequent TEAEs by preferred term and grade

Patients with events, n (%)[a]	N=12		
	All	Grade 1	Grade 2
Pollakiuria	7 (58)	5 (42)	2 (17)
Dysuria	5 (42)	4 (33)	1 (8)
Hematuria	5 (42)	5 (42)	0
Constipation	4 (33)	4 (33)	0
Penile pain	3 (25)	3 (25)	0

[a]TEAEs reported in ≥25% of patients.

Van Valenberg FJP et al. Genitourinary Cancers Symposium 2023;Abstract 505.

Phase Ib Study of TAR-200 for Intermediate-Risk NMIBC: Response

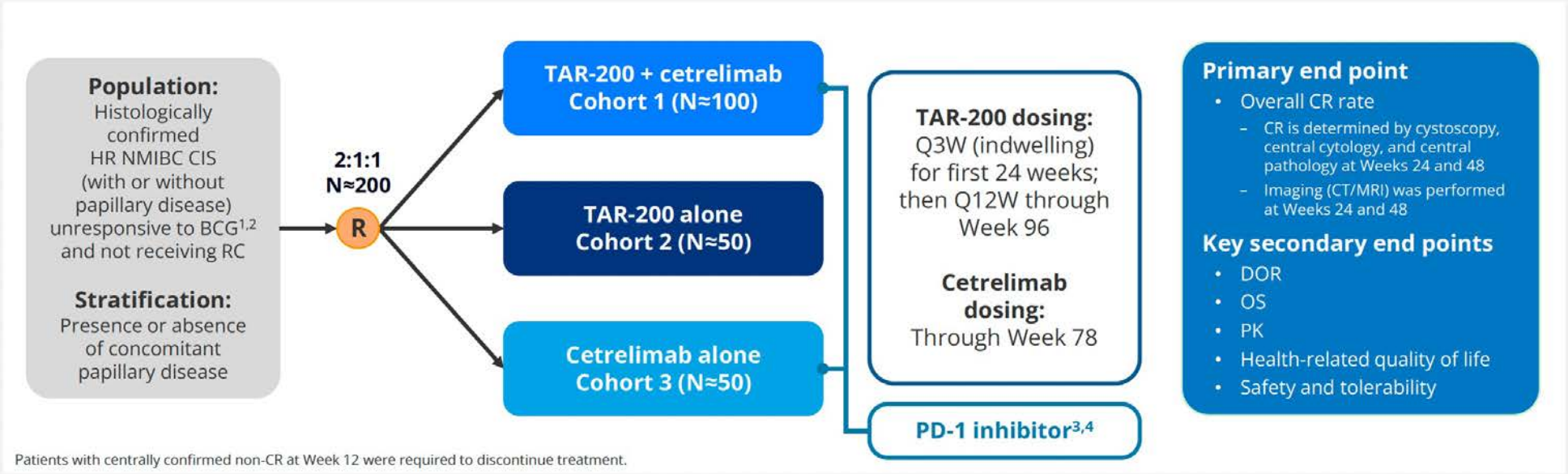


Van Valenberg FJP et al. Genitourinary Cancers Symposium 2023;Abstract 505.

RTP RESEARCH TO PRACTICE

SunRISe-1: Evaluating TAR-200, Cetrelimab, or the Combination for BCG-Unresponsive, High-Risk NMIBC

SunRISe-1 (NCT04640623) is a Phase 2b Randomized, Open-label Study



Primary Endpoint: Overall clinical response rate

Daneshmand S et al. AUA 2023;Abstract LBA02-03.

RTP RESEARCH TO PRACTICE

Nonmetastatic muscle-invasive bladder cancer

ASCO Genitourinary Cancers Symposium 2023;Abstract LBA443.

Extended follow-up results from the CheckMate 274 trial

Matthew D. Galsky,[1] Johannes Alfred Witjes,[2] Jürgen E. Gschwend,[3] Michael Schenker,[4] Begoña P. Valderrama,[5] Yoshihiko Tomita,[6] Aristotelis Bamias,[7] Thierry Lebret,[8] Shahrokh F. Shariat,[9] Se Hoon Park,[10] Mads Agerbaek,[11] Gautam Jha,[12] Frank Stenner,[13] Santanu Dutta,[14] Federico Nasroulah,[14] Joshua Zhang,[14] Lynne Brophy,[14] Dean F. Bajorin[15]

[1]Icahn School of Medicine at Mount Sinai, New York, NY; [2]Radboud University, Nijmegen, the Netherlands; [3]Technical University Munich, Munich, Germany; [4]Sf. Nectarie Oncology Center, Craiova, Romania; [5]Hospital Universitario Virgen del Rocío, Sevilla, Spain; [6]Niigata University Graduate School of Medical and Dental Sciences, Niigata, Japan; [7]National and Kapodistrian University of Athens, Athens, Greece; [8]Hôpital Foch, Paris-Saclay University UVSQ, Versailles, France; [9]Medical University of Vienna, Vienna General Hospital, Vienna, Austria; [10]Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; [11]Aarhus University Hospital, Aarhus, Denmark; [12]M Health Fairview Clinics and Surgery Center, Minneapolis, MN; [13]University Hospital Basel, Basel, Switzerland; [14]Bristol Myers Squibb, Princeton, NJ; [15]Memorial Sloan Kettering Cancer Center, New York, NY

CheckMate 274 Phase III Study Design

- CheckMate 274 is a phase 3, randomized, double-blind, multicenter study of adjuvant nivolumab versus placebo in patients with high-risk MIUC[a]

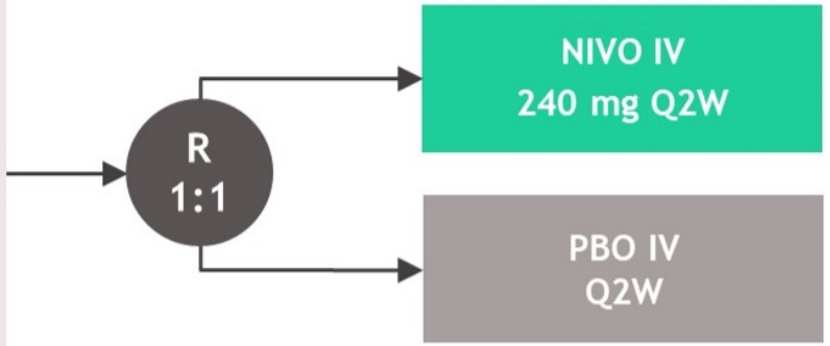
N = 709

Key inclusion criteria

- Patients with ypT2-ypT4a or ypN+ MIUC who had neoadjuvant cisplatin chemotherapy
- Patients with pT3-pT4a or pN+ MIUC without prior neoadjuvant cisplatin chemotherapy and not eligible/refuse adjuvant cisplatin chemotherapy
- Radical surgery within the past 120 days
- Disease-free status within 4 weeks of randomization

Stratification factors

- Tumor PD-L1 status (≥ 1% vs < 1% or indeterminate)[b]
- Prior neoadjuvant cisplatin-based chemotherapy
- Nodal status



Treat for up to 1 year of adjuvant therapy

Median (range) follow-up[c] (ITT population),
36.1 (0.0-75.3) months (37.4 months for NIVO, 33.9 months for PBO)
Minimum follow-up[d] (ITT population), 31.6 months
Median (range) follow-up[c] (PD-L1 ≥ 1% population),
37.1 (0.0-75.3) months (39.8 months for NIVO, 33.3 months for PBO)

Primary endpoints: DFS in all randomized patients (ITT population) and DFS in all randomized patients with tumor PD-L1 ≥ 1%
Secondary endpoints: NUTRFS, DSS, and OS[e]
Exploratory endpoints included: DMFS, PFS2, safety, HRQoL

Galsky MD et al. Genitourinary Cancers Symposium 2023;Abstract LBA443.

