Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

Kidney and Bladder Cancer

Thursday, March 2, 2023
5:00 PM – 6:00 PM ET

Faculty

Matthew Milowsky, MD

Thomas Powles, MBBS, MRCP, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

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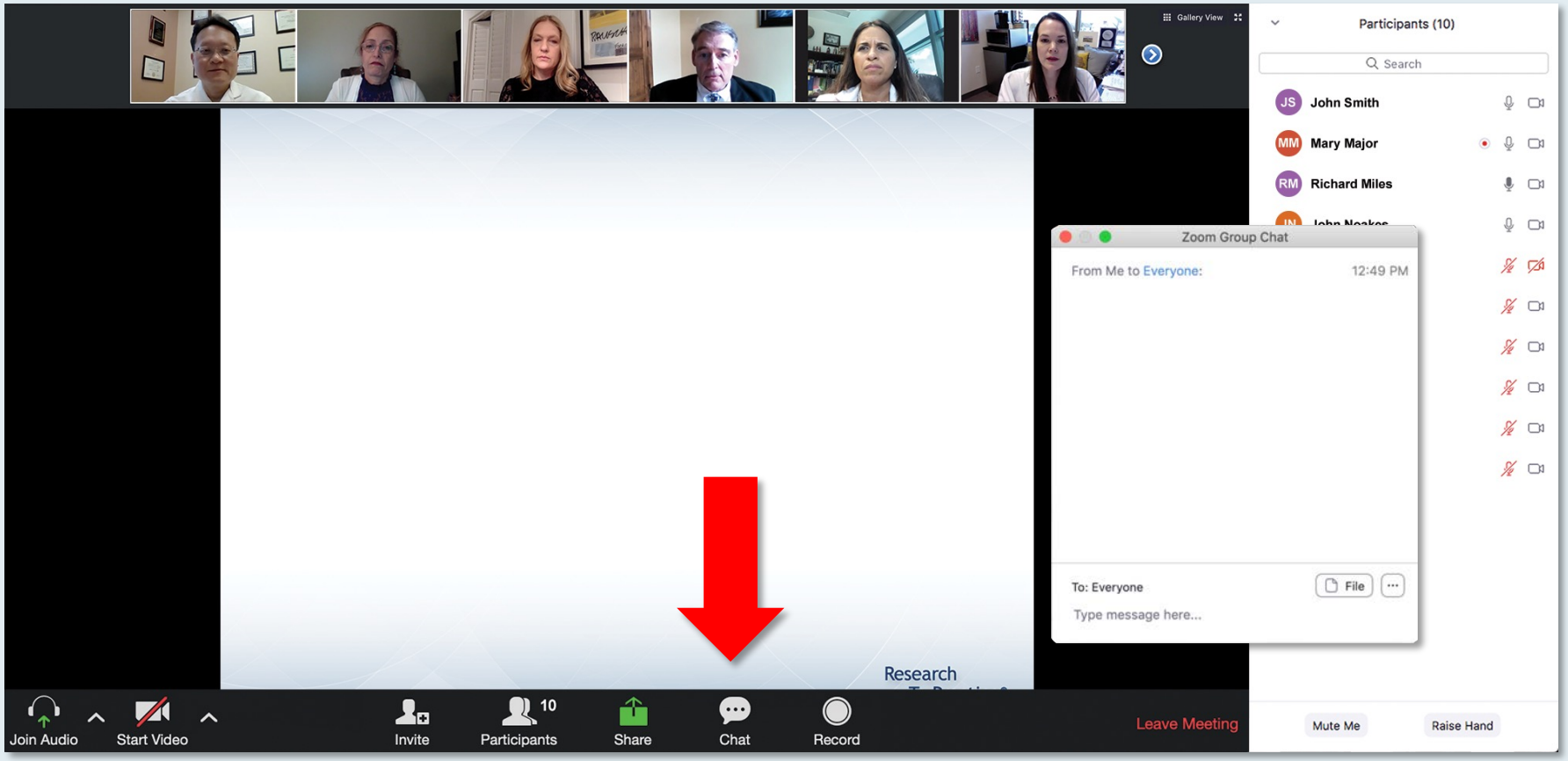
George Gabriel and Frances Gable Villere Distinguished Professor
Vice Chief for Research and Education
Section Chief, Genitourinary Oncology
UNC Division of Oncology
Co-Lead, Clinical and Translational Research
Co-Director, Urologic Oncology Program
UNC Lineberger Comprehensive Cancer Center
Chapel Hill, North Carolina

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Thomas Powles, MBBS, MRCP, MD
Director of Barts Cancer Institute
Queen Mary University of London
London, United Kingdom

We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

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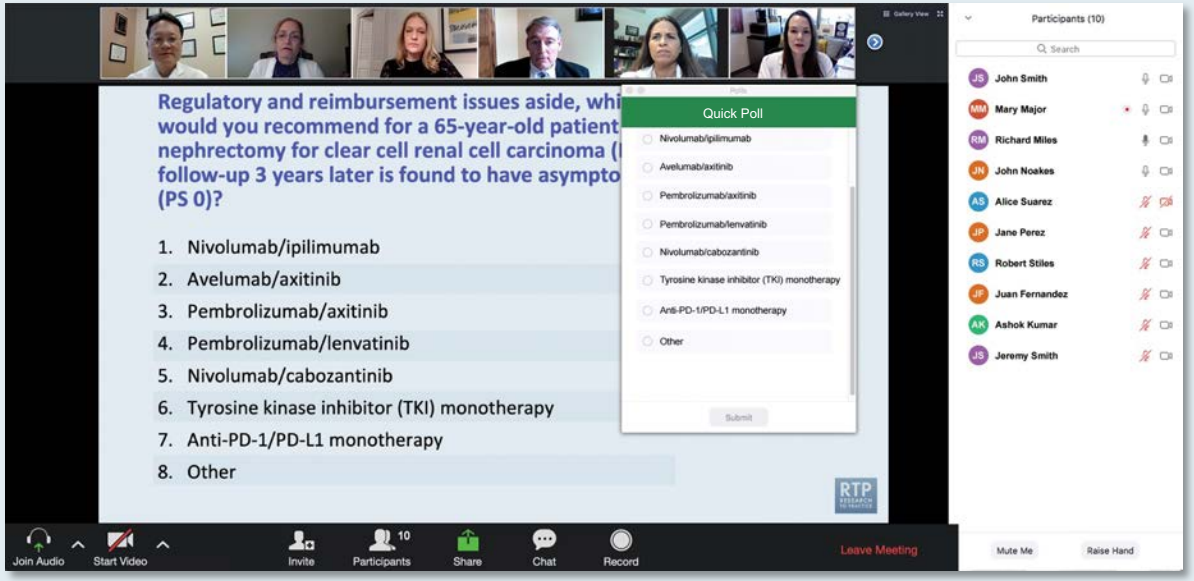

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ONCOLOGY TODAY

WITH DR NEIL LOVE

Management of Nonmetastatic Urothelial Bladder Cancer

PROFESSOR SIA DANESHMAND
USC/NORRIS COMPREHENSIVE CANCER CENTER

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Meet The Professor

Optimizing the Management of ER-Positive and Triple-Negative Breast Cancer

Tuesday, March 7, 2023
5:00 PM – 6:00 PM ET

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Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

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Cases from the Community: Investigators Discuss Available Research Guiding the Care of Patients with Gastroesophageal and Hepatobiliary Cancers — A 2023 Post-ASCO GI Webcast

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Meet The Professor
Optimizing the Management of Colorectal Cancer

Wednesday, March 22, 2023
5:00 PM – 6:00 PM ET

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Neil Love, MD

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RTP RESEARCH TO PRACTICE

Cases from the Community: Investigators Discuss Available Research Guiding the Care of Patients with Endometrial Cancer

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Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, BeyondSpring Pharmaceuticals Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma Corp, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Corporation, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab US Inc, Gilead Sciences Inc, Grail Inc, GSK, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Kronos Bio Inc, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc, and Zymeworks Inc.

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

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Dr Milowsky — Disclosures

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Contracted Research	ALX Oncology, Arvinas, Bristol-Myers Squibb Company, Clovis Oncology, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Incyte Corporation, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Mirati Therapeutics Inc, Seagen Inc
Stock Options/Ownership — Public Company	Gilead Sciences Inc, Merck, Pfizer Inc
Nonrelevant Financial Relationship	Alliance for Clinical Trials in Oncology, Alliance Foundation Trials LLC, Elsevier (Co-Editor-in-Chief, Clinical Genitourinary Cancer), Hoosier Cancer Research Network Inc, Medscape (educational videos)

Prof Powles — Disclosures

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Agenda

MODULE 1: Renal Cell Carcinoma

- Adjuvant therapy
- Choice of first-line treatment for metastatic disease
- New agents and strategies

MODULE 2: Urothelial Bladder Cancer

- Non-muscle-invasive disease
- Adjuvant immunotherapy
- Sequencing of therapies in metastatic disease

MODULE 3: Appendix

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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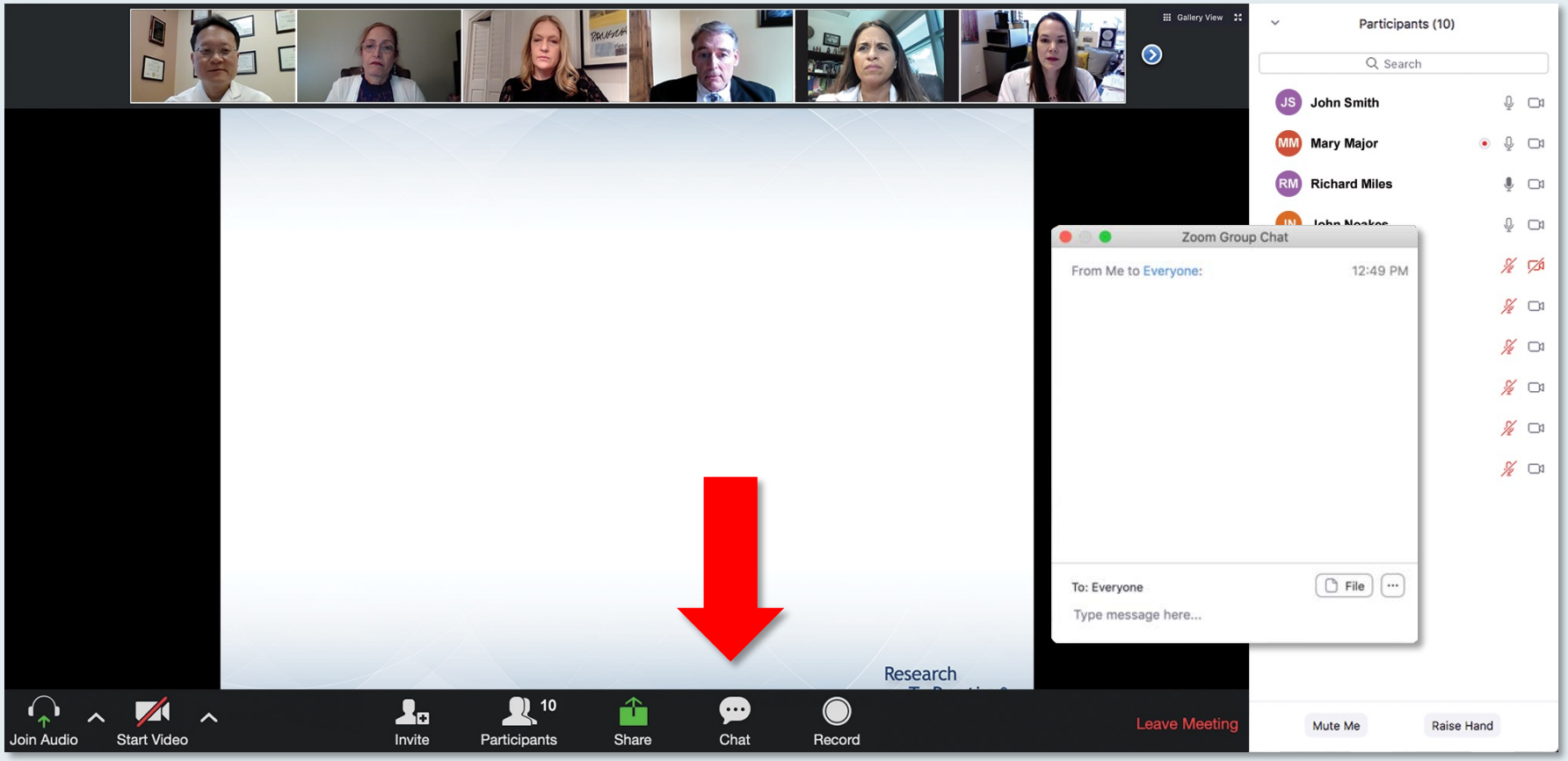

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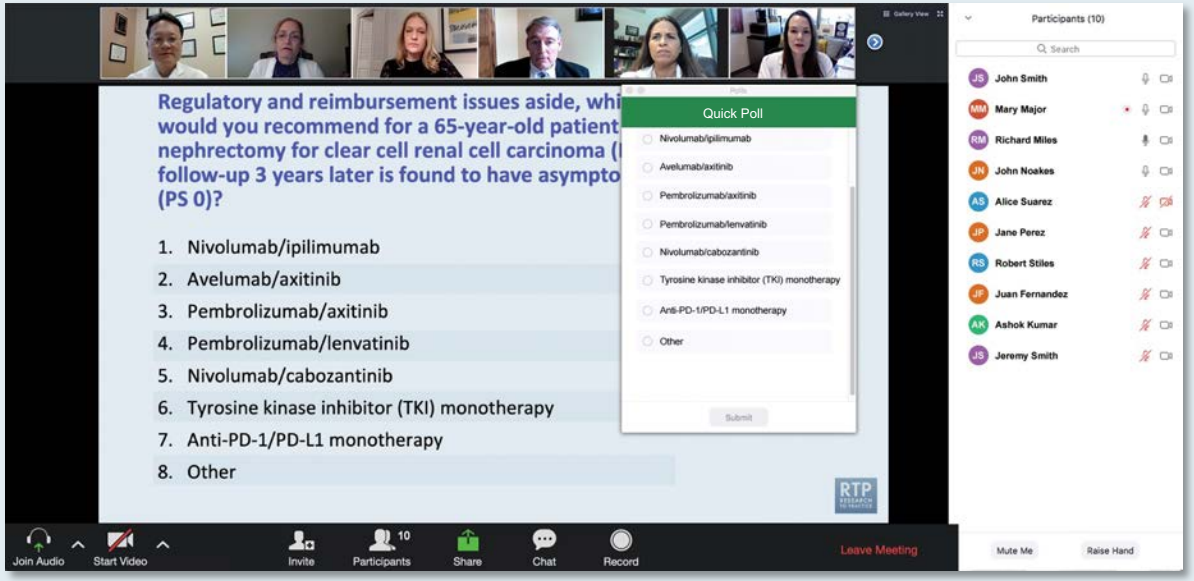

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Research To Practice CME Planning Committee Members, Staff and Reviewers

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Dr Milowsky — Disclosures

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Stock Options/Ownership — Public Company	Gilead Sciences Inc, Merck, Pfizer Inc
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Travel/Accommodation/ Expenses	AstraZeneca Pharmaceuticals LP, Ipsen Biopharmaceuticals Inc, Merck Sharp & Dohme LLC, Pfizer Inc, Roche Laboratories Inc

Year in review in clear cell RCC

Thomas Powles
Director of Barts Cancer Center.
Professor of Urology Cancer, Barts Cancer Institute.

