The Implications of Recent Datasets for the Current and Future Management of Genitourinary Cancers — An ASCO 2026 Review

A CME/MOC-Accredited Live Webinar

Thursday, July 16, 2026
5:00 PM – 6:30 PM ET

Faculty

Rahul Aggarwal, MD
Matthew D Galsky, MD
Tian Zhang, MD, MHS, FASCO

Moderator

Neil Love, MD

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Faculty

Rahul Aggarwal, MD
Professor of Medicine and Thomas Perkins Distinguished Professor of Cancer Research
Program Leader, Genitourinary Medical Oncology
Division of Hematology/Oncology
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Associate Director for Clinical Research
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MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

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This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Exelixis Inc, Johnson & Johnson, and Novartis.

Dr Love — Disclosures

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Dr Galsky — Disclosures

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Dr Zhang — Disclosures

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Data and Safety MonitoringBoards/Committees	Novartis
Nonrelevant Financial Relationships	MJH Life Sciences, PeerView

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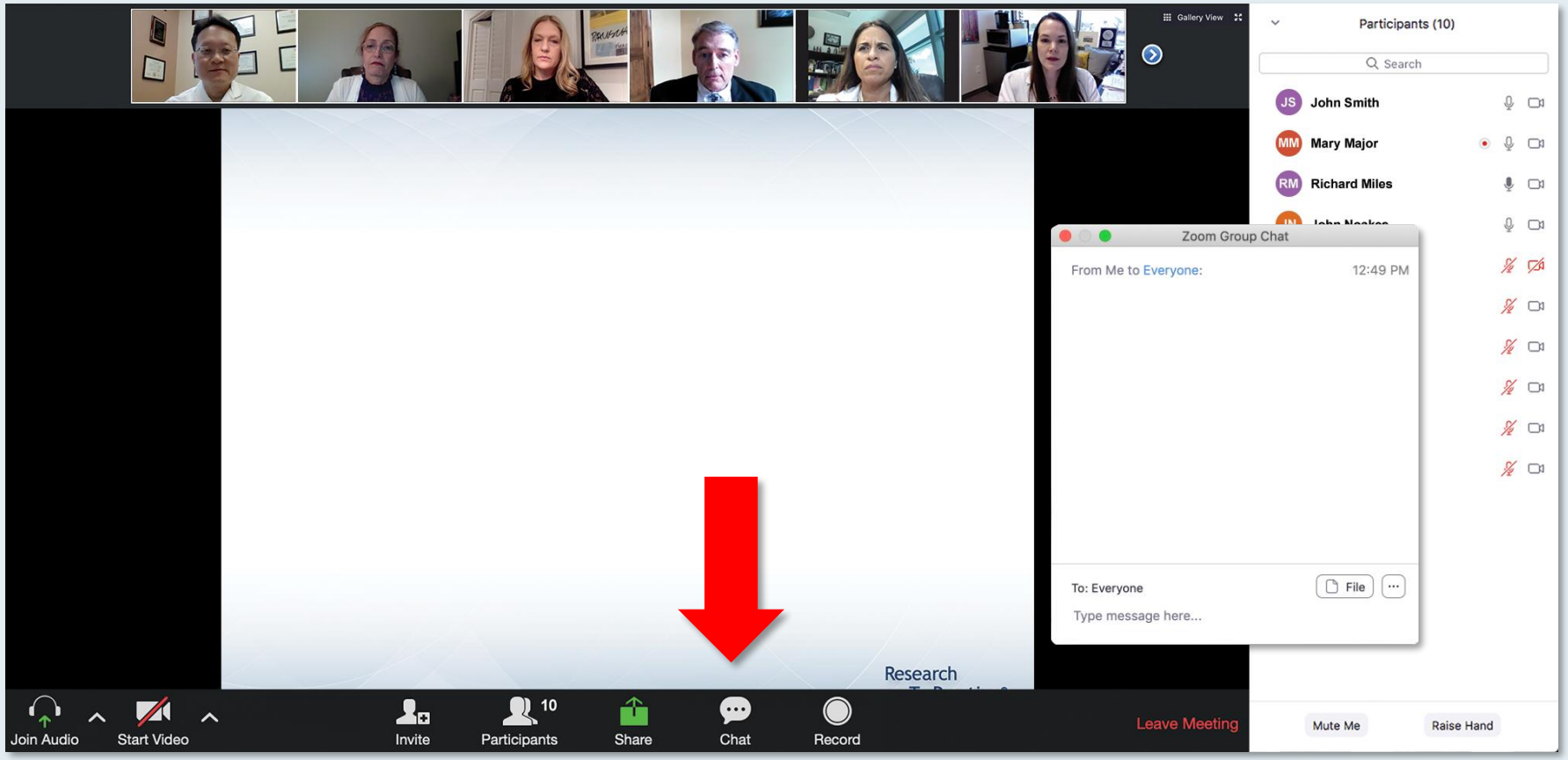