RTP RESEARCH TO PRACTICE

ELSEVIER

Urologic Oncology: Seminars and Original Investigations 40 (2022) 344.e1–344.e9

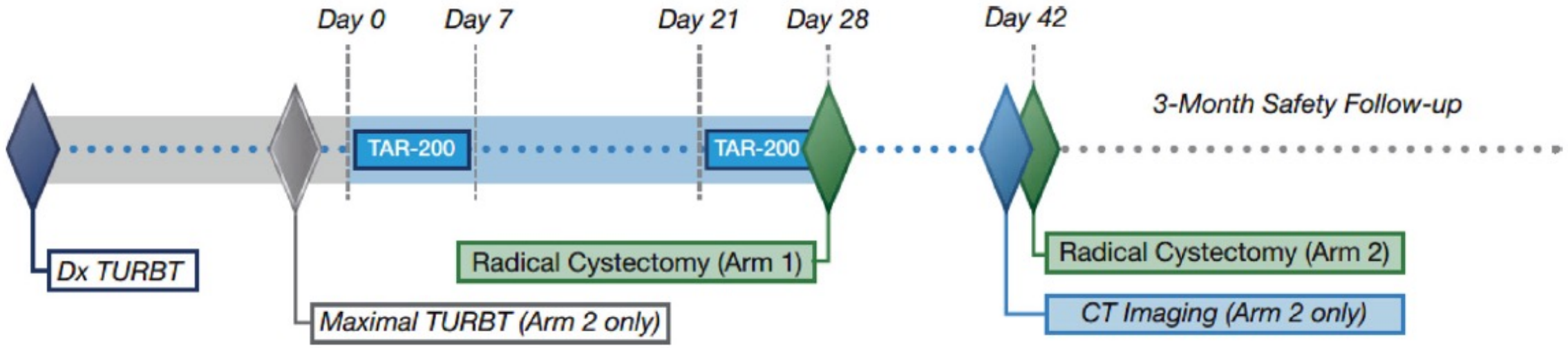
UROLOGIC ONCOLOGY

Clinical-Bladder cancer

The safety, tolerability, and efficacy of a neoadjuvant gemcitabine intravesical drug delivery system (TAR-200) in muscle-invasive bladder cancer patients: a phase I trial

Siamak Daneshmand, M.D.[a,*], Iris S.G. Brummelhuis, M.D.[b], Kamal S. Pohar, M.D.[c], Gary D. Steinberg, M.D.[d], Manju Aron, M.D.[e], Christopher J. Cutie, M.D.[f], Kirk A. Keegan, M.D.[f], John C. Maffeo, M.S.H.S.[f], Donald L. Reynolds, Ph.D.[f], Bradley Raybold, M.S.[g], Albert Chau, M.Sc.[h], J. Alfred Witjes, M.D., Ph.D.[b]