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

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Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology: Bladder Cancer Edition

Matthew Milowsky, MD
George Gabriel and Frances Gable Villere Distinguished Professor
Section Chief, Genitourinary Oncology

RTP Year in Review 2023

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- Rathmell WK et al. Management of metastatic clear cell renal cell carcinoma: ASCO guideline. *J Clin Oncol* 2022;40(25):2957-95.
- Burotto M et al. Nivolumab plus cabozantinib vs sunitinib for first-line treatment of advanced renal cell carcinoma (aRCC): 3-year follow-up from the phase 3 CheckMate 9ER trial. Genitourinary Cancers Symposium 2023;Abstract 603.
- Porta CG et al. Updated efficacy of lenvatinib (LEN) + pembrolizumab (PEMBRO) vs sunitinib (SUN) in patients (pts) with advanced renal cell carcinoma (aRCC) in the CLEAR study. ESMO 2022;Abstract 1449MO.
- Motzer RJ et al. Conditional survival and long-term efficacy with nivolumab plus ipilimumab versus sunitinib in patients with advanced renal cell carcinoma. *Cancer* 2022;128(11):2085-97.

Key Data Sets

Thomas Powles, MBBS, MRCP, MD (continued)

- Rini BI et al. Prospective cardiovascular surveillance of immune checkpoint inhibitor-based combination therapy in patients with advanced renal cell cancer: Data from the Phase III JAVELIN Renal 101 trial. J Clin Oncol 2022;40(17):1929-38.
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- Choeuiri TK et al. Phase III study of cabozantinib (C) in combination with nivolumab (N) and ipilimumab (I) in previously untreated advanced renal cell carcinoma (aRCC) of IMDC intermediate or poor risk (COSMIC-313). ESMO 2022;Abstract LBA8.
- Choueiri T et al. Biomarker analysis from the phase 3 CheckMate 9ER trial of nivolumab + cabozantinib v sunitinib for advanced renal cell carcinoma (aRCC). Genitourinary Cancers Symposium 2023;Abstract 608.
- Rini BI et al. Maturation of overall survival (OS) in TIVO-3 with long-term follow-up. ASCO 2022;Abstract 4557.

Key Data Sets

Thomas Powles, MBBS, MRCP, MD (continued)

- Zengin ZB et al. Temporal characteristics of adverse events of tivozanib and sorafenib in previously treated kidney cancer. Clin Genitourin Cancer 2022;20(6):553-7.
- Albiges L et al. CaboPoint: Interim results from a phase 2 study of cabozantinib after checkpoint inhibitor (CPI) therapy in patients with advanced renal cell carcinoma (RCC). Genitourinary Cancers Symposium 2023;Abstract 606.
- Merchan J et al. Phase II study of belzutifan plus cabozantinib as first-line treatment of advanced renal cell carcinoma (RCC): Cohort 1 of LITESPARK-003. ESMO 2022;Abstract 1447O.
- McGregor B et al. Cabozantinib in combination with atezolizumab in non-clear cell renal cell carcinoma: Extended follow-up results of cohort 10 of the COSMIC-021 study. Genitourinary Cancers Symposium 2023;Abstract 684.
- Lee CH et al. Phase II trial of cabozantinib plus nivolumab in patients with non-clear-cell renal cell carcinoma and genomic correlates. *J Clin Oncol* 2022;40(21):2333-41.
- Albiges L et al. Phase II KEYNOTE-B61 study of pembrolizumab (Pembro) + lenvatinib (Lenva) as first-line treatment for non-clear cell renal cell carcinoma (nccRCC). ESMO 2022;Abstract 1448O.

Key Data Sets

Matthew Milowsky, MD

- Necchi A et al. Pembrolizumab (pembro) monotherapy for patients (pts) with high-risk non–muscle-invasive bladder cancer (HR NMIBC) unresponsive to bacillus Calmette–Guérin (BCG): Results from cohort B of the phase 2 KEYNOTE-057 trial. Genitourinary Cancers Symposium 2023;Abstract LBA442.
- Hahn NM et al. A phase 1 trial of durvalumab in combination with bacillus Calmette-Guerin (BCG) or external beam radiation therapy in patients with BCG-unresponsive non-muscle-invasive bladder cancer: The Hoosier Cancer Research Network GU16-243 ADAPT-BLADDER study. *Eur Urol* 2023;[Online ahead of print].
- Catto J et al. Phase 2 study of the efficacy and safety of erdafitinib in patients (pts) with bacillus Calmette-Guérin (BCG)-unresponsive, high-risk non–muscle-invasive bladder cancer (HR-NMIBC) with FGFR3/2 alterations (alt) in THOR-2: Cohort 2 interim analysis results. Genitourinary Cancers Symposium 2023;Abstract 503.
- Daneshmand S et al. Phase 2 study of the efficacy and safety of erdafitinib in patients (pts) with intermediate-risk non–muscle-invasive bladder cancer (IR-NMIBC) with FGFR3/2 alterations (alt) in THOR-2: Cohort 3 interim analysis. Genitourinary Cancers Symposium 2023;Abstract 504.

Key Data Sets

Matthew Milowsky, MD (continued)

- Daneshmand S et al. 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. *Urol Oncol* 2022;40(7):344.e1-9.
- Psutka S et al. SunRISe-4: TAR-200 plus cetrelimab or cetrelimab alone as neoadjuvant therapy in patients with muscle-invasive bladder cancer (MIBC) who are ineligible for or refuse neoadjuvant platinum-based chemotherapy. Genitourinary Cancers Symposium 2023;Abstract TPS584.
- Vilaseca A et al. Safety and efficacy of the erdafitinib (erda) intravesical delivery system, TAR-210, in patients (pts) with non–muscle-invasive bladder cancer (NMIBC) or muscle-invasive bladder cancer (MIBC) harboring select FGFR mutations or fusions: Phase 1 first-in-human study. Genitourinary Cancers Symposium 2023;Abstract TPS583.
- Galsky MD et al. Extended follow-up results from the CheckMate 274 trial *(of adjuvant nivolumab versus placebo in muscle-invasive urothelial carcinoma)*. Genitourinary Cancers Symposium 2023;Abstract LBA443.

Key Data Sets

Matthew Milowsky, MD (continued)

- Bamias A et al. Final overall survival (OS) analysis of atezolizumab (atezo) monotherapy vs chemotherapy (chemo) in untreated locally advanced or metastatic urothelial carcinoma (mUC) from the phase 3 IMvigor130 study. Genitourinary Cancers Symposium 2023;Abstract LBA441.
- Hoimes CJ et al. Enfortumab vedotin plus pembrolizumab in previously untreated advanced urothelial cancer. *J Clin Oncol* 2023;41(1):22-31.
- Rosenberg JE et al. Study EV-103 Cohort K: Antitumor activity of enfortumab vedotin (EV) monotherapy or in combination with pembrolizumab (P) in previously untreated cisplatin-ineligible patients (pts) with locally advanced or metastatic urothelial cancer (la/mUC). ESMO 2022;Abstract LBA73.
- O'Donnell P et al. Enfortumab vedotin (EV) alone or in combination with pembrolizumab (P) in previously untreated cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer (la/mUC): Subgroup analyses of confirmed objective response rate (cORR) from EV-103 cohort K. Genitourinary Cancers Symposium 2023;Abstract 499.

Key Data Sets

Matthew Milowsky, MD (continued)

- Milowsky M et al. Patient-reported outcomes (PROs) in cisplatin-ineligible patients (pts) with locally advanced or metastatic urothelial cancer (la/mUC) treated with enfortumab vedotin (EV) alone or in combination with pembrolizumab (P) in the phase 1b/2 EV-103 Cohort K study. Gastrointestinal Cancers Symposium 2023;Abstract 439
- Rosenberg JE et al. Long-term outcomes in EV-301: 24-month findings from the phase 3 trial of enfortumab vedotin versus chemotherapy in patients with previously treated advanced urothelial carcinoma. ASCO 2022;Abstract 4516.
- Siefker-Radtke AO et al. Efficacy and safety of erdafitinib in patients with locally advanced or metastatic urothelial carcinoma: Long-term follow-up of a phase 2 study. *Lancet Oncol* 2022;23(2):248-58.
- Petrylak DP et al. Primary analysis of TROPHY-U-01 cohort 2, a phase 2 study of sacituzumab govitecan (SG) in platinum (PT)-ineligible patients (pts) with metastatic urothelial cancer (mUC) that progressed after prior checkpoint inhibitor (CPI) therapy. Genitourinary Cancers Symposium 2023;Abstract 520.

Key Data Sets

Matthew Milowsky, MD (continued)

- Rosenberg JE et al. Durvalumab plus olaparib in previously untreated, platinum-ineligible patients with metastatic urothelial carcinoma: A multicenter, randomized, Phase II trial (BAYOU). *J Clin Oncol* 2023;41(1):43-53.
- Sheng X et al. RC48-ADC for metastatic urothelial carcinoma with HER2-positive: Combined analysis of RC48-C005 and RC48-C009 trials. ASCO 2022;Abstract 4520.
- Xu H et al. A phase II study of RC48-ADC in HER2-negative patients with locally advanced or metastatic urothelial carcinoma. ASCO 2022;Abstract 4519.
- Sheng X et al. Preliminary results of a phase Ib/II combination study of RC48-ADC, a novel humanized anti-HER2 antibody-drug conjugate (ADC) with toripalimab, a humanized IgG4 mAb against programmed death-1 (PD-1) in patients with locally advanced or metastatic urothelial carcinoma. ASCO 2022;Abstract 4518.

Agenda

MODULE 1: Renal Cell Carcinoma

- Adjuvant therapy
- Choice of first-line treatment for metastatic disease
- New agents and strategies

MODULE 2: Urothelial Bladder Cancer

- Non-muscle-invasive disease
- Adjuvant immunotherapy
- Sequencing of therapies in metastatic disease

MODULE 3: Appendix

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MODULE 3: Appendix

Key Discussion Questions

- In what situations would you consider or have you used adjuvant immunotherapy for a patient with renal cell carcinoma (RCC)?
- What factors influence your choice of first-line therapy for patients with metastatic RCC, and specifically for IMDC favorable- and non-favorable-risk disease?
- What are some of the most promising agents on the horizon for patients with metastatic RCC?

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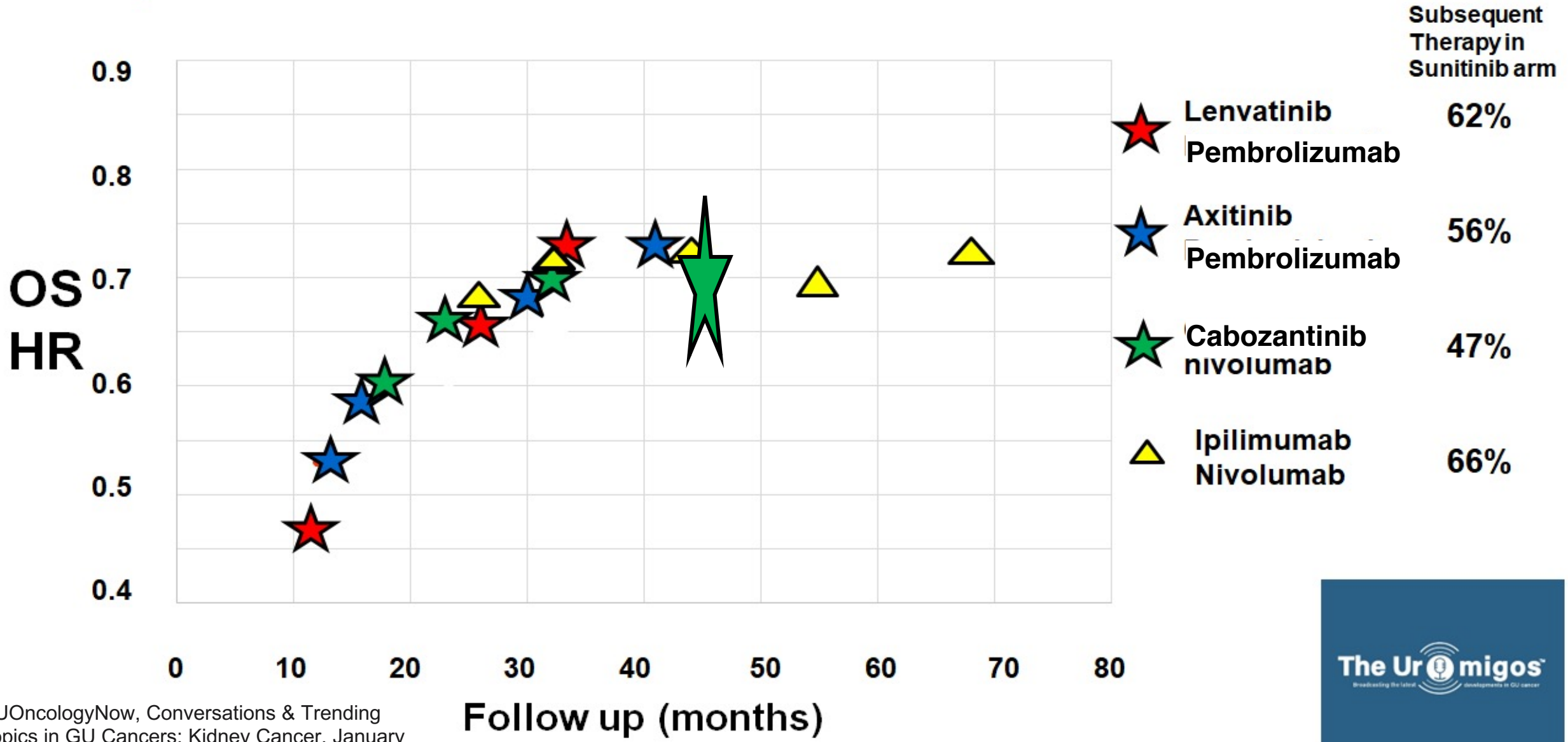
- Rini BI et al. Prospective cardiovascular surveillance of immune checkpoint inhibitor-based combination therapy in patients with advanced renal cell cancer: Data from the Phase III JAVELIN Renal 101 trial. J Clin Oncol 2022;40(17):1929-38.
- Powles T et al. Outcomes by IMDC risk in the COSMIC-313 phase 3 trial evaluating cabozantinib (C) plus nivolumab (N) and ipilimumab (I) in first-line advanced RCC (aRCC) of IMDC intermediate or poor risk. Genitourinary Cancers Symposium 2023;Abstract 605.
- Choeuiri TK et al. Phase III study of **cabozantinib** (C) in combination with **nivolumab** (N) and ipilimumab (I) in previously untreated advanced renal cell carcinoma (aRCC) of IMDC intermediate or poor risk (**COSMIC-313**). ESMO 2022;Abstract LBA8.
- Choueiri T et al. Biomarker analysis from the phase 3 CheckMate 9ER trial of nivolumab + cabozantinib v sunitinib for advanced renal cell carcinoma (aRCC). Genitourinary Cancers Symposium 2023;Abstract 608.
- Rini BI et al. Maturation of overall survival (OS) in **TIVO-3** with long-term follow-up. ASCO 2022;Abstract 4557.