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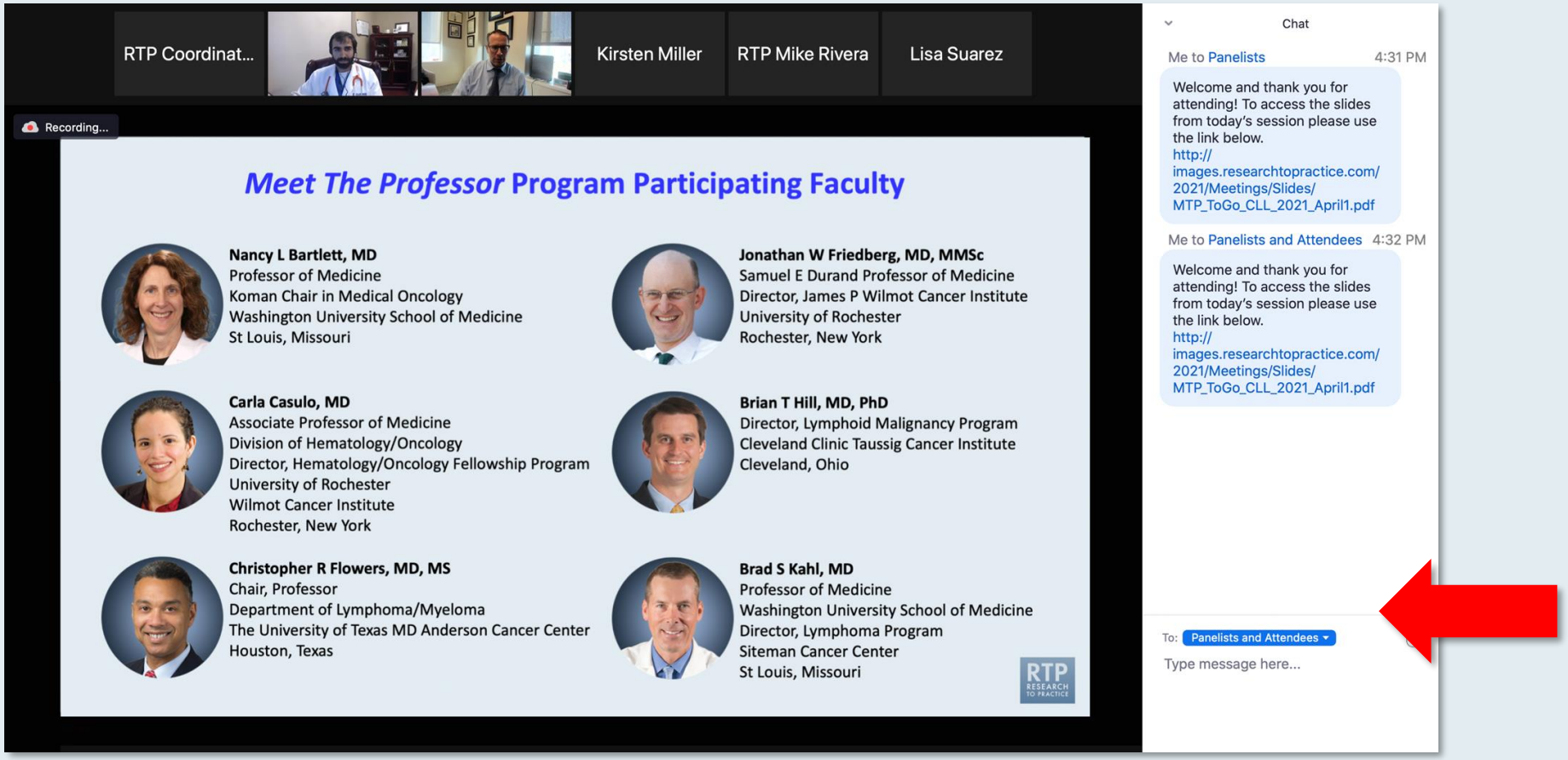