TAR-200-101: Study Design and Outcomes

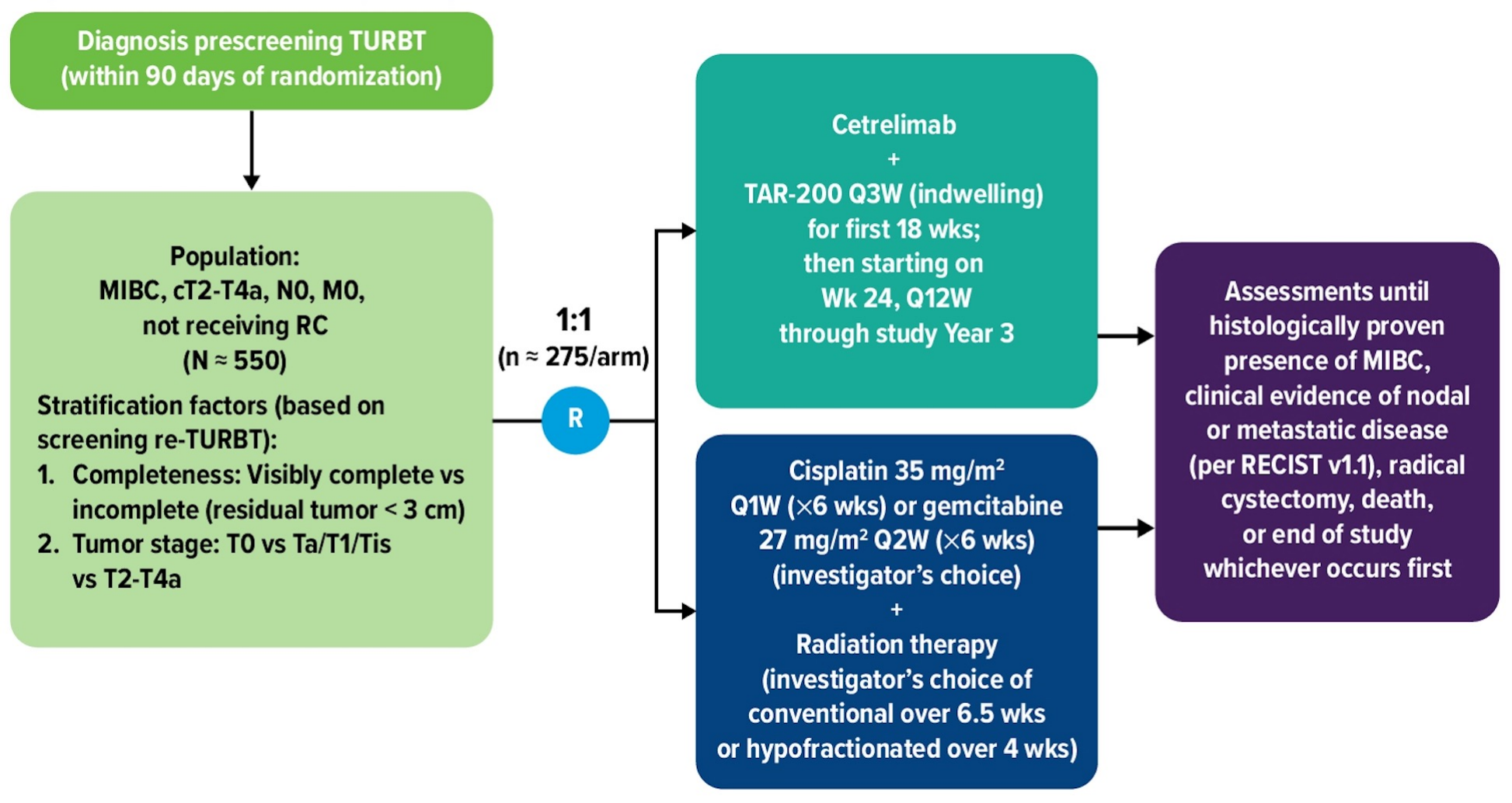


Response	Arm 1 (>3 cm)	Arm 2 (max TURBT)
Underwent pathology at RC, *n/N* (%)	10/11 (90.9)	10/12 (83.3)
Pathologic response, *n/N* (%)	4/10 (40.0)	6/10 (60.0)
Complete response, *n/N* (%)	1/10 (10.0)	3/10 (30.0)
Partial response, *n/N* (%)	3/10 (30.0)	3/10 (30.0)

Treatment-emergent adverse event, *n* (%)	TAR-200 related[a]	Procedure related[b]
Pollakiuria	3 (13)	2 (9)
Urinary incontinence	2 (9)	2 (9)
Micturation urgency	2 (9)	0
Urinary tract infection	1 (4)	2 (9)
Gross hematuria	0	1 (4)
Hematoma[c]	0	0

Daneshmand S et al. *Urol Oncol* 2022;40:344e1-9.

SunRISe-2: TAR-200 in Combination with Cetrelimab versus Concurrent Chemoradiation Therapy for MIBC



Williams SB et al. ASCO 2021;Abstract TPS4586.

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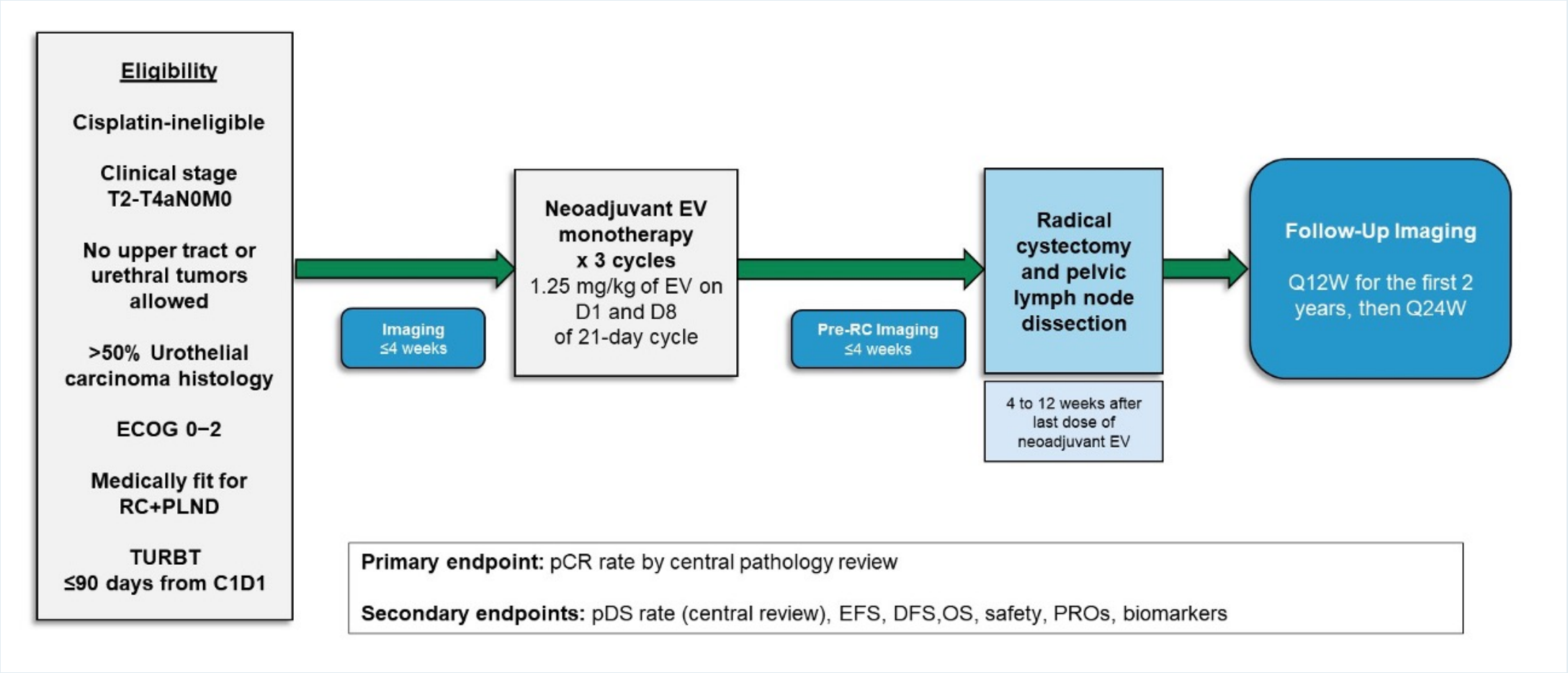
EV-103 Cohort H Study Schema



Petrylak DP et al. Genitourinary Cancers Symposium 2022;Abstract 435.

EV-103 Cohort H: Efficacy by Central Pathology Review

Pathological Response	Central Pathology Results (N=22) n (%) [95% Confidence Interval]
Pathological Complete Response Rate (defined as absence of any viable tumor tissue: ypT0 and N0)	**8 (36.4%)** [17.2–59.3]
Pathological Downstaging Rate (defined as presence of ypT0, ypTis, ypTa, ypT1, and N0)	**11 (50.0%)** [28.2–71.8]

Petrylak DP et al. Genitourinary Cancers Symposium 2022;Abstract 435.