Key Data Sets

Thomas Powles, MBBS, MRCP, MD (continued)

- Zengin ZB et al. Temporal characteristics of adverse events of **tivozanib** and sorafenib in previously treated kidney cancer. Clin Genitourin Cancer 2022;20(6):553-7.
- Albiges L et al. CaboPoint: Interim results from a phase 2 study of **cabozantinib after checkpoint inhibitor (CPI) therapy** in patients with advanced renal cell carcinoma (RCC). Genitourinary Cancers Symposium 2023;Abstract 606.
- Merchan J et al. Phase II study of **belzutifan plus cabozantinib** as first-line treatment of advanced renal cell carcinoma (RCC): Cohort 1 of LITESPARK-003. ESMO 2022;Abstract 1447O.
- McGregor B et al. **Cabozantinib in combination with atezolizumab** in **non-clear cell** renal cell carcinoma: Extended follow-up results of cohort 10 of the COSMIC-021 study. Genitourinary Cancers Symposium 2023;Abstract 684.
- Lee CH et al. Phase II trial of **cabozantinib plus nivolumab** in patients with **non-clear-cell** renal cell carcinoma and genomic correlates. *J Clin Oncol* 2022;40(21):2333-41.
- Albiges L et al. Phase II **KEYNOTE-B61** study of **pembrolizumab** (Pembro) + **lenvatinib** (Lenva) as first-line treatment for non-clear cell renal cell carcinoma (nccRCC). ESMO 2022;Abstract 1448O.

Overall survival Hazard ratios of 1st line PD-1 combinations compared to sunitinib with time at different data cuts in ITT.



GUOncologyNow, Conversations & Trending Topics in GU Cancers: Kidney Cancer, January 2023

Courtesy of Thomas Powles, MBBS, MRCP, MD

The Uromigos

ASCO Genitourinary Cancers Symposium

Biomarker analysis from the phase 3 CheckMate 9ER trial of nivolumab plus cabozantinib versus sunitinib for advanced renal cell carcinoma

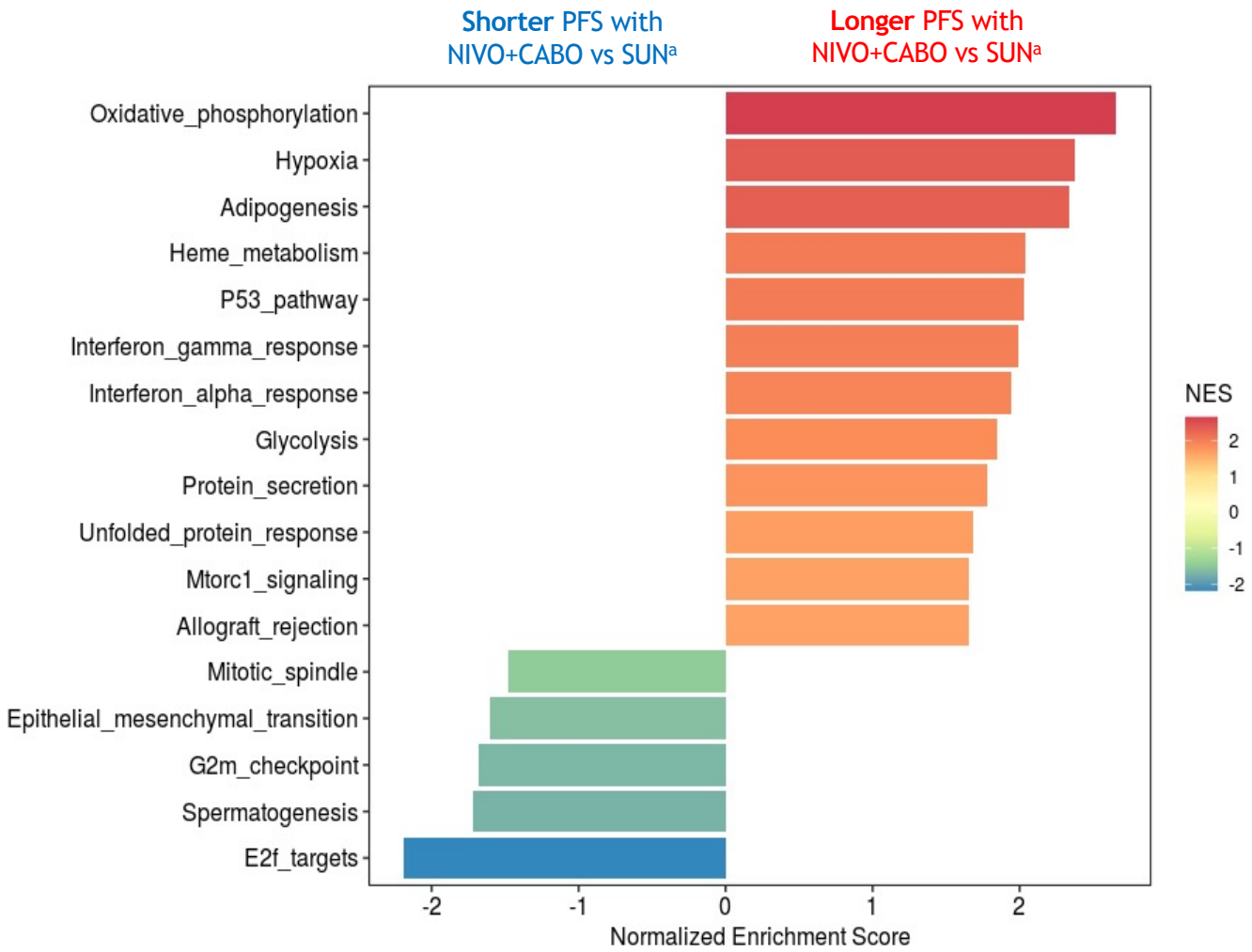
Toni K. Choueiri,[1] Robert J. Motzer,[2] Thomas Powles,[3] Mauricio Burotto,[4] Andrea B. Apolo,[5] Bernard Escudier,[6] Yoshihiko Tomita,[7] David McDermott,[8] David A. Braun,[9] Celine Han,[10] George Lee,[10] Bhakti Dwivedi,[10] Sai Vikram Vemula,[10] Jun Li,[10] Viktor Fedorov,[10] Saurabh Gupta[10]

[1]Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Harvard Medical School, Boston, MA; [2]Memorial Sloan Kettering Cancer Center, New York, NY; [3]Barts Cancer Institute, Cancer Research UK Experimental Cancer Medicine Centre, Queen Mary University of London, Royal Free National Health Service Trust, London, UK; [4]Bradford Hill Clinical Research Center, Santiago, Chile; [5]Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD; [6]Gustave Roussy, Villejuif, France; [7]Niigata University Graduate School of Medical and Dental Sciences, Niigata, Japan; [8]Beth Israel Deaconess Medical Center, Boston, MA; [9]School of Medicine, Yale University, New Haven, CT; [10]Bristol Myers Squibb, Princeton, NJ

Presentation number D7

Courtesy of Thomas Powles, MBBS, MRCP, MD

CheckMate 9ER: Association of hallmark gene sets and GES with PFS outcomes



Individual genes from some enriched hallmark gene sets associated with PFS outcome were prognostic but did not appear to be predictive (data in poster)

- In Cox PH analysis, none of the 7 published GES tested were predictive for PFS outcome with NIVO+CABO versus SUN[b,c]

[a]Enriched hallmark gene set results that were significant based on FDR < 0.01 are shown. [b]IMmotion150 Angio, IMmotion150 Myeloid Inflammation, IMmotion150 T-effector (T-eff), JAVELIN Renal 101 Immuno Signature, Tumor Inflammation Signature (TIS), Interferon-γ, and epithelial mesenchymal transition (EMT)-8. [c]Cox PH analysis was based on FDR < 0.05, after *P* value correction for FDR and multiple biomarker testing (q values).
FDR, false discovery rate; NES, normalized enrichment score.

Courtesy of Thomas Powles, MBBS, MRCP, MD

Choueiri TK et al. ASCO GU 2023;Abstract 608.

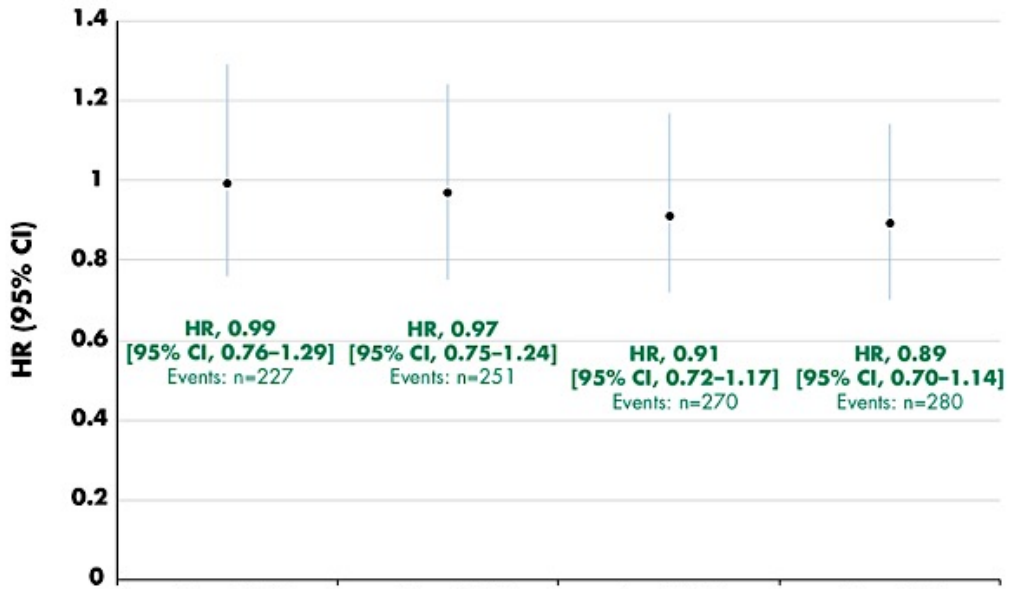
Maturation of Overall Survival in TIVO-3 With Long-Term Follow-Up

4557

Brian I. Rini,[1] Sumanta K. Pal,[2] Bernard Escudier,[3] Michael B. Atkins,[4] David F. McDermott,[5] Elena Verzoni,[6] Camillo Porta,[7,8] Vijay Kasturi,[9] Thomas E. Hutson[10]

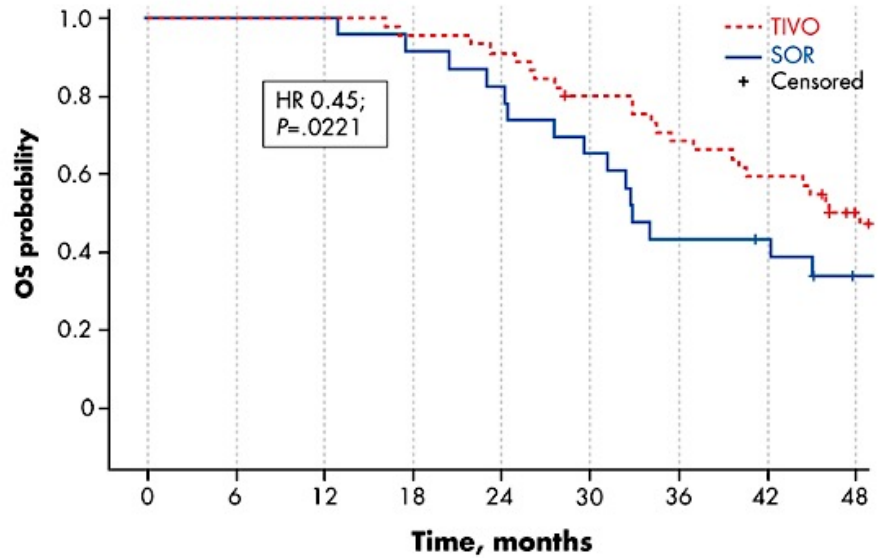
[1]Vanderbilt-Ingram Cancer Center, Nashville, TN, USA; [2]Department of Medical Oncology and Therapeutics, City of Hope Comprehensive Cancer Center, Duarte, CA, USA; [3]Gustave Roussy, Villejuif, France; [4]Georgetown Lombardi Comprehensive Cancer Center, Washington, DC, USA; [5]Beth Israel Deaconess Medical Center, Dana-Farber/Harvard Cancer Center, Boston, MA, USA; [6]Department of Medical Oncology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy; [7]Chair of Oncology, Department of Biomedical Sciences and Human Oncology, University of Bari Aldo Moro, Bari, Italy; [8]Division of Medical Oncology, A.O.U. Consorziale Policlinico di Bari, Bari, Italy; [9]AVEO Oncology, Boston, MA, USA; [10]Texas A&M College of Medicine, Bryan, TX, USA

Figure 2. Serial OS With Extended Follow-Up



Mean follow-up (95% CI), months	17.9 (16.7-19.1)	20.3 (18.8-21.8)	21.9 (20.2-23.6)	22.8 (20.9-24.6)

Figure 3. KM Survival Curve of Conditional OS in Patients With 12-Month PFS



Number at risk									
TIVO, n=	45	45	45	43	41	35	30	26	18
SOR, n=	23	23	23	21	19	15	10	9	5

Rini BI et al. ASCO 2022;Abstract 4557.

RTP RESEARCH TO PRACTICE

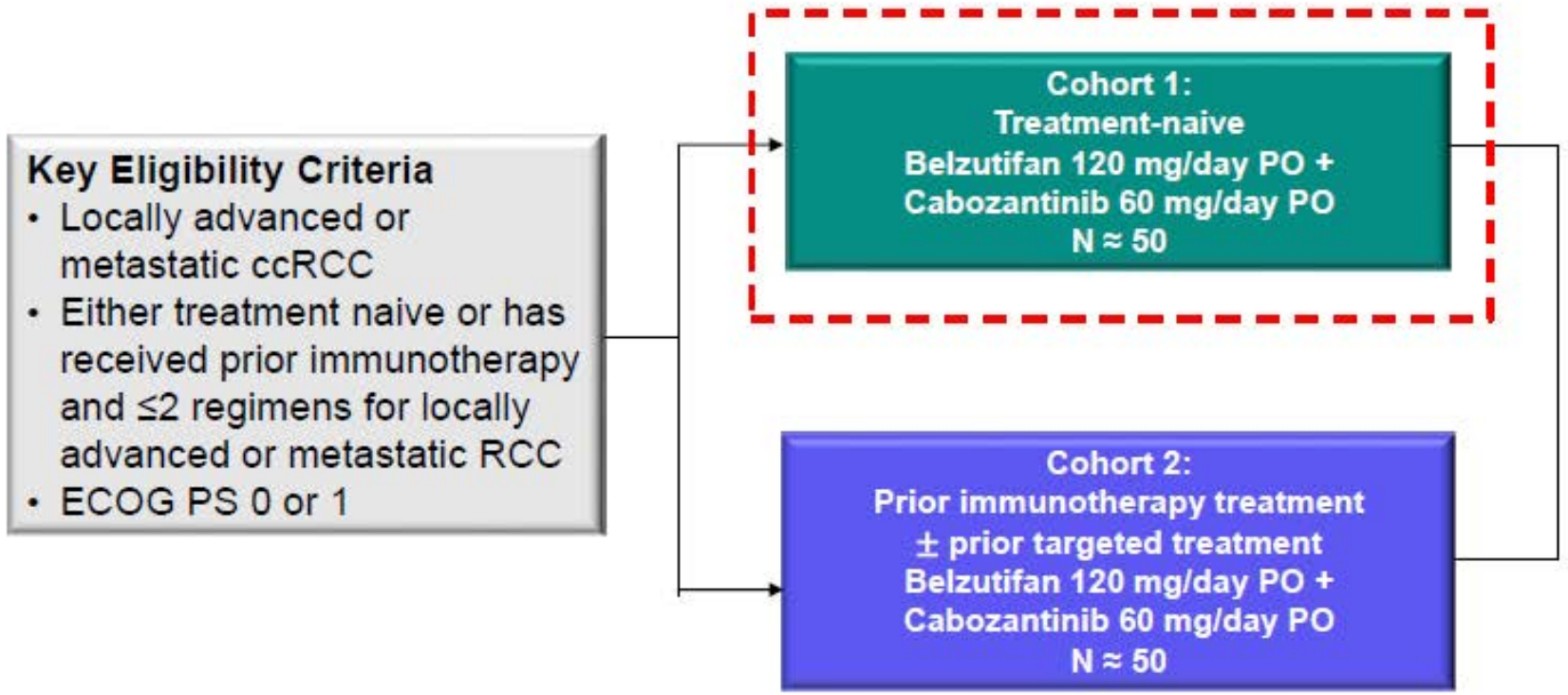
Ongoing Phase III Trials in the Post-IO Setting