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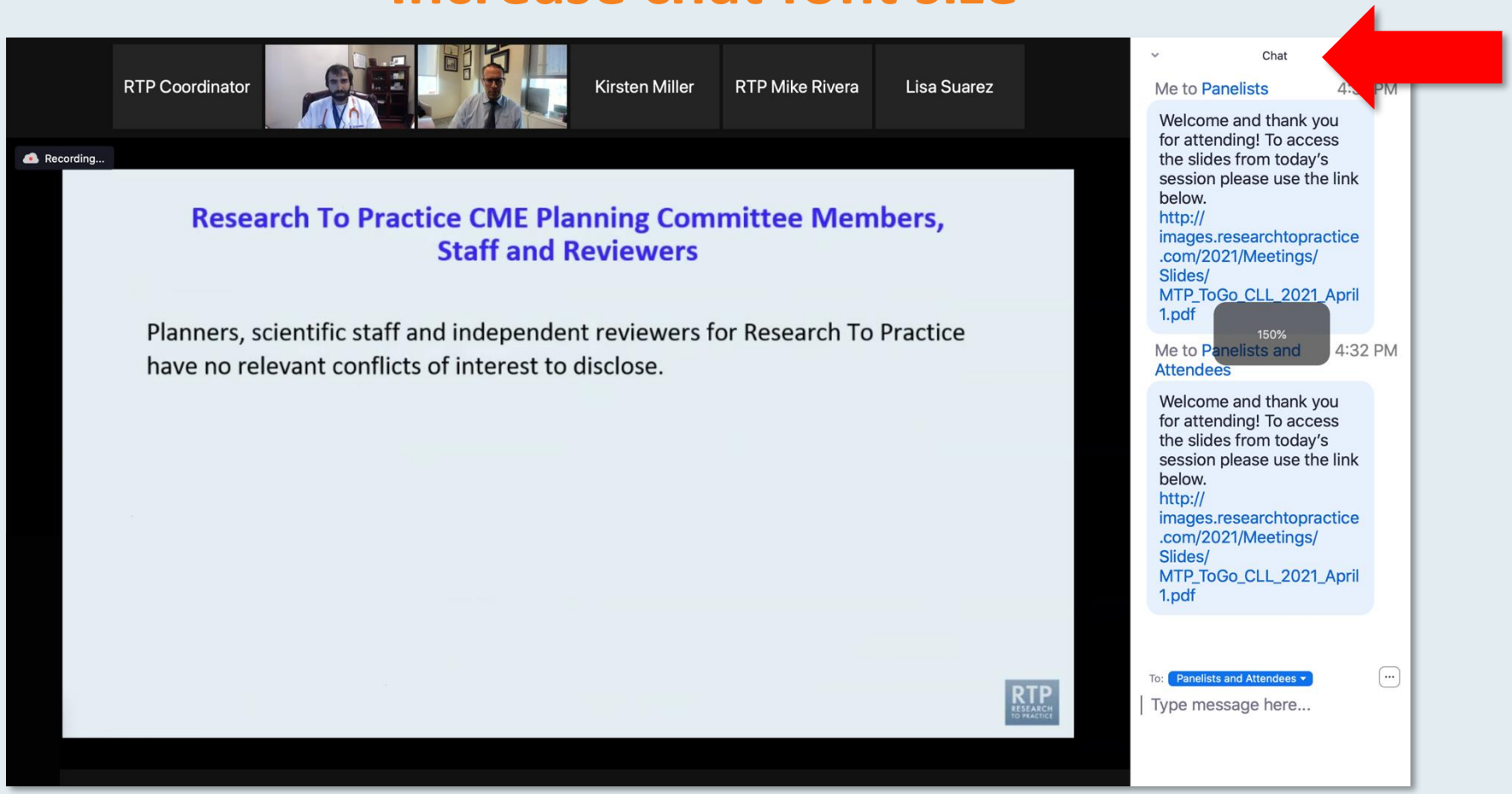