Antibody-drug conjugates

2022 ASCO® ANNUAL MEETING

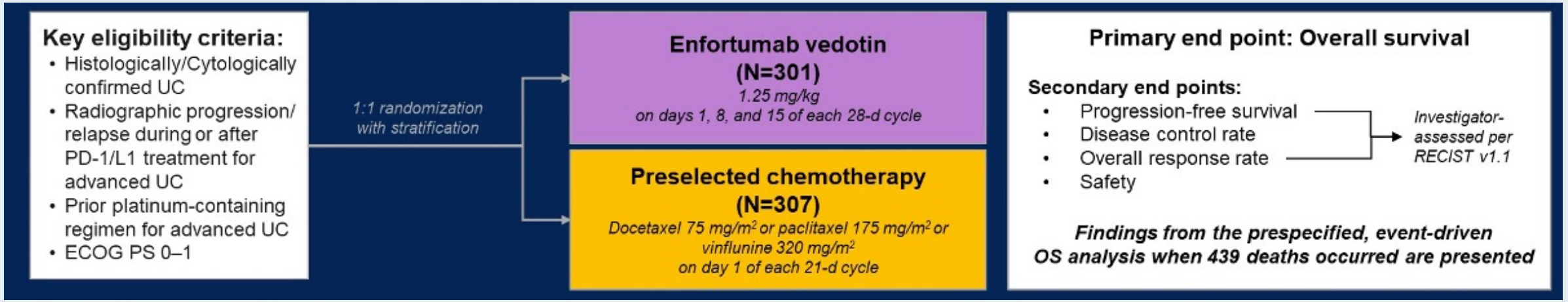
Abstract 4516

Long-Term Outcomes in EV-301: 24-Month Findings From the Phase 3 Trial of Enfortumab Vedotin vs Chemotherapy in Patients With Previously Treated Advanced Urothelial Carcinoma

Jonathan E. Rosenberg, MD[1]; Thomas Powles, MD[2]; Guru P. Sonpavde, MD[3]; Yohann Loriot, MD, PhD[4]; Ignacio Duran, MD, PhD[5]; Jae-Lyun Lee, MD, PhD[6]; Nobuaki Matsubara, MD[7]; Christof Vulsteke, MD, PhD[8]; Daniel Castellano, MD[9]; Ronac Mamtani, MD[10]; Chunzhang Wu, PhD[11]; Maria Matsangou, MD[11]; Mary Campbell, MD[12]; Daniel P. Petrylak, MD[13]

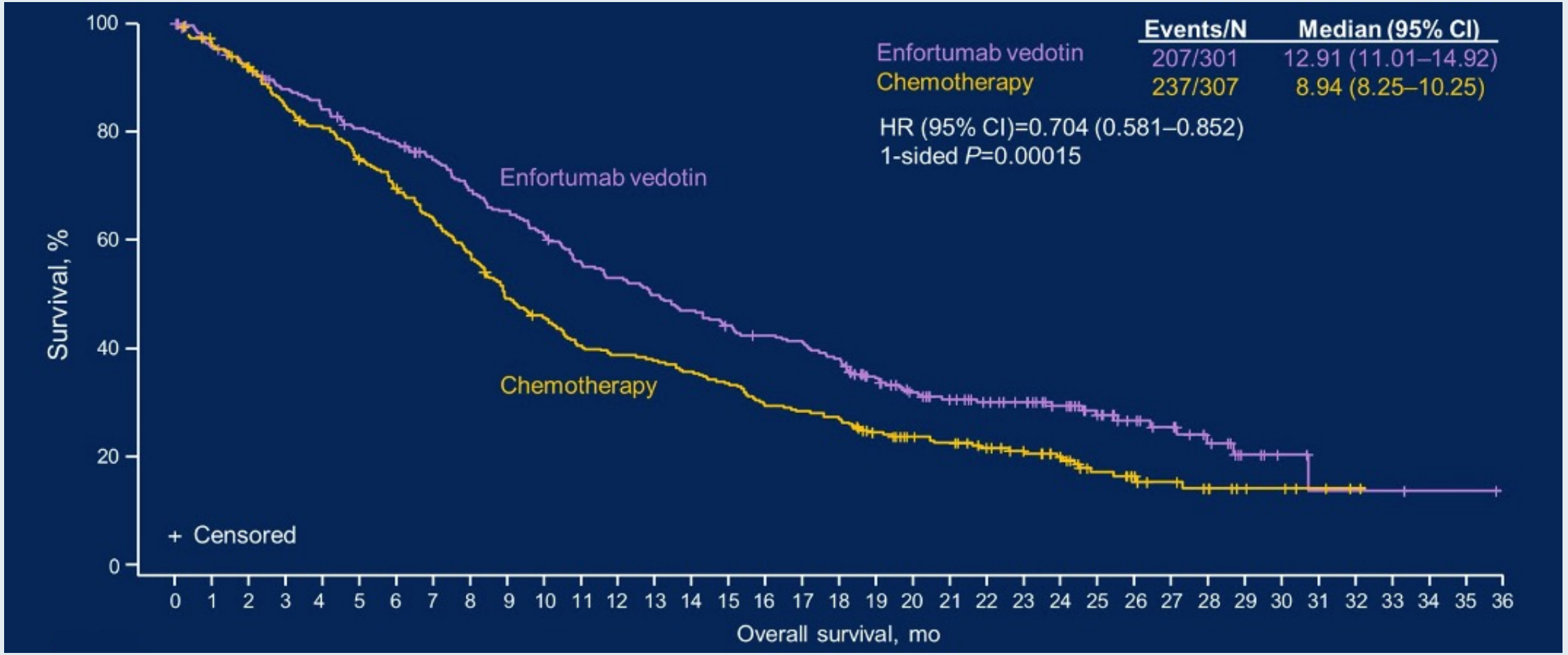
[1]Department of Medicine, Division of Solid Tumor Oncology, Genitourinary Oncology Service, Memorial Sloan Kettering Cancer Center, New York, NY; [2]Barts Cancer Institute, CRUK Experimental Cancer Medicine Centre, London, UK; [3]Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA; [4]Gustave Roussy, Université Paris-Saclay, Villejuif, France; [5]Hospital Universitario Marques de Valdecilla, IDIVAL, Cantabria, Spain; [6]Asan Medical Center and University of Ulsan College of Medicine, Seoul, South Korea; [7]National Cancer Center Hospital East, Chiba, Japan; [8]Center for Oncological Research (CORE), University of Antwerp, Integrated Cancer Center Ghent, Ghent, Belgium; [9]Hospital Universitario 12 de Octubre, Madrid, Spain; [10]Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA; [11]Astellas Pharma, Inc., Northbrook, IL; [12]Seagen Inc., Bothell, WA; [13]Yale Cancer Center, New Haven, CT

EV-301 Study Design



Rosenberg JE et al. ASCO 2022;Abstract 4516.