Title	Inclusion	Treatment Arms
CONTACT-03: Phase III Trial of Atezo + Cabo vs Cabo in Advanced RCC After PD-1/PD-L1 Therapy (n = 500)[2]	▪ Clear-cell RCC or non–clear-cell RCC (papillary or unclassified) ▪ Prior first- or second-line therapy with PD-1/PD-L1 inhibitor as immediate preceding therapy ▪ No more than 1 previous PD-1/PD-L1 inhibitor	Atezolizumab + cabozantinib vs Cabozantinib
TiNivo-2: Phase III Trial of Tivozanib + Nivolumab vs Tivozanib in Advanced RCC After IO Therapy (n = 326)[3]	▪ Clear-cell RCC ▪ PD during or following ≥6 wk of treatment with an IO therapy ▪ ≤2 previous lines of therapy	Nivolumab + tivozanib vs Tivozanib

1. NCT04338269. 2. NCT04987203.

Courtesy of Brian I. Rini, MD, FASCO

Study Design of LITESPARK-003 (NCT03634540)



Tumor Assessments

- Week 9, then Q8W through month 12 and Q12W thereafter

End Points

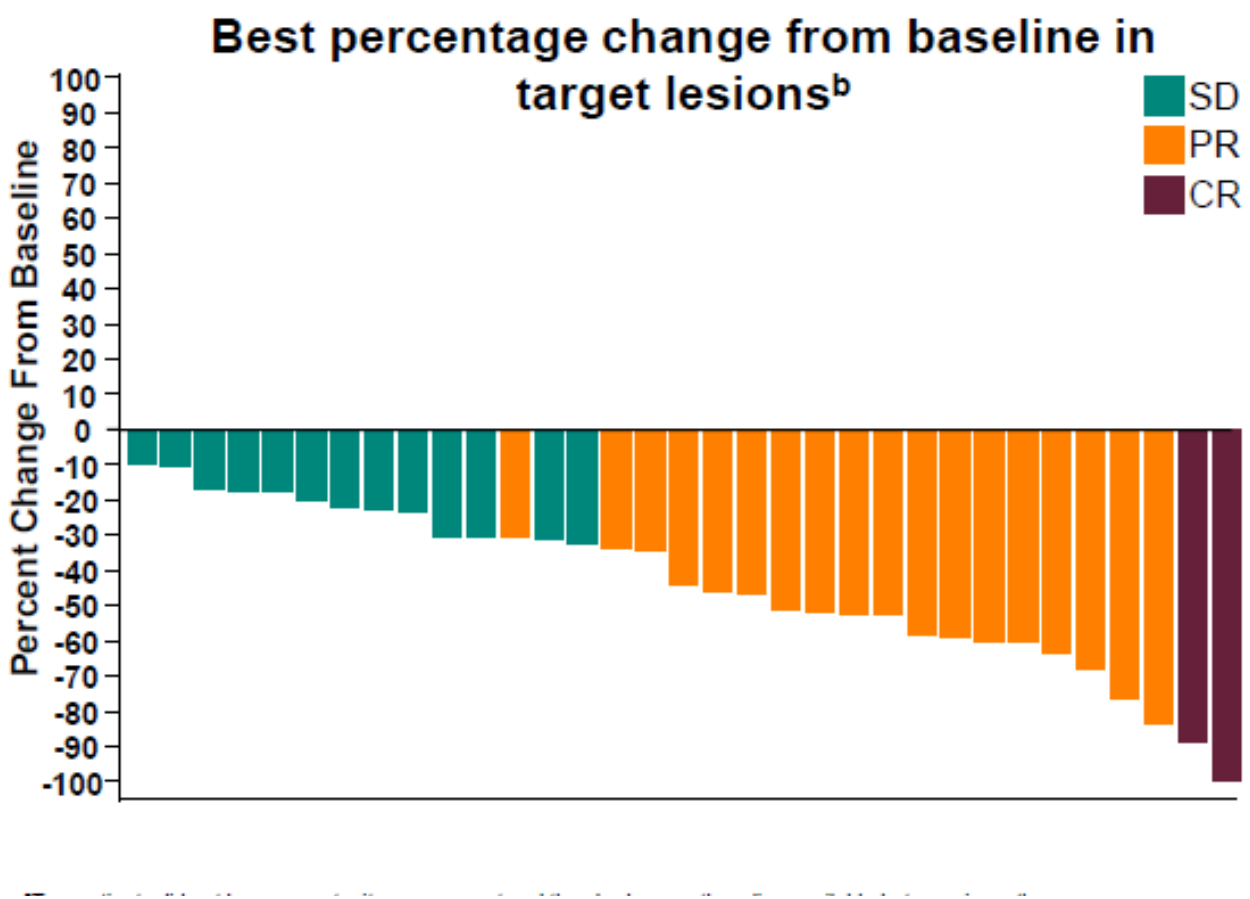
- Primary: ORR per RECIST v1.1 by investigator
- Secondary: PFS, DOR, and TTR per RECIST v1.1 by investigator, OS, safety/tolerability

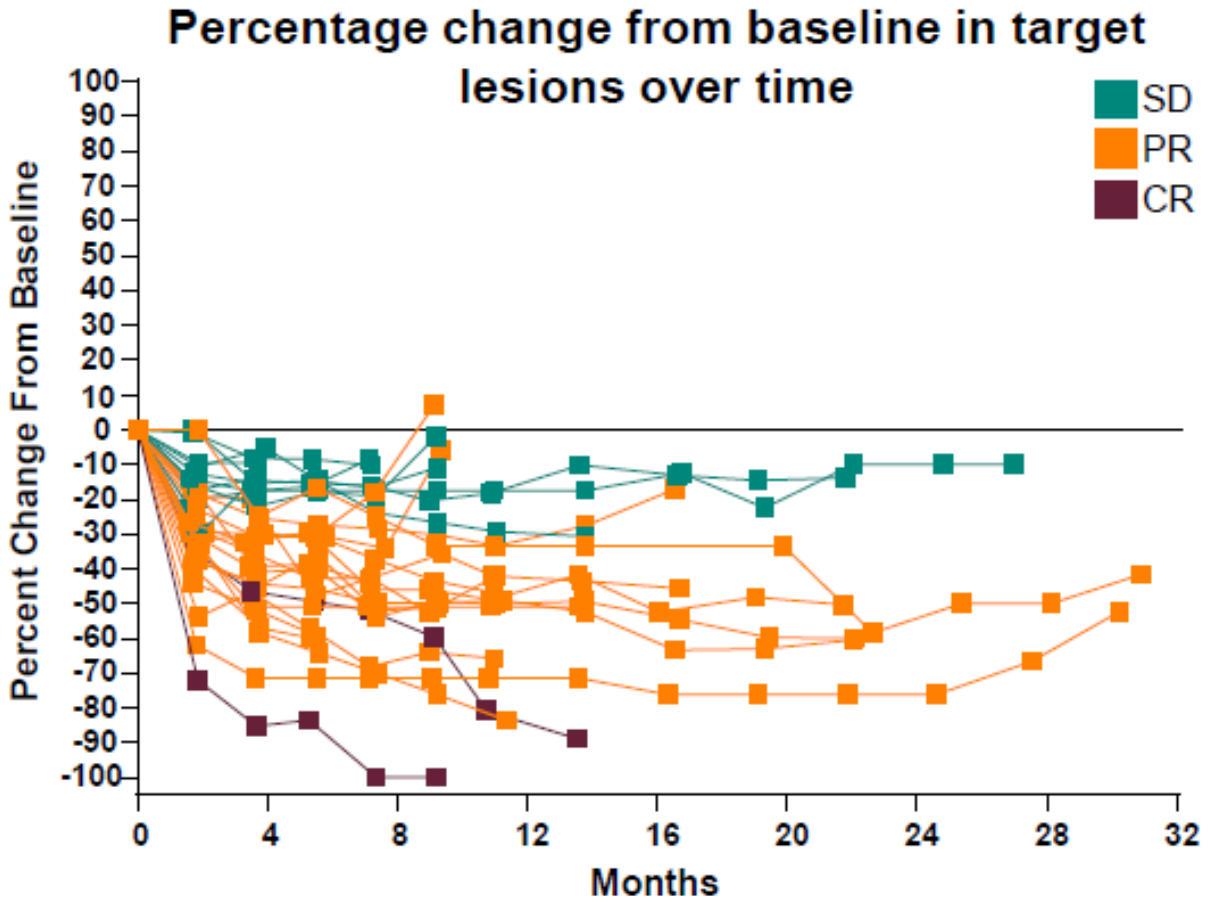
Courtesy of Thomas Powles, MBBS, MRCP, MD

Merchan J et al. ESMO 2022;Abstract 1447O.

LITESPARK-003: Change From Baseline in Target Lesions by Investigator

- 33 of 35 patients (94%) experienced a reduction in target lesion size[a]





Courtesy of Thomas Powles, MBBS, MRCP, MD

Merchan J et al. ESMO 2022;Abstract 1447O.

LITESPARK-003: Summary of Treatment-Related Adverse Events

n (%)	All patients N = 35
Any-grade treatment-related AE	34 (97)
Grade 3 treatment-related AE	13 (37)
Grade 4 or 5 treatment-related AE	0 (0)
Discontinued any drug because of a treatment-related AE	
Discontinued belzutifan	0 (0)
Discontinued cabozantinib	1 (3)
Serious treatment-related AE	2 (6)
Dose reduction because of a treatment-related AE	26 (74)
Belzutifan dose reduced	7 (20)
Cabozantinib dose reduced	26 (74)

Data cutoff date: February 1, 2022.

Courtesy of Thomas Powles, MBBS, MRCP, MD

Merchan J et al. ESMO 2022;Abstract 1447O.

Pivotal Phase III STELLAR-304 Trial Initiated to Evaluate Zanzalintinib for Advanced Non-Clear Cell RCC

Press Release: December 22, 2022

"Today [the initiation was announced] of STELLAR-304, a phase 3 pivotal trial evaluating zanzalintinib in combination with nivolumab versus sunitinib in patients with advanced non-clear cell renal cell carcinoma (nccRCC). Zanzalintinib, which was adopted as the generic name for XL092, is a next-generation tyrosine kinase inhibitor (TKI) in development for multiple advanced tumor types.

'In September at ESMO 2022, we presented zanzalintinib phase 1 data which demonstrated promising clinical activity across a range of tumors with a manageable safety profile. We were particularly encouraged by the activity of zanzalintinib in advanced kidney cancer patients, including patients with non-clear cell subtypes. Based on this zanzalintinib data and given that nivolumab has shown activity in non-clear cell kidney cancer, we are excited to evaluate this combination regimen in this population in STELLAR-304,' said [the company's] Chief Medical Officer. 'STELLAR-304 is the first and only randomized controlled phase 3 study to focus specifically across non-clear cell renal cell carcinoma subtypes, a patient population with limited clinical data and poorer treatment outcomes. We look forward to continuing our legacy of working towards improving care for all kidney cancer patients.'"

https://www.businesswire.com/news/home/20221221005589/en/Exelixis-Announces-Initiation-of-the-STELLAR-304-Phase-3-Pivotal-Trial-Evaluating-Zanzalintinib-in-Patients-with-Advanced-Non-Clear-Cell-Kidney-Cancer

Summary

WE HAVE REACHED A BIT OF A PLATEAU IN DRUG DEVELOPMENT IN RENAL CANCER

THERE IS ACTIVE DEBATE ABOUT
GOOD RISK DISEASE, THE ROLE OF TKI AND CTLA4

THE VEGF TKIS ARE SIMILAR WHEN SEQUENCED AFTER STANDARD FIRST LINE THERAPY

HIF-2A SEEMS THE MOST ATTRACTIVE NEW AGENT

BIOMARKER DATA HAS BEEN INCONCLUSIVE

NEW COMBINATIONS APPEAR ACTIVE IN PAPILLARY RENAL CANCER

Courtesy of Thomas Powles, MBBS, MRCP, MD

Agenda

MODULE 1: Renal Cell Carcinoma

- Adjuvant therapy
- Choice of first-line treatment for metastatic disease
- New agents and strategies

MODULE 2: Urothelial Bladder Cancer

- Non-muscle-invasive disease
- Adjuvant immunotherapy
- Sequencing of therapies in metastatic disease

MODULE 3: Appendix

Key Discussion Questions

- What is the current optimal treatment approach for patients with BCG-resistant non-muscle-invasive bladder cancer, and what trials are addressing this question?
- In what situations do you recommend adjuvant immunotherapy for patients with urothelial bladder cancer?
- What is your approach to selection and sequencing of therapy for patients with metastatic disease with and without an FGFR mutation?

Key Data Sets

Matthew Milowsky, MD

- Necchi A et al. **Pembrolizumab** (pembro) monotherapy for patients (pts) with high-risk non–muscle-invasive bladder cancer (HR NMIBC) **unresponsive to bacillus Calmette–Guérin** (BCG): Results from cohort B of the phase 2 KEYNOTE-057 trial. Genitourinary Cancers Symposium 2023;Abstract LBA442.
- Hahn NM et al. A phase 1 trial of **durvalumab in combination with bacillus Calmette-Guerin** (BCG) or external beam radiation therapy in patients with BCG-unresponsive non-muscle-invasive bladder cancer: The Hoosier Cancer Research Network GU16-243 ADAPT-BLADDER study. *Eur Urol* 2023;[Online ahead of print].
- Catto J et al. Phase 2 study of the efficacy and safety of **erdafitinib** in patients (pts) with bacillus Calmette-Guérin (BCG)-unresponsive, high-risk non–muscle-invasive bladder cancer (HR-NMIBC) with FGFR3/2 alterations (alt) in **THOR-2**: Cohort 2 interim analysis results. Genitourinary Cancers Symposium 2023;Abstract 503.
- Daneshmand S et al. Phase 2 study of the efficacy and safety of erdafitinib in patients (pts) with intermediate-risk non–muscle-invasive bladder cancer (IR-NMIBC) with FGFR3/2 alterations (alt) in THOR-2: Cohort 3 interim analysis. Genitourinary Cancers Symposium 2023;Abstract 504.

Key Data Sets

Matthew Milowsky, MD (continued)

- Daneshmand S et al. 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. *Urol Oncol* 2022;40(7):344.e1-9.
- Psutka S et al. SunRISe-4: **TAR-200 plus cetrelimab or cetrelimab alone** as neoadjuvant therapy in patients with muscle-invasive bladder cancer (MIBC) who are ineligible for or refuse neoadjuvant platinum-based chemotherapy. Genitourinary Cancers Symposium 2023;Abstract TPS584.
- Vilaseca A et al. Safety and efficacy of the **erdafitinib (erda) intravesical delivery system, TAR-210**, in patients (pts) with non–muscle-invasive bladder cancer (NMIBC) or muscle-invasive bladder cancer (MIBC) harboring select FGFR mutations or fusions: Phase 1 first-in-human study. Genitourinary Cancers Symposium 2023;Abstract TPS583.
- Galsky MD et al. Extended follow-up results from the **CheckMate 274** trial *(of adjuvant nivolumab versus placebo in muscle-invasive urothelial carcinoma)*. Genitourinary Cancers Symposium 2023;Abstract LBA443.
- Bamias A et al. Final overall survival (OS) analysis of **atezolizumab** (atezo) monotherapy vs chemotherapy (chemo) in untreated locally advanced or metastatic urothelial carcinoma (mUC) from the phase 3 IMvigor130 study. Genitourinary Cancers Symposium 2023;Abstract LBA441.