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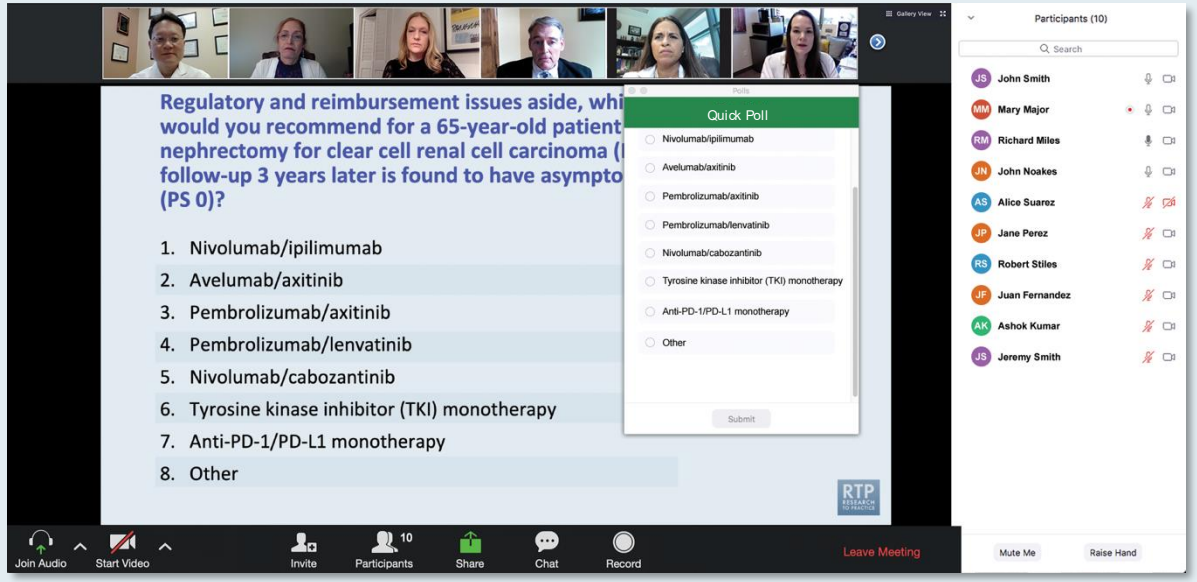

ONCOLOGY TODAY

WITH DR NEIL LOVE

Androgen Deprivation Therapy for Prostate Cancer — An Interview with Dr Rana R McKay

RANA R MCKAY, MD, FASCO
UC SAN DIEGO MOORES CANCER CENTER

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Patterns of Care: Exploring How Community Oncologists Manage Metastatic Triple-Negative Breast Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, July 21, 2026

5:00 PM – 6:00 PM ET

Faculty

Professor Peter Schmid, FRCP, MD, PhD

Melinda Telli, MD, FASCO

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Bringing the Investigator into the Equation — Optimal Use of Hormonal Therapy in the Care of Patients with Prostate Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, July 29, 2026
5:00 PM – 6:00 PM ET

Faculty

William K Oh, MD
Mary-Ellen Taplin, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

The Implications of Recent Datasets for the Current and Future Management of Breast Cancer — An ASCO 2026 Review

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Thursday, July 30, 2026
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Faculty

Kevin Kalinsky, MD, MS, FASCO
Joyce O'Shaughnessy, MD
Additional faculty to be announced.

Moderator

Neil Love, MD

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Join Us In Person or Virtually

Integrating New Advances into the Care of Patients with Cancer

A Multitumor Symposium in Partnership with the American Oncology Network

Saturday, August 22, 2026

JW Marriott Nashville | Nashville, Tennessee

Chronic Lymphocytic Leukemia
9:00 AM – 9:50 AM CT

Gastroesophageal Cancers
9:50 AM – 10:40 AM CT

Gynecologic Cancers
10:55 AM – 11:45 AM CT

Diffuse Large B-Cell Lymphoma
12:35 PM – 1:25 PM CT

Lung Cancer
1:25 PM – 2:15 PM CT

Moderator
Stephen “Fred” Divers, MD

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Grand Rounds

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Regional Activities

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Optimizing the Use of Novel Therapies for Patients with Diffuse Large B-Cell Lymphoma