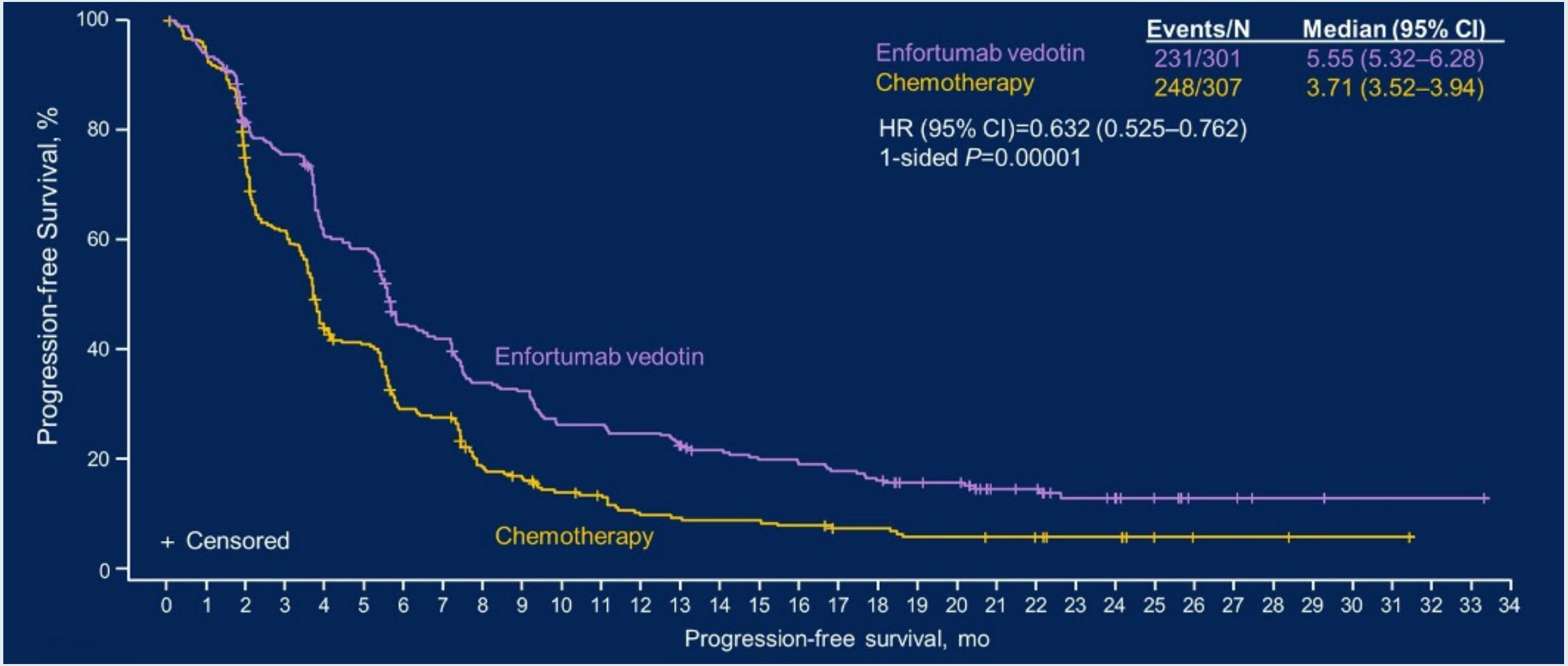
EV-301: Overall Survival



Rosenberg JE et al. ASCO 2022;Abstract 4516.

RTP RESEARCH TO PRACTICE

EV-301: Progression-Free Survival



Rosenberg JE et al. ASCO 2022;Abstract 4516.

ASCO GU Cancers Symposium 2023

Poster ID: 526

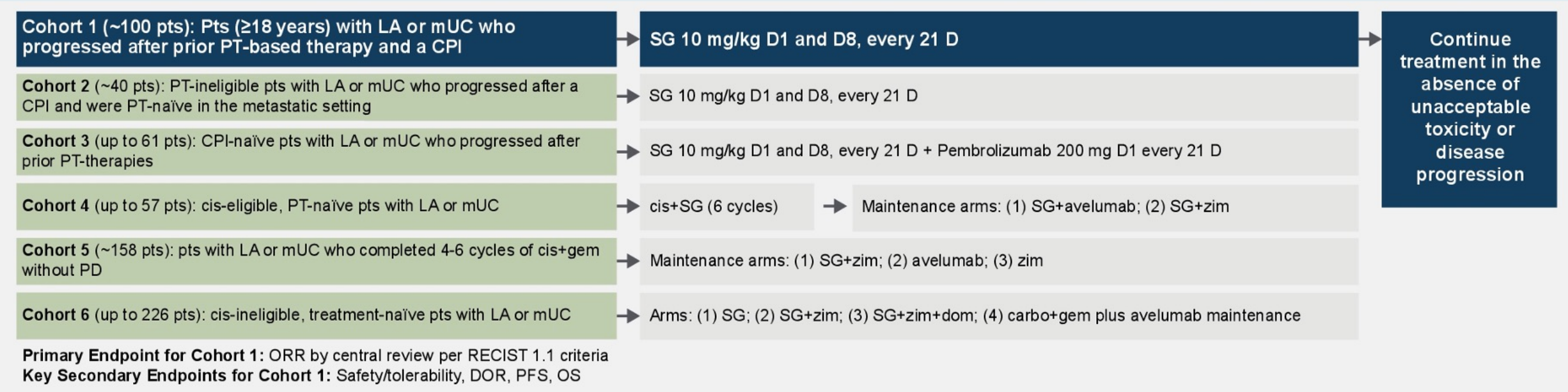
trophy U-01

Updated Outcomes in TROPHY-U-01 Cohort 1, a Phase 2 Study of Sacituzumab Govitecan in Patients With Metastatic Urothelial Cancer Who Progressed After Platinum-Based Chemotherapy and a Checkpoint Inhibitor

Scott T. Tagawa,[1] Arjun V. Balar,[2] Daniel P. Petrylak,[3] Arash Rezazadeh Kalebasty,[4] Yohann Loriot,[5] Aude Fléchon,[6] Rohit K. Jain,[7] Neeraj Agarwal,[8] Manojkumar Bupathi,[9] Philippe Barthélémy,[10] Philippe Beuzeboc,[11] Phillip Palmbos,[12] Christos E. Kyriakopoulos,[13] Damien Pouessel,[14] Cora N. Sternberg,[1] Julia Tonelli,[15] Mitch Sierecki,[15] Huafeng Zhou,[15] and Petros Grivas[16]