Pembro for BCG-unresponsive HR NMIBC: Cohort B results (KEYNOTE-057)

Background

- High-risk non–muscle-invasive bladder cancer (HR NMIBC) is defined as high-grade Ta, any T1, and/or carcinoma in situ (CIS)
  - Standard of care for HR NMIBC is TURBT followed by therapy with intravesical BCG
  - Prognosis is poor for patients whose disease does not respond to BCG or relapses within 12 months[1]; these patients are directed to radical cystectomy (RC)

- Criteria for the definition of adequate BCG and BCG-unresponsive HR NMIBC are well-established and endorsed by the US FDA[2]
  - Adequate BCG induction: ≥5 instillations of BCG and ≥7 instillations within 9 months of the first instillation of induction therapy
  - BCG-unresponsive HR NMIBC was defined as 1 of the following:
    - Stage progression at 3 months despite adequate BCG induction
    - High-grade T1 disease at first evaluation after adequate BCG induction
    - Persistent HR NMIBC at 6 months after adequate BCG
    - Recurrent HR NMIBC within 9 months of the last BCG instillation despite adequate BCG

BCG, bacillus Calmette-Guérin; TURBT, transurethral resection of bladder tumor.

1. Jeong et al. *BMC Cancer*. 2022;22:361. 2. Kamat AM et al. *J Clin Oncol*. 2016;34:1935-1944.

Pembro for BCG-unresponsive HR NMIBC: Cohort B results (KEYNOTE-057)

Background (continued)

- The multicohort phase 2 KEYNOTE-057 trial (NCT02625961) evaluated the efficacy and safety of pembrolizumab monotherapy in patients with BCG-unresponsive HR NMIBC who were ineligible for or declined RC
  - Results from cohort A (CIS ± papillary tumors) showed a clinical complete response (CR) rate of 40.6% at 3 months[1] with a median duration of response of 16.2 months,[1] leading to the US FDA approval of pembrolizumab for these patients
  - CR was maintained for ≥18 months in 33.3% of responders; 23.1% remained in CR for ≥24 months[2]
- Additional studies have provided results in the BCG-unresponsive CIS population,[3] but data are limited regarding the efficacy of novel systemic therapies in non-CIS, high-grade papillary T1 or Ta disease[3]
- Here we present results from cohort B (papillary tumors only, without CIS)

1. Balar AV et al. *Lancet Oncol*. 2021;22:919-930. 2. Balar AV et al. *J Clin Oncol*. 2021;39:(suppl_6). Abstract 451. 3. Dinney CPN et al. *Lancet Oncol*. 2021;22:107-117.

Phase 1 trial of Durvalumab plus BCG or EBRT in BCG-unresponsive NMIBC: HCRN GU16-243 ADAPT-BLADDER

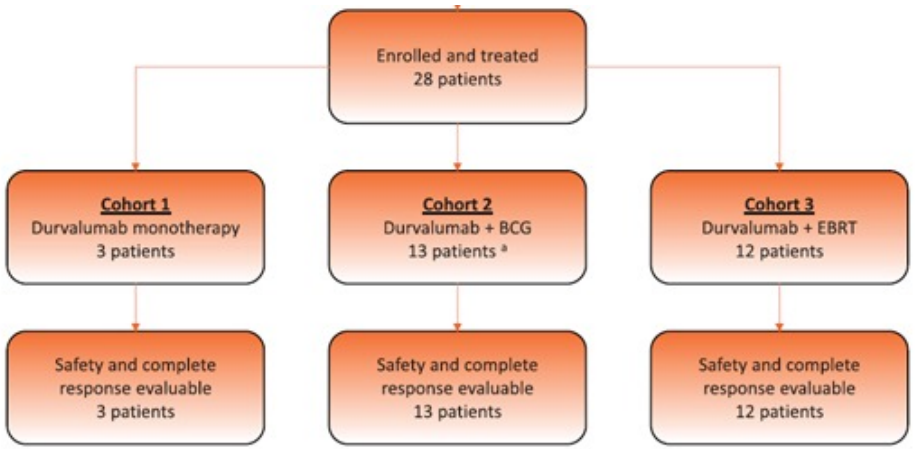


Table 1 – Patient demographics

	Durvalumab (cohort 1; *n* = 3)	Durvalumab + BCG (cohort 2; *n* = 13)	Durvalumab + EBRT (cohort 3; *n* = 12)
Age, median (IQR)	72 (68–74)	74 (71–77)	74 (66–78)
Gender, *n* (%)			
Male	3 (100)	10 (77)	10 (83)
Race, *n* (%)			
Caucasian	2 (67)	12 (92)	12 (100)
African American	0 (0)	1 (8)	0 (0)
Asian	1 (33)	0 (0)	0 (0)
ECOG PS, *n* (%)			
0	1 (33)	10 (77)	11 (92)
1	2 (67)	3 (23)	1 (8)
Prior BCG regimens, median (IQR)	1 (1–4)	2 (2–2)	3 (2–3)
Bladder T stages, *n* (%)			
CIS	2 (67)	6 (46)	6 (50)
HG Ta + CIS	0 (0)	1 (8)	0 (0)
HG T1 + CIS	0 (0)	2 (15)	1 (8)
HG Ta	0 (0)	4 (31)	1 (8)
HG T1	1 (33)	0 (0)	4 (33)
UTUC T stages, *n* (%)			
HG Ta	1 (33)	0 (0)	0 (0)
Prostatic urethra T stages, *n* (%)			
CIS	1 (33)	0 (0)	0 (0)
HG T1 + CIS	0 (0)	0 (0)	1 (8)
HG T1	1 (33)	0 (0)	0 (0)

BCG = bacillus Calmette-Guerin; CIS = carcinoma in situ; EBRT = external beam radiation therapy; ECOG = Eastern Cooperative Oncology Group; HG = high grade; IQR = interquartile range; PS = performance status; UTUC = upper tract urothelial carcinoma.

Cohort 1: 1120 mg of D intravenously every 3 wk for maximum of eight cycles.
Cohort 2: D + BCG patients also received full-dose intravesical BCG weekly for 6 wk with BCG maintenance recommended.
Cohort 3: D + EBRT patients received concurrent EBRT (6 Gy 3 in cycle 1 only)

Post-treatment cystoscopy/urine cytology at 3 and 6 mo, with bladder biopsies required at 6 mo.

Hahn NM et al. Eur Urol, 2023. Online ahead of print.

Courtesy of Matthew Milowsky, MD

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

Conclusions: ADAPT BLADDER

- **Feasible, safe in BCG-unresponsive NMIBC**
- **Encouraging preliminary efficacy seen**
- **Novel MA-MS ADAPT-BLADDER trial design facilitates rapid evaluation of novel therapies**
- **Justification for further study of combination approaches to BCG-unresponsive NMIBC**

Hahn NM et al. Eur Urol, 2023. Online ahead of print.

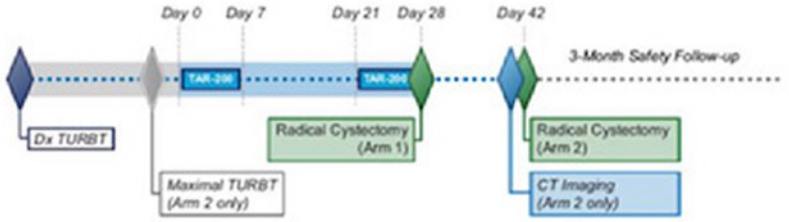
Courtesy of Matthew Milowsky, MD

Safety, tolerability, and efficacy of a neoadjuvant gemcitabine intravesical drug delivery system (TAR-200) in MIBC: A phase I trial.

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

TAR-200-101 (NCT02722538): a phase I, open-label study

- Patients with histologically confirmed T_{2a}-T_{3b} N_{0-1} M_0 urothelial bladder cancer received two 7-day cycles of **TAR-200**
  - > **Arm 1** – patients with residual tumor >3 cm after TURBT
  - > **Arm 2** – patients with residual tumor <3 cm after TURBT

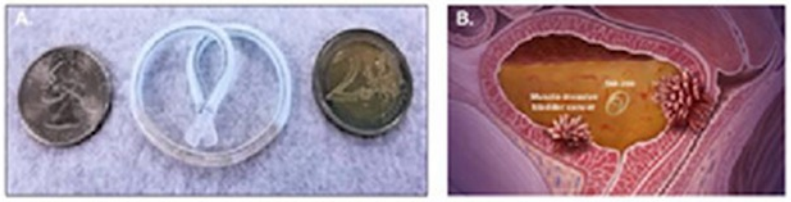


- **Primary endpoint:** Safety assessed via TEAEs

TAR-200: a novel intravesical drug delivery system

A. TAR-200 consists of a small, flexible silicone tube that contains gemcitabine

B. It is designed to release drug continuously inside the bladder over the indwelling period



Daneshmand S, *et al. Urol Oncol.*

Safety profile of neoadjuvant TAR-200 in MIBC

- Of the 23 patients in the ITT population, 10 (4 in Arm 1; 6 in Arm 2) experienced ≥1 TEAEs
  - – Pollakiuria (n = 3) and urinary incontinence (n = 2) were the most common TAR-200-related TEAEs

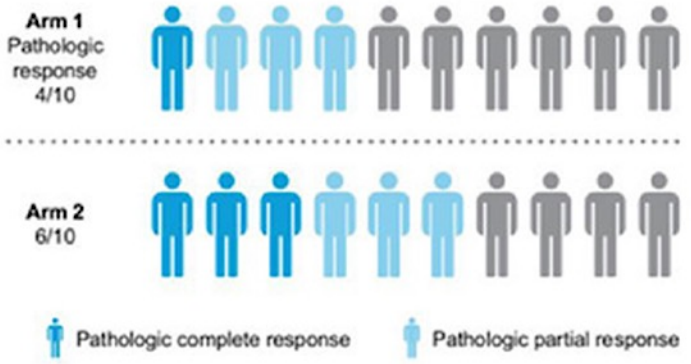
- All patients were considered tolerant of TAR-200, with no unscheduled TAR-200 removals
- No systemic toxicity was observed – systemic gemcitabine absorption from TAR-200 was negligible

Majority (n = 9; 39%) of TEAEs from first TAR-200 insertion through RC were **grade 1 or 2**

No grade 4 or 5 TEAEs were reported through RC

Preliminary antitumor response

Of 20 patients overall who underwent pathology at RC, 10 had a pathologic response



Conclusions

- Controlled intravesical gemcitabine release via TAR-200 was safe and well tolerated in patients with muscle-invasive bladder cancer
- Results from this phase I study provide promising preliminary evidence of the antitumor response to neoadjuvant TAR-200 prior to RC

Daneshmad S et al. Urol Oncol. 2022;40(7):344.e1-344.e9

Courtesy of Matthew Milowsky, MD

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

Key Data Sets

Matthew Milowsky, MD (continued)

- Hoimes CJ et al. **Enfortumab vedotin plus pembrolizumab** in previously untreated advanced urothelial cancer. *J Clin Oncol* 2023;41(1):22-31.
- Rosenberg JE et al. Study EV-103 Cohort K: Antitumor activity of enfortumab vedotin (EV) monotherapy or in combination with pembrolizumab (P) in previously untreated cisplatin-ineligible patients (pts) with locally advanced or metastatic urothelial cancer (la/mUC). ESMO 2022;Abstract LBA73.
- O'Donnell P et al. Enfortumab vedotin (EV) alone or in combination with pembrolizumab (P) in previously untreated cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer (la/mUC): Subgroup analyses of confirmed objective response rate (cORR) from EV-103 cohort K. Genitourinary Cancers Symposium 2023;Abstract 499.

Key Data Sets

Matthew Milowsky, MD (continued)

- Milowsky M et al. Patient-reported outcomes (PROs) in cisplatin-ineligible patients (pts) with locally advanced or metastatic urothelial cancer (la/mUC) treated with enfortumab vedotin (EV) alone or in combination with pembrolizumab (P) in the phase 1b/2 EV-103 Cohort K study. Gastrointestinal Cancers Symposium 2023;Abstract 439
- Rosenberg JE et al. Long-term outcomes in EV-301: 24-month findings from the phase 3 trial of **enfortumab vedotin versus chemotherapy** in patients with previously treated advanced urothelial carcinoma. ASCO 2022;Abstract 4516.
- Siefker-Radtke AO et al. Efficacy and safety of **erdafitinib** in patients with locally advanced or metastatic urothelial carcinoma: Long-term follow-up of a phase 2 study. *Lancet Oncol* 2022;23(2):248-58.
- Petrylak DP et al. Primary analysis of **TROPHY-U-01 cohort 2**, a phase 2 study of sacituzumab govitecan (SG) in platinum (PT)-ineligible patients (pts) with metastatic urothelial cancer (mUC) that progressed after prior checkpoint inhibitor (CPI) therapy. Genitourinary Cancers Symposium 2023;Abstract 520.

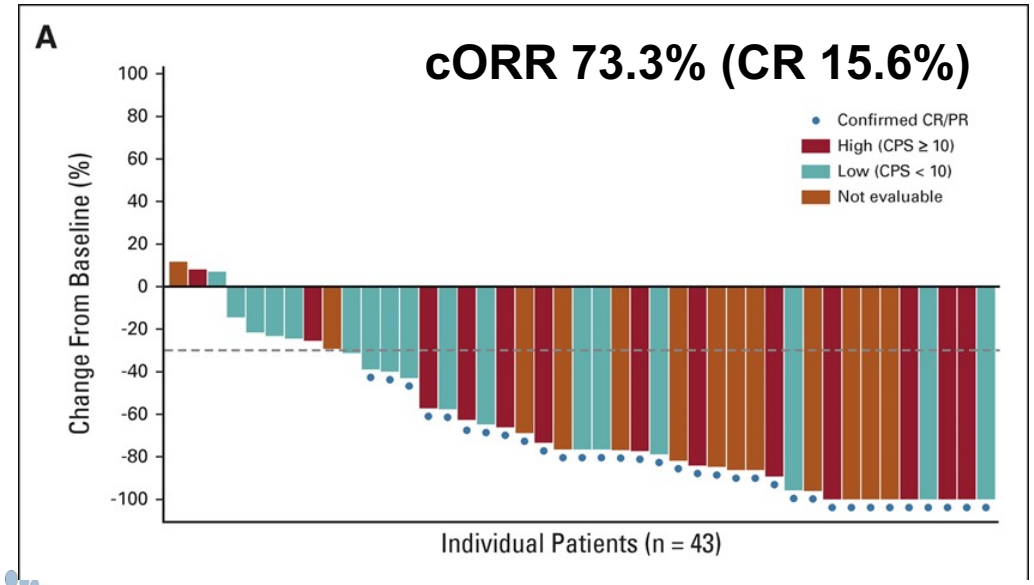
Key Data Sets

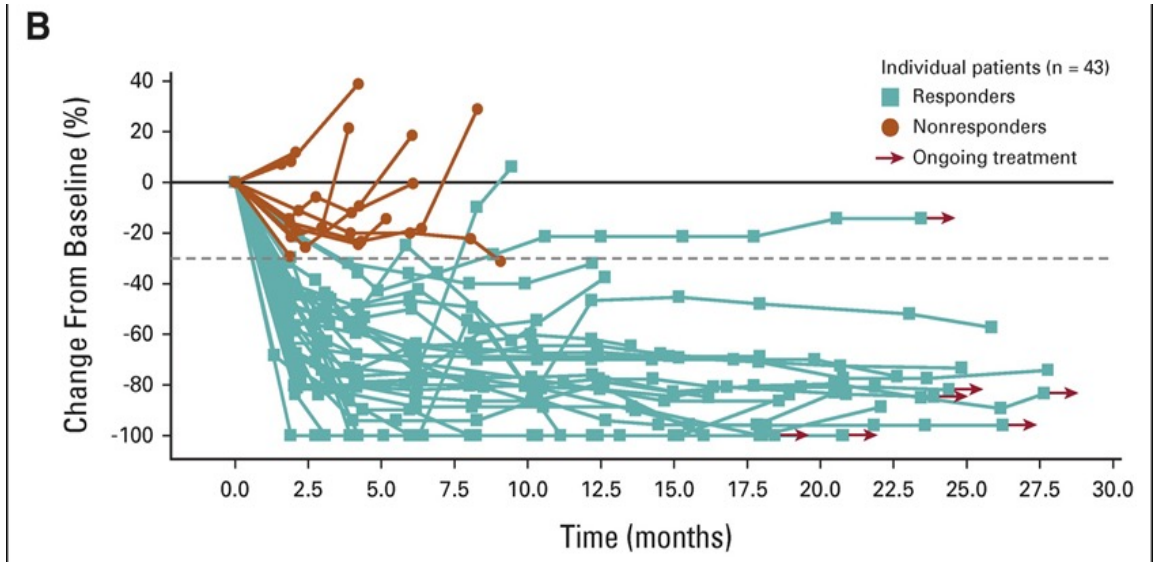
Matthew Milowsky, MD (continued)