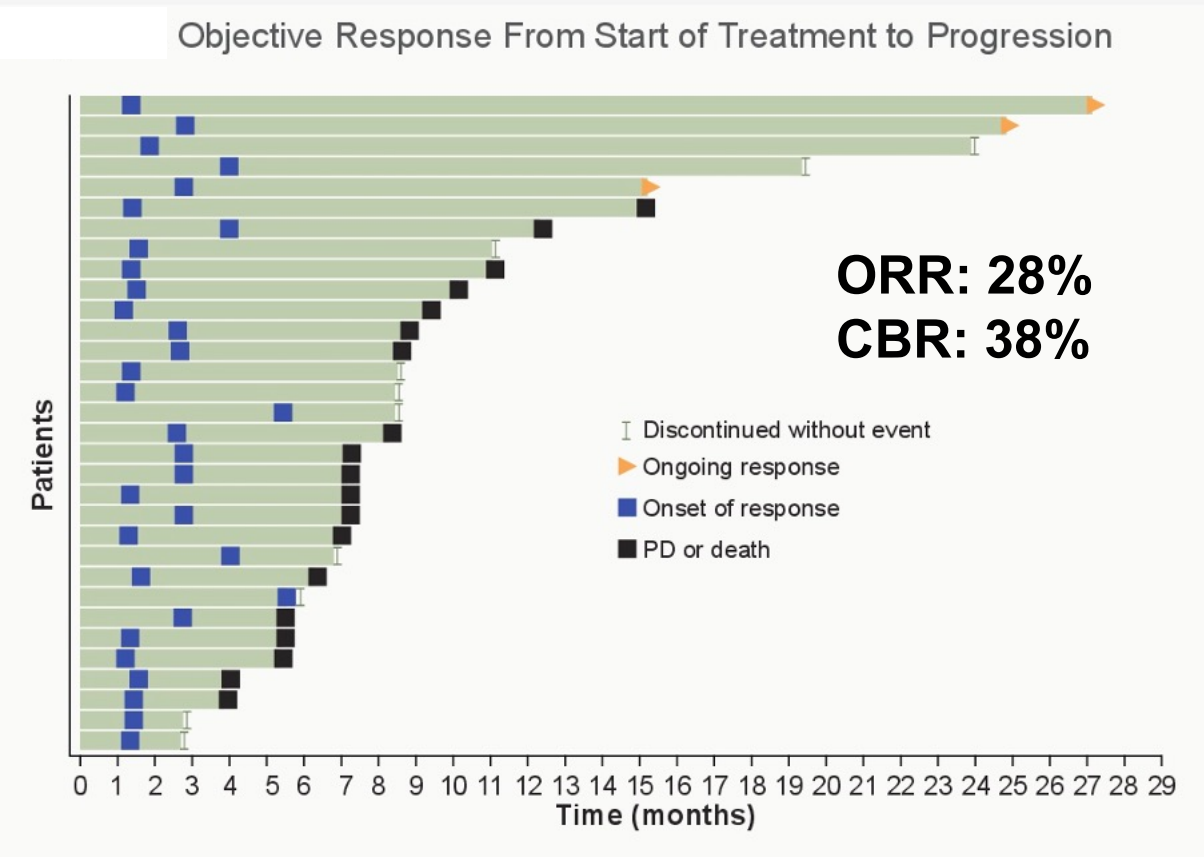
RTP RESEARCH TO PRACTICE

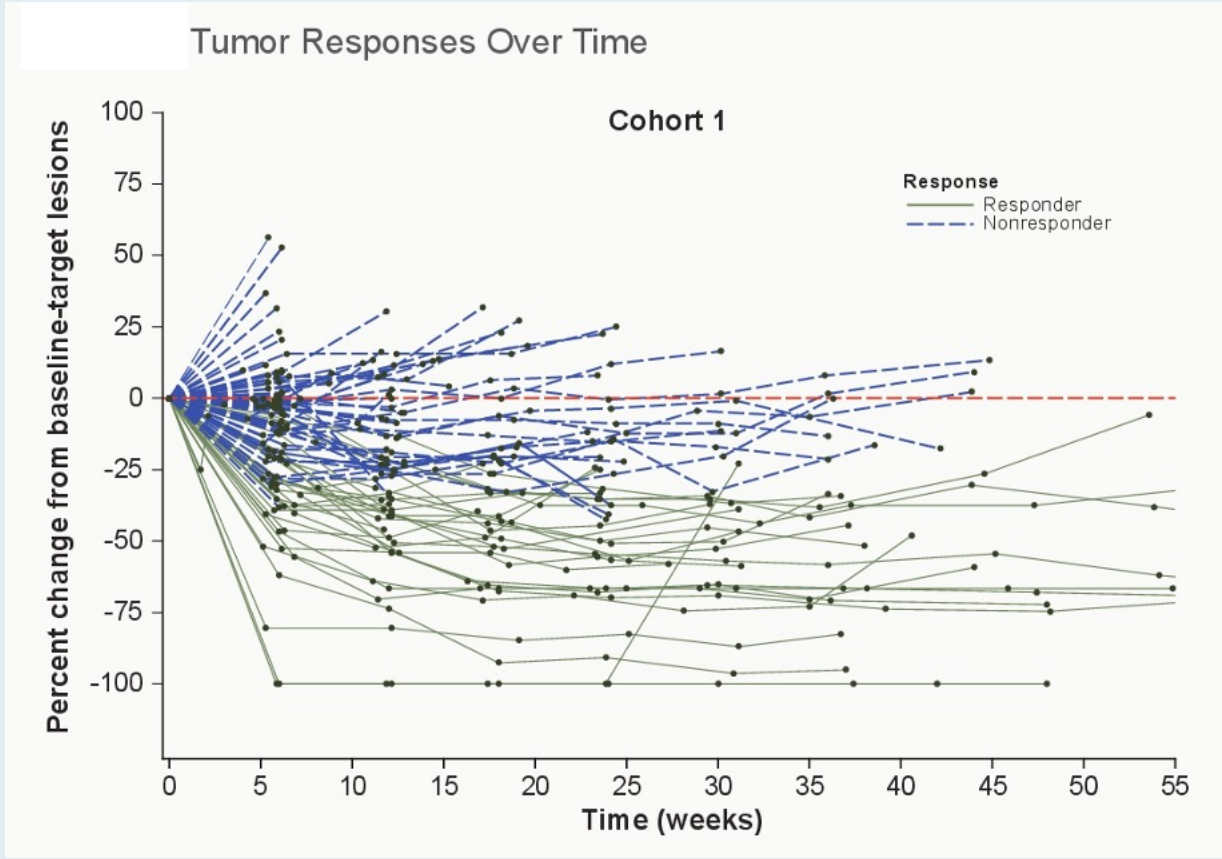
TROPHY U-01 (Cohort 1) Study Design



Tagawa ST et al. Genitourinary Cancers Symposium 2023;Abstract 526.

TROPHY U-01 (Cohort 1): Response





Tagawa ST et al. Genitourinary Cancers Symposium 2023;Abstract 526.

ASCO GU Cancers Symposium 2023

Poster ID: 520

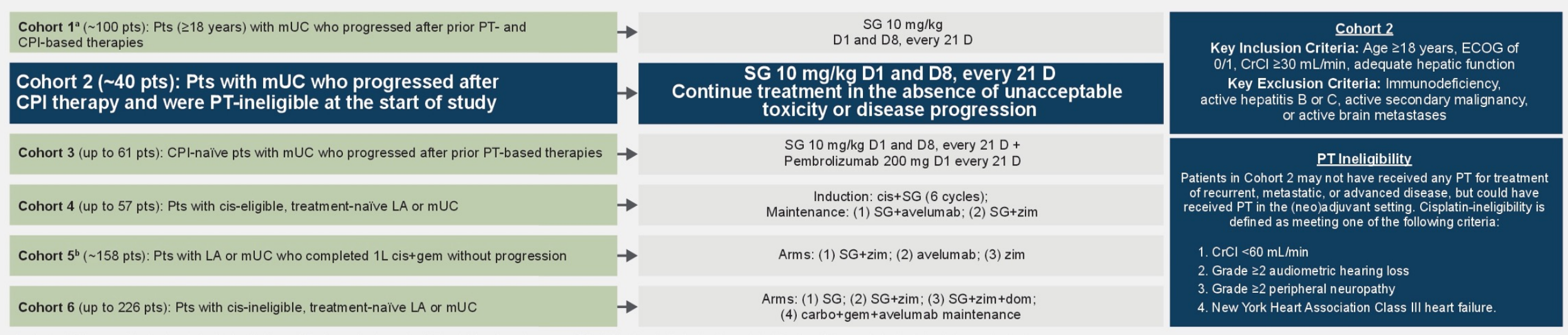
trophy U-01

Primary Analysis of TROPHY-U-01 Cohort 2, a Phase 2 Study of Sacituzumab Govitecan in Platinum-Ineligible Patients With Metastatic Urothelial Cancer Who Progressed After Prior Checkpoint Inhibitor Therapy

Daniel P. Petrylak,[1] Scott T. Tagawa,[2] Rohit K. Jain,[3] Manojkumar Bupathi,[4] Arjun Balar,[5] Arash Rezazadeh Kalebasty,[6] Saby George,[7] Phillip Palmbos,[8] Luke Nordquist,[9] Nancy Davis,[10] Chethan Ramamurthy,[11] Cora N. Sternberg,[2] Yohann Loriot,[12] Neeraj Agarwal,[13] Chandler Park,[6] Julia Tonelli,[14] Morganna Vance,[14] Huafeng Zhou,[14] and Petros Grivas[15]

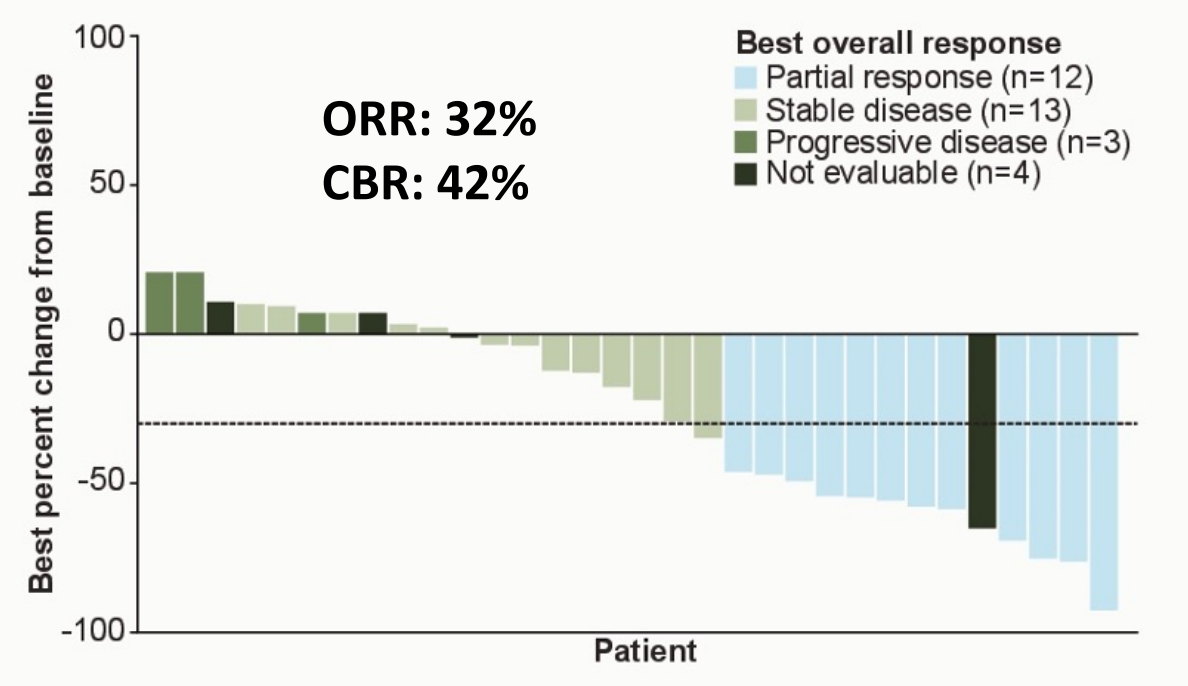
RTP RESEARCH TO PRACTICE

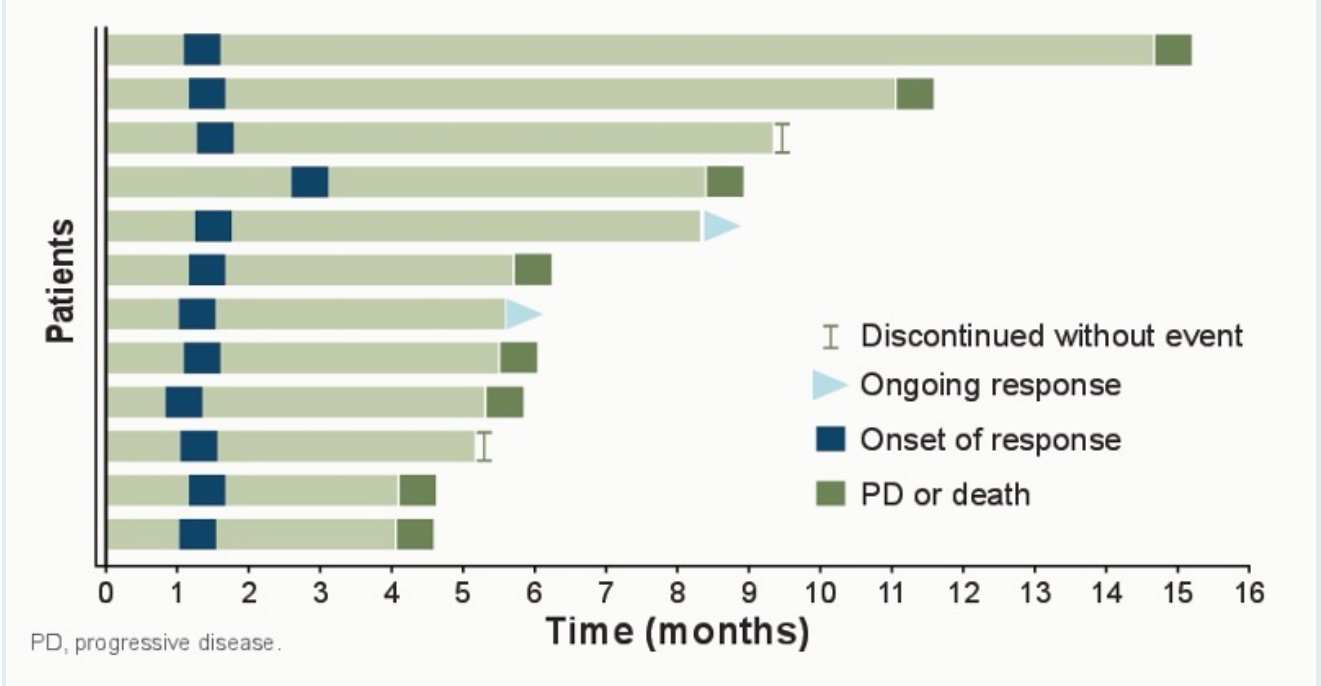
TROPHY U-01 (Cohort 2) Trial Design



Petrylak DP et al. Genitourinary Cancers Symposium 2023;Abstract 520.