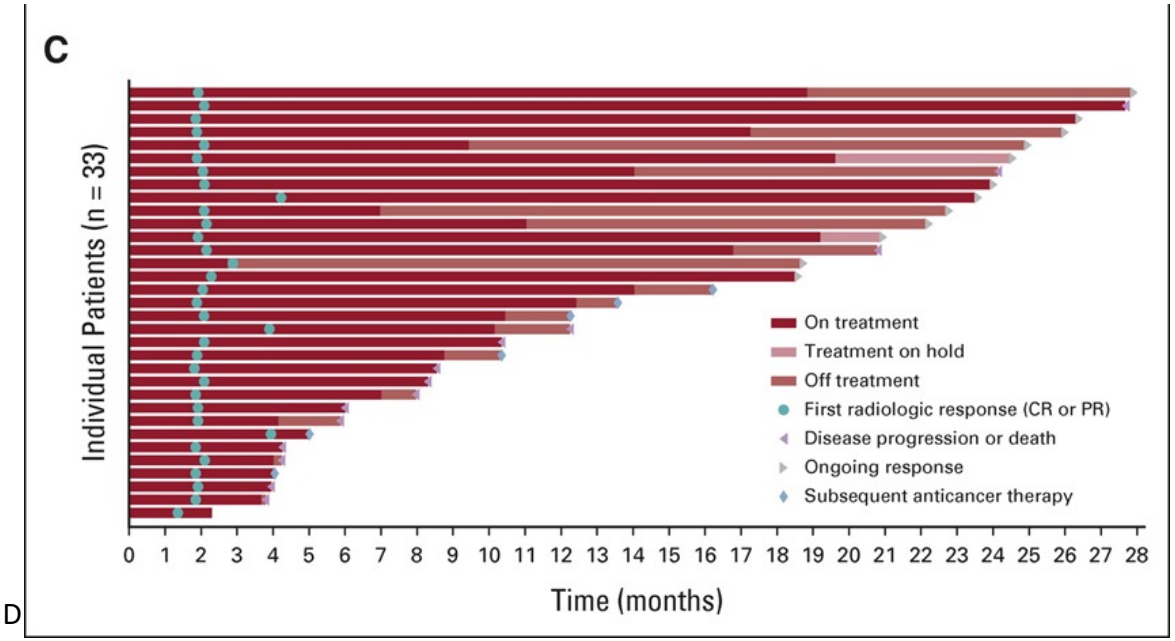
- Rosenberg JE et al. **Durvalumab plus olaparib** in previously untreated, platinum-ineligible patients with metastatic urothelial carcinoma: A multicenter, randomized, Phase II trial (BAYOU). *J Clin Oncol* 2023;41(1):43-53.
- Sheng X et al. **RC48-ADC** for metastatic urothelial carcinoma with HER2-positive: Combined analysis of RC48-C005 and RC48-C009 trials. ASCO 2022;Abstract 4520.
- Xu H et al. A phase II study of RC48-ADC in HER2-negative patients with locally advanced or metastatic urothelial carcinoma. ASCO 2022;Abstract 4519.
- Sheng X et al. Preliminary results of a phase Ib/II combination study of RC48-ADC, a novel humanized anti-HER2 antibody-drug conjugate (ADC) with toripalimab, a humanized IgG4 mAb against programmed death-1 (PD-1) in patients with locally advanced or metastatic urothelial carcinoma. ASCO 2022;Abstract 4518.

Enfortumab vedotin plus pembrolizumab in previously untreated advanced urothelial cancer (EV-103 Cohort A).

- **Phase Ib/II, multicenter, open-label study, 1L cisplatin-ineligible patients with la/mUC**
  - **EV 1.25 mg/kg once daily on days 1 and 8 and P 200 mg (day 1) IV once daily in 3-wk cycles.**
  - **Primary end point was safety.**
  - **Key secondary end points included cORR, DOR, and OS.**



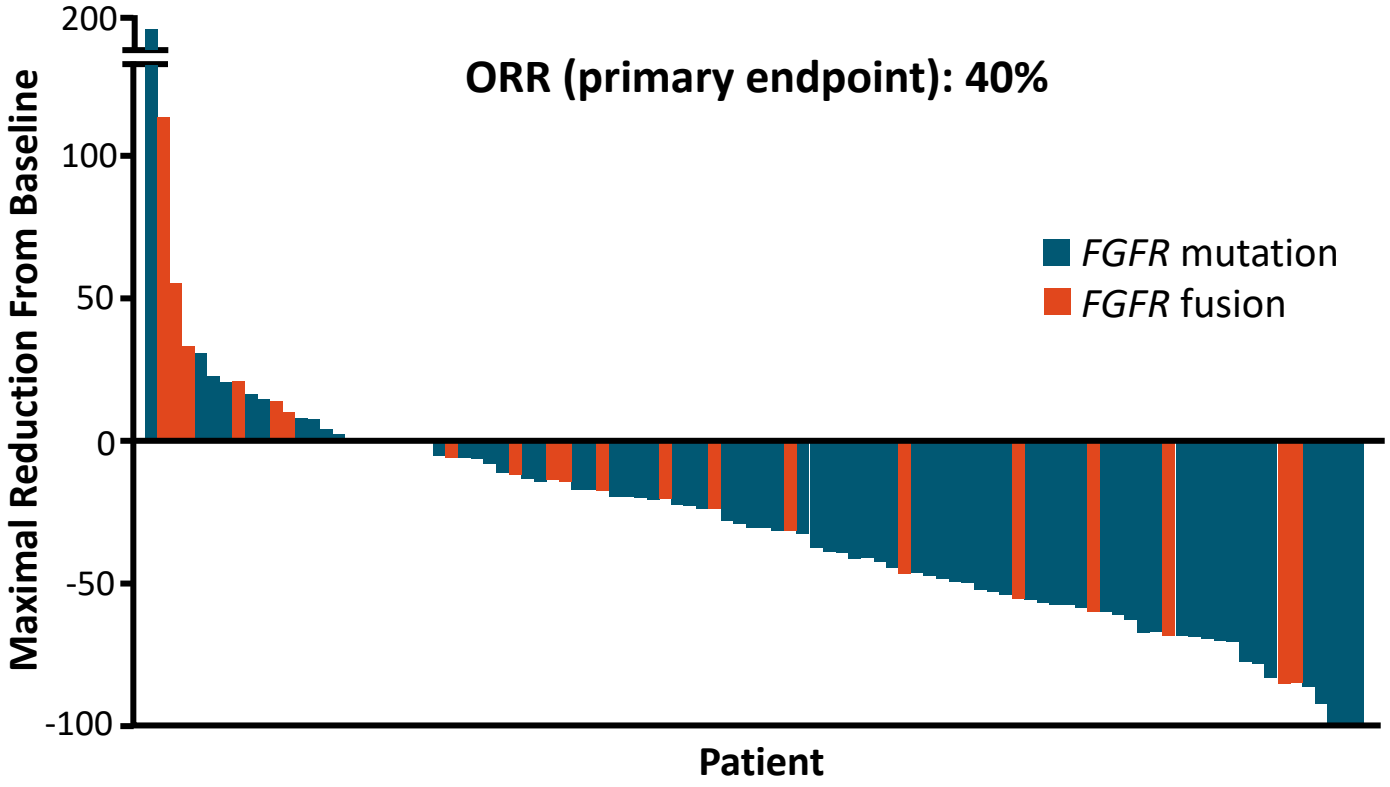


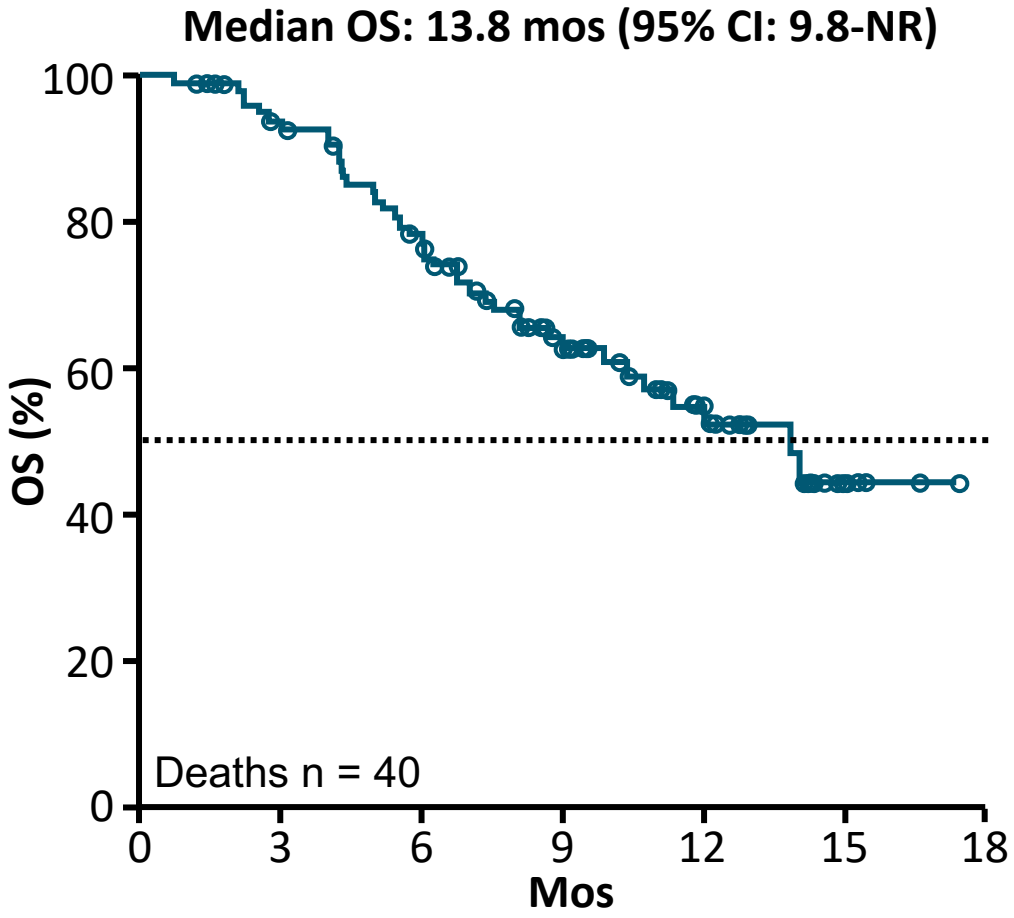


Hoimes CJ et al. J Clin Oncol. 2023;41(1):22-31. Courtesy of Matthew Milowsky, MD

Efficacy and safety of erdafitinib in patients with locally advanced or metastatic urothelial carcinoma: Long-term follow-up of a phase 2 study

- Erdafitinib: oral pan-FGFR (1-4) inhibitor
- Patients with metastatic UC and *FGFR* mutation or fusion (prevalence in metastatic UC: 15% to 20%)
  - At least 1 prior systemic therapy; prior ICI allowed





Siefker-Radtke A et al. Lancet Oncol 2022;23(2):248-58.
Siefker-Radtke. ASCO 2018. Abstr 4503.
Loriot. NEJM. 2019;381:338.

Courtesy of Matthew Milowsky, MD

Efficacy and safety of erdafitinib in patients with locally advanced or metastatic urothelial carcinoma: Long-term follow-up of a phase 2 study

TRAEs in > 20% of Patients, n (%)	Erdafitinib 8 mg QD (N = 99)	
	Any Grade	Grade 3
Hyperphosphatemia	72 (73)	2 (2)
Stomatitis	54 (55)	9 (9)
Dry mouth	43 (43)	0
Diarrhea	37 (37)	4 (4)
Dysgeusia	35 (35)	1 (1)
Dry skin	32 (32)	0
Alopecia	27 (27)	0
Decreased appetite	25 (25)	0
Hand–foot syndrome	22 (22)	5 (5)
Fatigue	21 (21)	2 (2)

TRAEs of Special Interest or Clinical Importance, n (%)[1]	Erdafitinib 8 mg QD (n = 99)	
	Any Grade	Grade ≥ 3
Hyperphosphatemia	72 (73)	2 (2)
Skin events	48 (49)	6 (6)
▪ Dry skin	32 (32)	0
▪ Hand–foot syndrome	22 (22)	5 (5)
Nail events	51 (52)	14 (14)
▪ Onycholysis	16 (16)	2 (2)
▪ Paronychia	14 (14)	3 (3)
▪ Nail dystrophy	16 (16)	6 (6)
Ocular events		
▪ CSR	21 (21)	3 (3)
▪ Non-CSR events*	51 (52)	5 (5)

*Most common non-CSR events: dry eye, 19%; blurry vision, 16%; increased lacrimation, 11%; conjunctivitis, 9%.

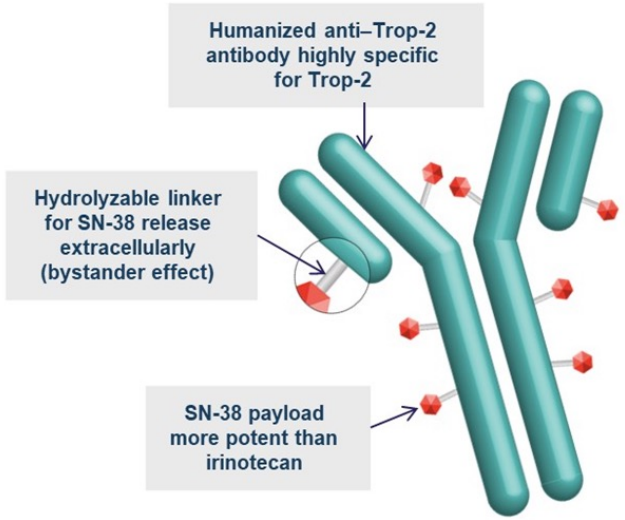
Siefker-Radtke. ASCO 2018.