TROPHY U-01 (Cohort 2): Response





Petrylak DP et al. Genitourinary Cancers Symposium 2023;Abstract 520.

RTP RESEARCH TO PRACTICE

FGFR-targeted treatment

Phase 2 Study of the Efficacy and Safety of Erdafitinib in Patients With Intermediate-Risk Non–Muscle-Invasive Bladder Cancer (IR-NMIBC) With *FGFR3/2* Alterations (*alt*) in THOR-2: Cohort 3 Interim Analysis

Siamak Daneshmand,[1] Renata Zaucha,[2] Benjamin A. Gartrell,[3] Yair Lotan,[4] Syed A. Hussain,[5] Eugene K. Lee,[6] Giuseppe Procopio,[7] Fernando Galanternik,[8] Vahid Naini,[9] Jenna Cody Carcione,[10] Spyros Triantos,[10] Mahadi Baig,[10] Jodi K. Maranchie[11]

Genitourinary Cancers Symposium 2023;Abstract 504.

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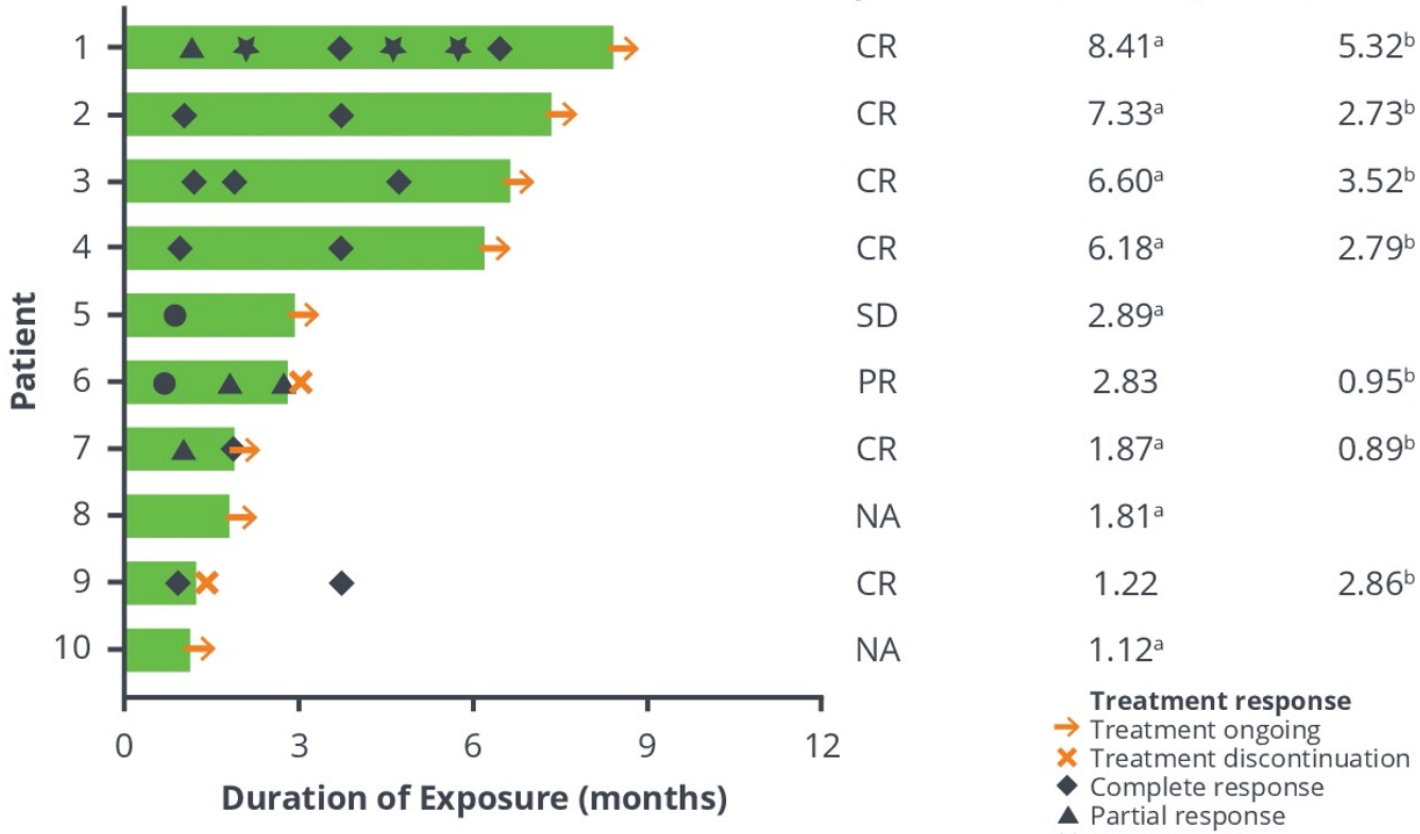
THOR-2 (Cohort 3): Response Duration in Evaluable Patients



	Best overall response	Total duration of exposure (months)	DOR (months)
1	CR	8.41[a]	5.32[b]
2	CR	7.33[a]	2.73[b]
3	CR	6.60[a]	3.52[b]
4	CR	6.18[a]	2.79[b]
5	SD	2.89[a]	
6	PR	2.83	0.95[b]
7	CR	1.87[a]	0.89[b]
8	NA	1.81[a]	
9	CR	1.22	2.86[b]
10	NA	1.12[a]	

NA, not assessed.
[a]Patient is still on treatment. [b]DOR for patient is currently censored.

Daneshmand S et al. Genitourinary Cancers Symposium 2023;Abstract 504.

THOR-2 (Cohort 3): Safety Summary and Most Common TEAEs

TEAEs summary	n (%)
Any grade TEAEs Treatment related	9 (90) 9 (90)
Grade ≥3 TEAEs Treatment related	2 (20) 1 (10)
Serious TEAEs	0
TEAEs leading to treatment discontinuation	0
Deaths on study	0

TEAE by preferred term	Any grade (≥30%) n (%)	Grade ≥3 (all events) n (%)
Hyperphosphatemia	9 (90)	0
Diarrhea	5 (50)	1 (10)
Dry mouth	5 (50)	0
Dysgeusia	3 (30)	0

Daneshmand S et al. Genitourinary Cancers Symposium 2023;Abstract 504.

Lunch with the Investigators: Gastroesophageal Cancers

A CME Symposium Held in Conjunction with the 2023 ASCO® Annual Meeting

Friday, June 2, 2023

11:45 AM – 12:45 PM CT (12:45 PM – 1:45 PM ET)

Faculty

Yelena Y Janjigian, MD

Manish A Shah, MD

Harry H Yoon, MD, MHS

Moderator

Neil Love, MD

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Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open up to 5 minutes after the meeting ends.

NCPD credit information will be emailed to each participant within 5 business days.

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