Courtesy of Matthew Milowsky, MD

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

TROPHY-U-01: Sacituzumab govitecan in platinum-ineligible pts with mUC that progressed after prior checkpoint inhibitor

Sacituzumab Govitecan[4]



Study Design

Cohort 1[a] (~100 pts): Pts (≥18 years) with mUC who progressed after prior PT- and CPI-based therapies	SG 10 mg/kg D1 and D8, every 21 D
Cohort 2 (~40 pts): Pts with mUC who progressed after CPI therapy and were PT-ineligible at the start of study	SG 10 mg/kg D1 and D8, every 21 D Continue treatment in the absence of unacceptable toxicity or disease progression
Cohort 3 (up to 61 pts): CPI-naïve pts with mUC who progressed after prior PT-based therapies	SG 10 mg/kg D1 and D8, every 21 D + Pembrolizumab 200 mg D1 every 21 D
Cohort 4 (up to 57 pts): Pts with cis-eligible, treatment-naïve LA or mUC	Induction: cis+SG (6 cycles); Maintenance: (1) SG+avelumab; (2) SG+zim
Cohort 5[b] (~158 pts): Pts with LA or mUC who completed 1L cis + gem without progression	Arms: (1) SG+zim; (2): avelumab; (3): zim
Cohort 6 (up to 226 pts): Pts with cis-ineligible, treatment-naïve LA or mUC	Arms: (1) SG; (2) SG+zim; (3) SG+zim+dom; (4) carbo+gem+avelumab maintenance

Cohort 2

Primary endpoint: ORR per central review by RECIST 1.1

- Assuming the second-line ORR of 40% can be reproduced, 40 pts would give a 95% CI with a lower limit of 25% (CI is 0.25 to 0.57) for the response rate

Secondary endpoints: DOR, CBR, and PFS per central review by RECIST 1.1 and ORR, DOR, CBR, and PFS per investigator assessment by RECIST 1.1

PT Ineligibility

- Pts in Cohort 2 may not have received any PT for treatment of recurrent, metastatic, or advanced disease, but could have received PT in the (neo)adjuvant setting
- Cisplatin-ineligibility is defined as meeting one of the following criteria: 1. CrCl <60 mL/min; 2. Grade ≥2 audiometric hearing loss; 3. Grade ≥2 peripheral neuropathy; 4. New York Heart Association Class III heart failure

[a]Accelerated FDA approval for treatment of patients with LA or mUC who previously received PT-containing chemotherapy and PD-1/L1 inhibitor9. [b]Patients will complete 4-6 cycles of cis+gem induction before being randomized.

carbo, carboplatin; CBR, clinical benefit rate; cis, cisplatin; CPI, checkpoint inhibitor; CrCl, creatinine clearance; D, day; dom, domvanalimab; DOR, duration of response; FDA, US Food and Drug Administration; gem, gemcitabine; LA, locally advanced; mUC, metastatic urothelial cancer; ORR, objective response rate; PD-1, programmed death-1; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PT, platinum; pts, patients; SG, sacituzumab govitecan; UC, urothelial cancer; zim, zimberelimab.

3

Petrylak D et al. GU Cancers Symposium 2023;Abstract 520.

Courtesy of Matthew Milowsky, MD

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

TROPHY-U-01: Sacituzumab govitecan in platinum-ineligible pts with mUC that progressed after prior checkpoint inhibitor

Updated Safety Outcomes

TRAEs Occurring in >20% of Patients, n (%)	Cohort 2 (N=38)	
	All Grade	Grade ≥3
Diarrhea	24 (63)	6 (16)
Alopecia	19 (50)	0
Nausea	18 (47)	0
Neutropenia	17 (45)	13 (34)
Fatigue	16 (42)	7 (18)
Anemia	14 (37)	8 (21)
Leukopenia	13 (34)	7 (18)
Decreased appetite	10 (26)	0

- 26 (68%) patients had grade ≥3 TRAEs
  - The most common were neutropenia (34%), anemia (21%), leukopenia (18%), fatigue (18%), diarrhea (16%)
- 3 (8%) patients had treatment-related febrile neutropenia (2 with grade 3; 1 with grade 4)
- 14 (37%) patients had SG dose reduction due to TRAEs
- 7 (18%) patients discontinued treatment due to TRAEs
- No treatment-related death occurred
- G-CSF was received by 7 (18%) patients for primary prophylaxis and 10 (26%) patients for secondary prophylaxis

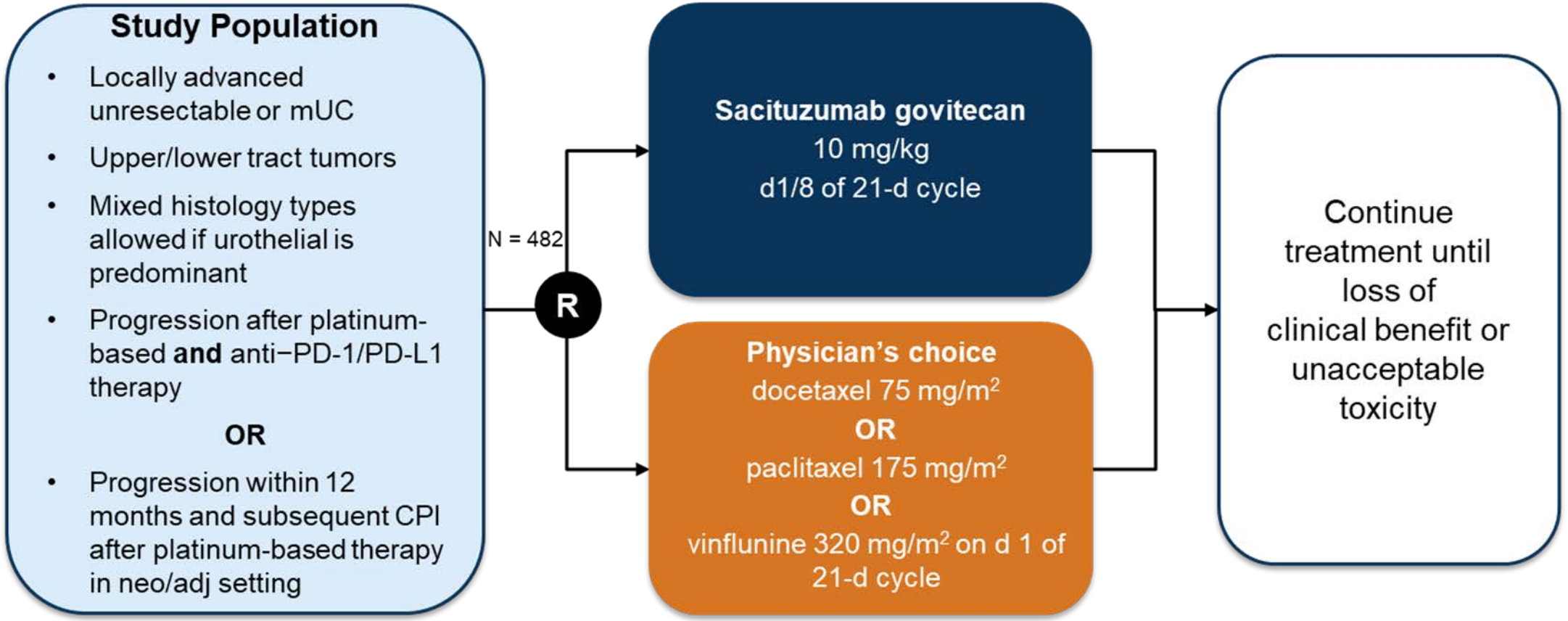
G-CSF, granulocyte colony-stimulating factor; SG, sacituzumab govitecan; TRAE, treatment-related adverse event.

8

Petrylak D et al. GU Cancers Symposium 2023;Abstract 520.

Courtesy of Matthew Milowsky, MD

Phase 3 TROPICS-04 study (NCT04527991)



- **Primary endpoint:** OS
- **Secondary endpoints:** PFS by PI assessment using RECIST v1.1; ORR, DOR, and CBR by PI assessment using RECIST v1.1; EORTC QLQ C30 score and EuroQOL EQ-5D-5L QOL score

1. https://clinicaltrials.gov/ct2/show/NCT04527991.

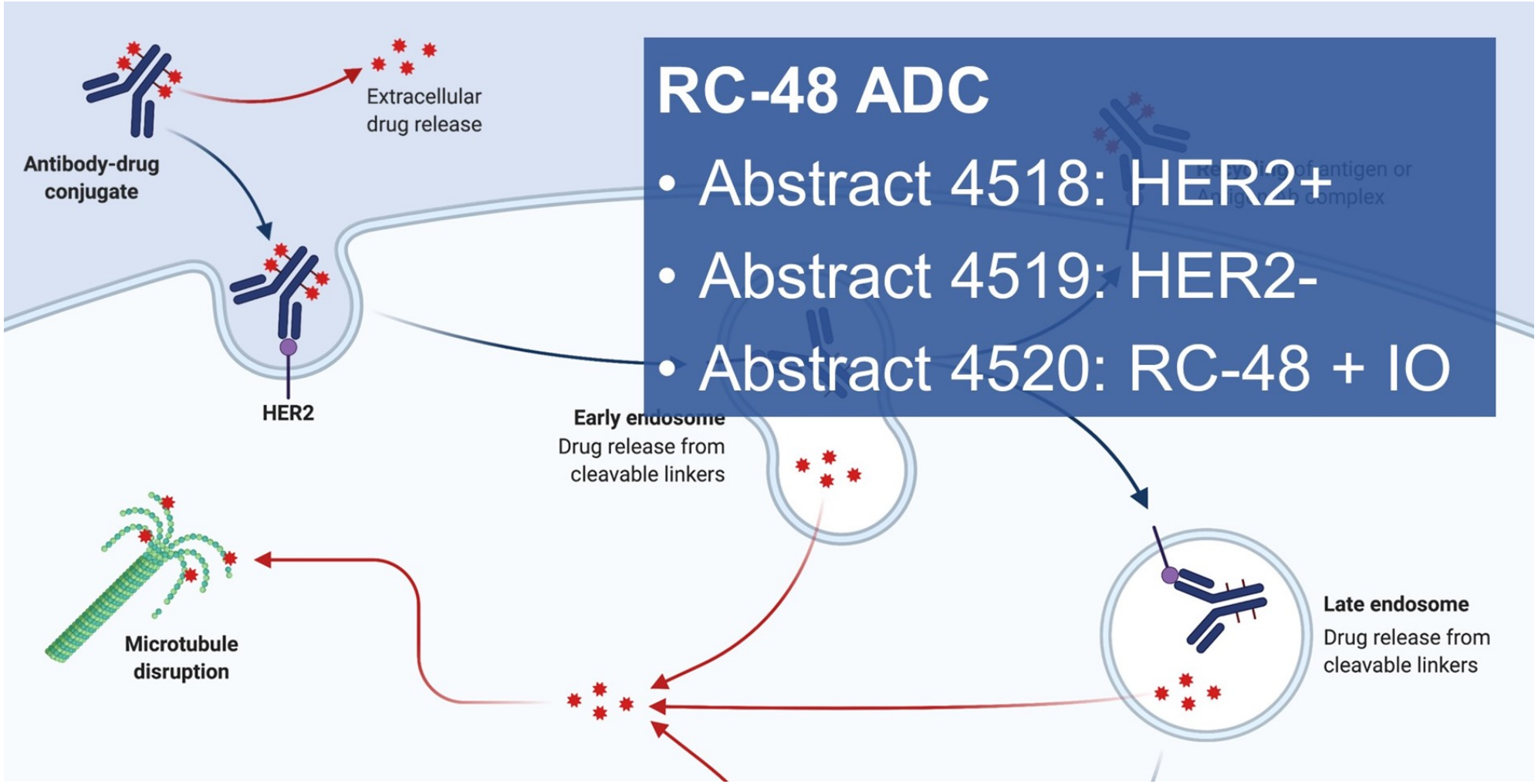
https://clinicaltrials.gov/ct2/show/NCT04527991

Courtesy of Matthew Milowsky, MD

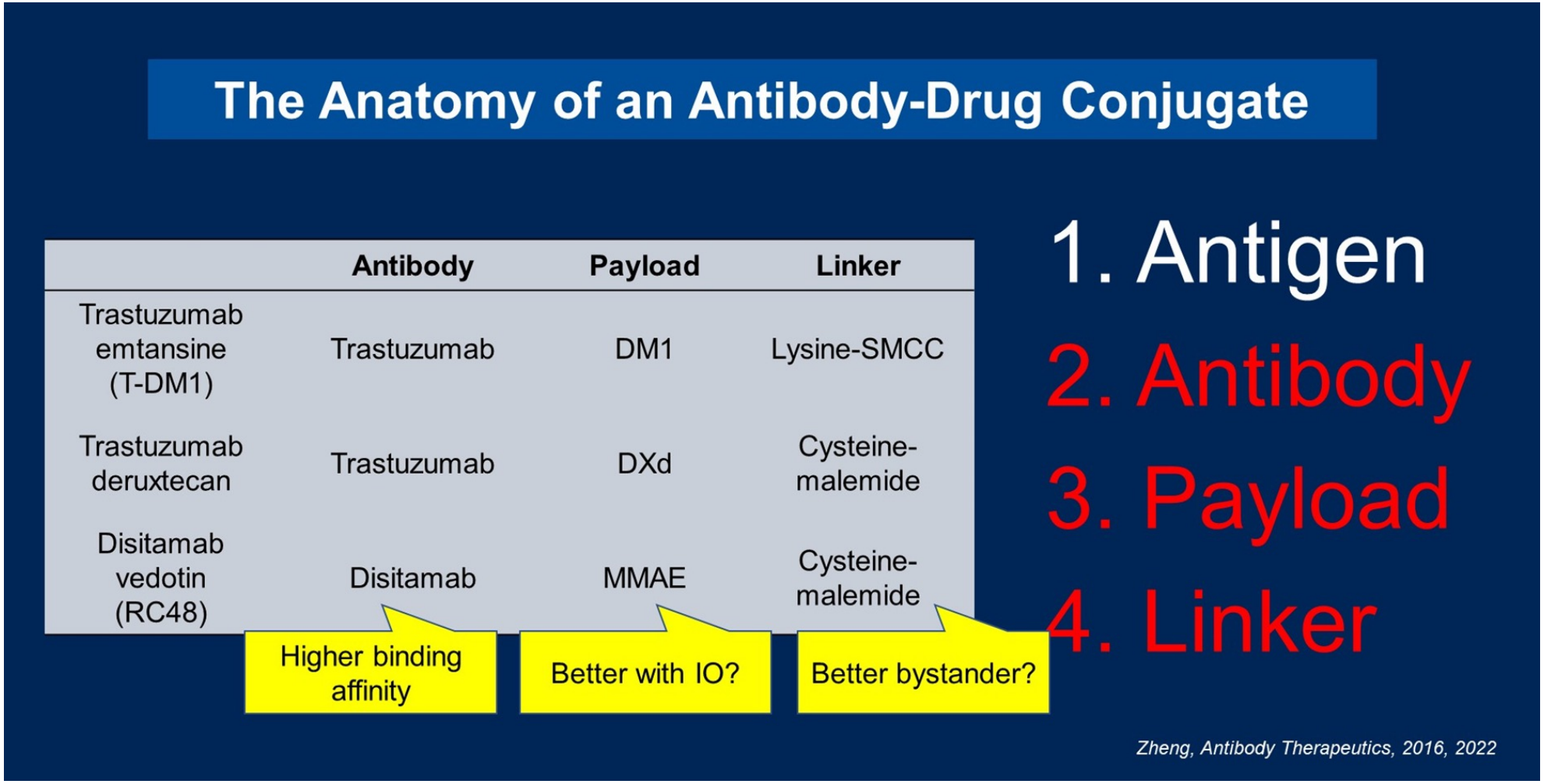
Durvalumab plus olaparib in previously untreated, platinum-ineligible patients with metastatic urothelial carcinoma: A multicenter, randomized, Phase II trial (BAYOU)

- Homologous recombination repair gene mutations (HRRm) are common in UC, rendering tumor cells sensitive to PARP inhibition.
- Randomized, multicenter, double-blind, phase II trial enrolled untreated, platinum-ineligible patients with mUC.
  - Patients (N = 154) were randomly assigned 1:1 to receive durvalumab (1,500 mg intravenously once every 4 weeks) plus olaparib (300 mg orally, twice daily) or durvalumab plus placebo.
- The primary end point was progression-free survival (PFS) assessed by investigators per RECIST version 1.1. Secondary end points included overall survival in all patients and PFS in patients with HRRm.

RC-48 ADC


RC-48 ADC
• Abstract 4518: HER2+
• Abstract 4519: HER2-
• Abstract 4520: RC-48 + IO
Antibody-drug conjugate
Extracellular drug release
HER2
Early endosome
Drug release from cleavable linkers
Microtubule disruption
Late endosome
Drug release from cleavable linkers

HER2 ADCs


The Anatomy of an Antibody-Drug Conjugate
Antibody
Payload
Linker
Trastuzumab emtansine (T-DM1)
Trastuzumab
DM1
Lysine-SMCC
Trastuzumab deruxtecan
Trastuzumab
DXd
Cysteine-malemide
Disitamab vedotin (RC48)
Disitamab
MMAE
Cysteine-malemide
Higher binding affinity
Better with IO?
Better bystander?
1. Antigen
2. Antibody
3. Payload
4. Linker
Zheng, Antibody Therapeutics, 2016, 2022

Is there something special about MMAE?

Regimen	Payload	N	Population	HER2	ORR
Enfortumab vedotin + Pembrolizumab	MMAE (tubulin)	43	Cis-ineligible, tx naive	All	73%
Disitimab vedotin + Toripalimab	MMAE (tubulin)	39	60% tx naive	All	72%
Trastuzumab deruxtecan + Nivolumab	Dxd (Topo I)	26	Progressed despite prior platinum	2+ or 3+	36%
Sacitizumab govitecan + Pembrolizumab	SN38 (Topo I)	41	Progressed despite prior platinum	All	34%

Galsky, M. ASCO Annual Meeting 2022

Courtesy of Matthew Milowsky, MD

Agenda

MODULE 1: Renal Cell Carcinoma

- Adjuvant therapy
- Choice of first-line treatment for metastatic disease
- New agents and strategies

MODULE 2: Urothelial Bladder Cancer

- Non-muscle-invasive disease
- Adjuvant immunotherapy
- Sequencing of therapies in metastatic disease

MODULE 3: Appendix

RTP RESEARCH TO PRACTICE

Renal Cell Carcinoma

Abstract 605

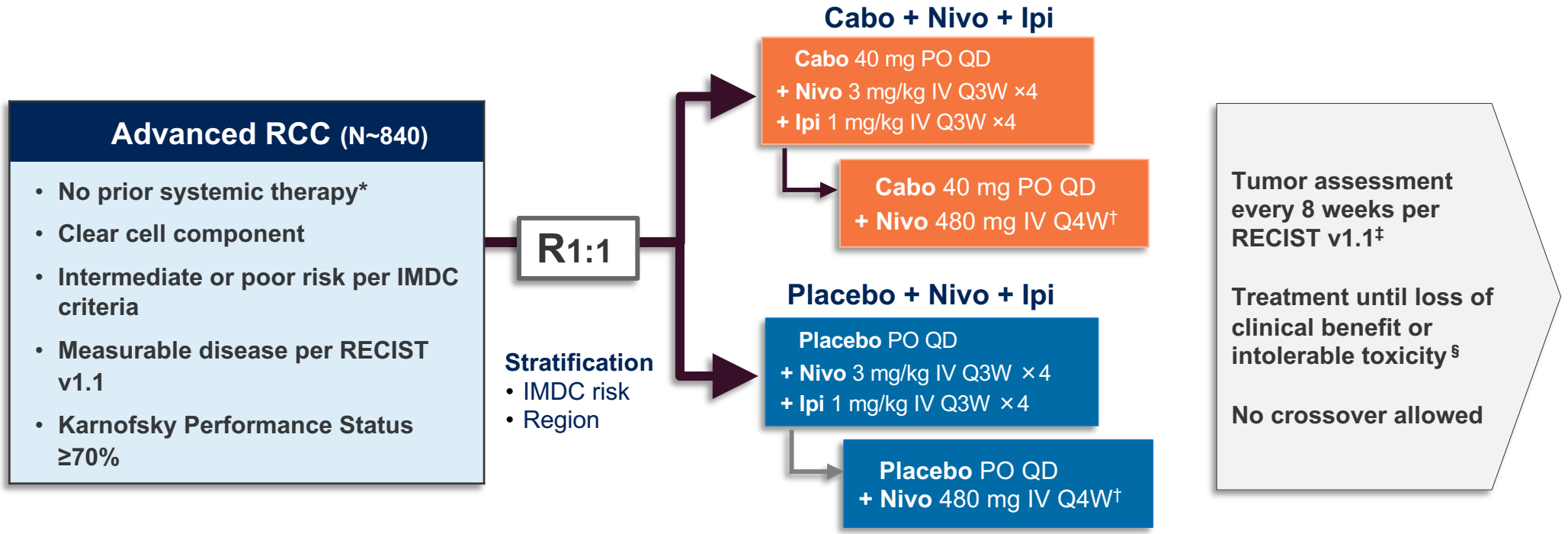
Outcomes by IMDC risk in the COSMIC-313 phase 3 trial evaluating cabozantinib plus nivolumab and ipilimumab in first-line advanced RCC of IMDC intermediate or poor risk

Thomas Powles,[1] Robert J. Motzer,[2] Laurence Albiges,[3] Cristina Suarez,[4] Fabio A. Schutz,[5] Daniel Y.C. Heng,[6] Christine Chevreau,[7] Ravindran Kanesvaran,[8] Howard Gurney,[9] Fong Wang,[10] Fabio Mataveli,[10] Yu-Lin Chang,[10] Maximiliano van Kooten Losio,[11] Toni K. Choueiri[12]

[1]Barts Cancer Institute, Cancer Research UK Experimental Cancer Medicine Centre, Queen Mary University of London, Royal Free National Health Service Trust, London, UK; [2]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [3]Institut Gustave Roussy, Université Paris Saclay, Villejuif, France; [4]Vall d'Hebron Institute of Oncology, Hospital Universitari Vall d'Hebron, Vall d'Hebron Barcelona Hospital Campus, Barcelona, Spain; [5]Latin American Cooperative Oncology Group, Porto Alegre, Brazil; Beneficência Portuguesa de Sao Paulo, Sao Paulo, Brazil; [6]Tom Baker Cancer Center, University of Calgary, Calgary, AB, Canada; [7]Institut Universitaire Du Cancer de Toulouse, Toulouse, France; [8]National Cancer Centre Singapore, Singapore; [9]Macquarie University, Macquarie Park NSW, Australia; [10]Exelixis, Inc., Alameda, CA, USA; [11]Bristol Myers Squibb, Boudry, Neuchâtel, Switzerland; [12]Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Harvard Medical School, Boston, MA, USA

Courtesy of Thomas Powles, MBBS, MRCP, MD

COSMIC-313 Study Design



Primary endpoint: PFS per RECIST v1.1 by BIRC after the 249th event in the first 550 randomized patients (PITT population)
Secondary endpoint (ongoing): OS after 433 events in all randomized patients (ITT patients)
Additional endpoints: ORR, DOR, and safety

*One prior systemic adjuvant therapy allowed for completely resected RCC and if recurrence occurred ≥6 months after the last dose of adjuvant therapy; adjuvant PD-1 or PD-L1 inhibitor in combination with a CTLA-4 inhibitor not permitted. †Nivolumab given for a maximum of 2 years. ‡Tumor assessment (RECIST v1.1) at week 10, then every 8 weeks through week 50, then every 12 weeks thereafter. §Discontinuation of one agent did not mandate discontinuation of all agents.

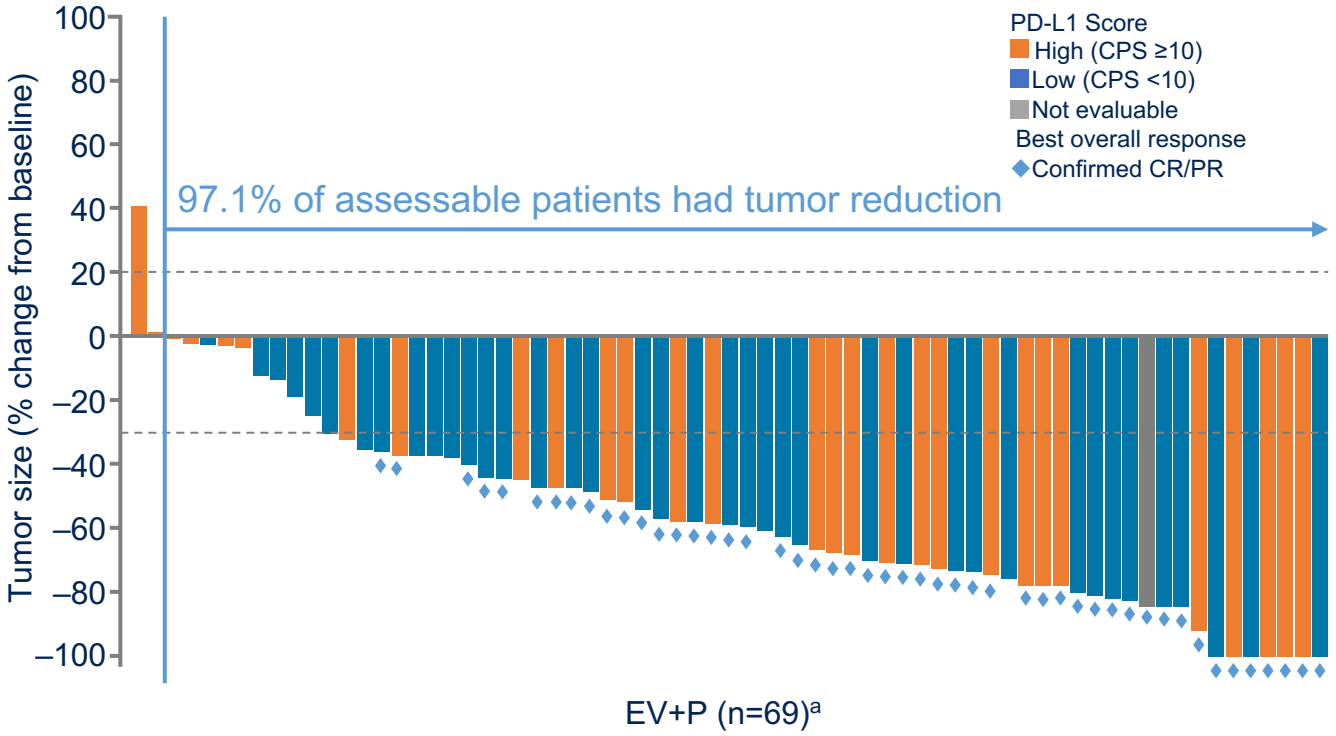
BIRC, blinded independent radiology committee; DOR, duration of response; ITT, intention-to-treat; PITT, progression-free survival ITT.

Thomas Powles, MD

Courtesy of Thomas Powles, MBBS, MRCP, MD

Powles T et al. Genitourinary Cancers Symposium 2023;Abstract 605.

EV-103 Cohort K: EV mono or EV+P in previously untreated cisplatin-ineligible pts with la/mUC



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**.

2L, second-line; AEs, adverse events; BICR, blinded independent central review; CI, confidence interval; cORR: confirmed objective response rate; CPS, combined positive score; CR, complete response; EV, enfortumab vedotin; la/mUC, locally advanced/metastatic urothelial cancer; mono, monotherapy; NR, not reached; P, pembrolizumab; PD-L1, programmed death-ligand-1; PR, partial response; TRAEs, treatment-related adverse events.

	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

Previously presented at ESMO 2022, Rosenberg et al. Study EV-103 Cohort K: Antitumor activity of enfortumab vedotin (EV) monotherapy or in combination with pembrolizumab (P) in previously untreated cisplatin-ineligible patients (pts) with locally advanced or metastatic urothelial cancer (la/mUC).

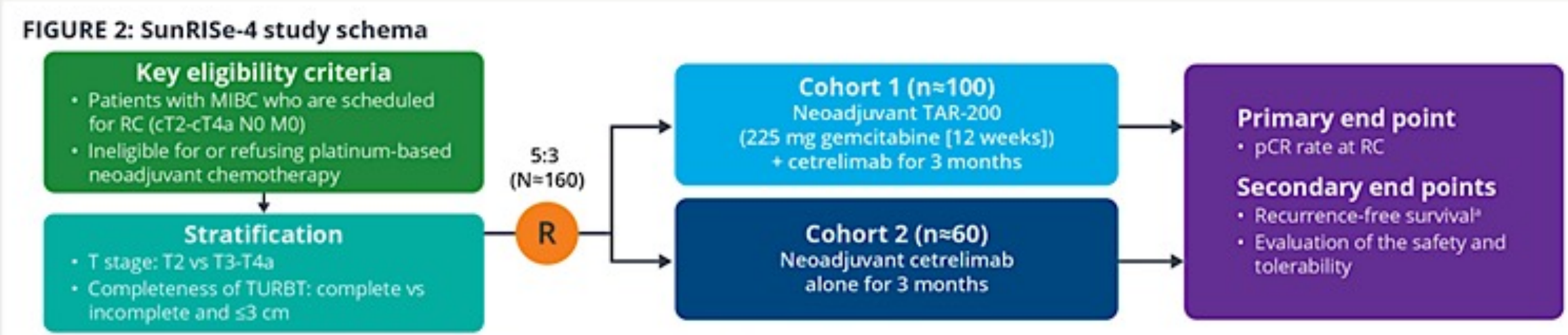
Urothelial Bladder Cancer

TPS: Neoadjuvant TAR-200 plus cetrelimab or cetrelimab alone for MIBC

SunRISe-4: TAR-200 Plus Cetrelimab or Cetrelimab Alone as Neoadjuvant Therapy in Patients With Muscle-Invasive Bladder Cancer (MIBC) Who Are Ineligible for or Refuse Neoadjuvant Platinum-Based Chemotherapy

Sarah P. Psutka,[1] Christopher J. Cutie,[2] Sumeet Kaur Bhanvadia,[2] Kirk A. Keegan,[2] Wendy Crist,[3] Shaozhou Ken Tian,[3] John Maffeo,[2] Bradley Raybold,[2] Marietta Kashmer,[2] Mohamad Hasan,[3] Xiang Li,[3] Neil Beeharry,[3] Shibu Thomas,[3] Hui Tian,[3] Thomas Powles[4,5]

[1]University of Washington, Fred Hutchinson Cancer Center, Seattle, WA; [2]Janssen Research & Development, Lexington, MA; [3]Janssen Research & Development, Spring House, PA; [4]Barts Cancer Centre, London, UK; [5]The Royal Free London NHS Foundation Trust, London, UK



Meet The Professor

Optimizing the Management of ER-Positive and Triple-Negative Breast Cancer

Tuesday, March 7, 2023
5:00 PM – 6:00 PM ET

Faculty

Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

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.

CME and MOC credit information will be emailed to each participant within 5 business days.

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