Optimizing Therapy for Patients with Hormone Receptor-Positive Localized Breast Cancer

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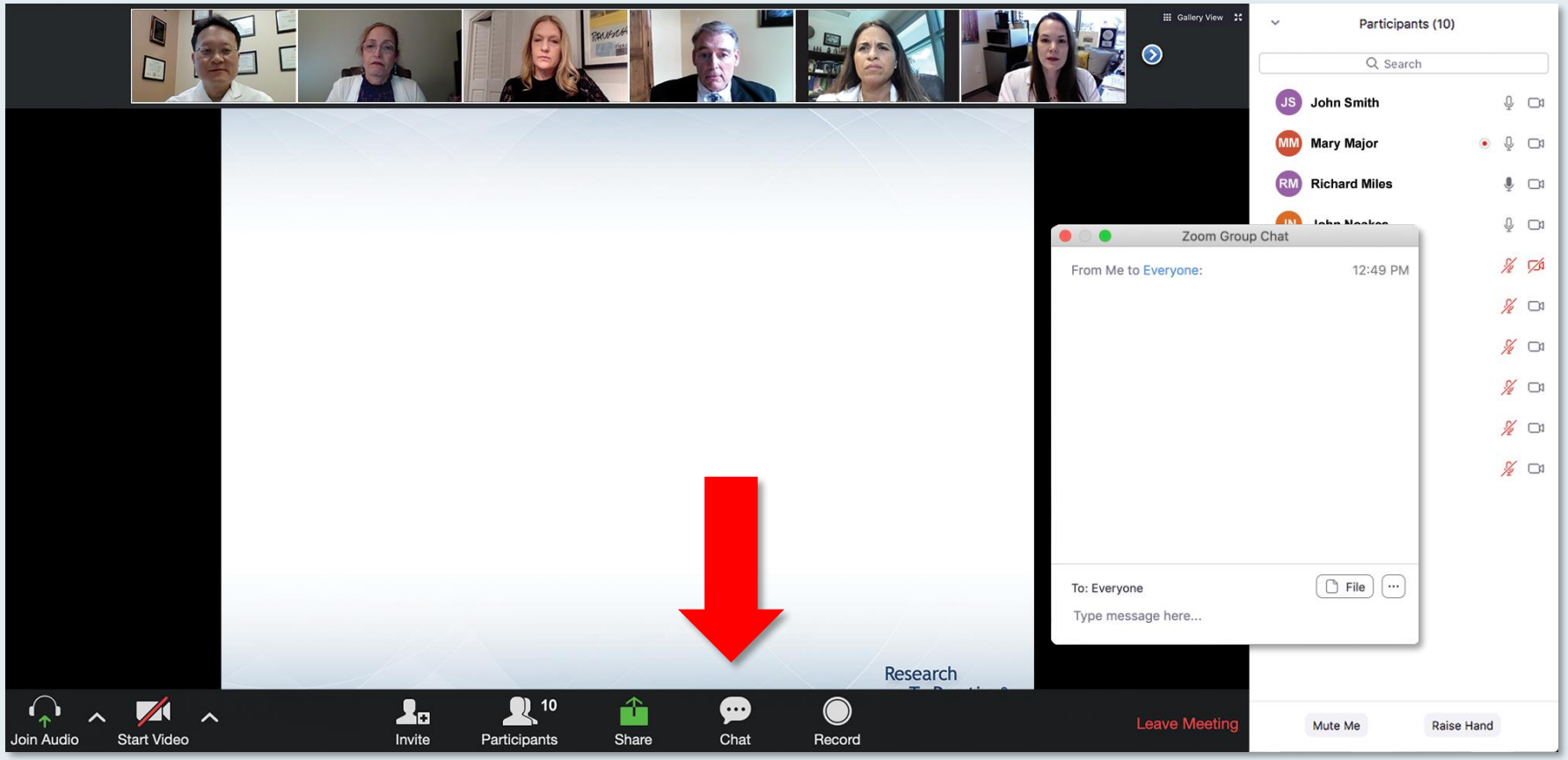

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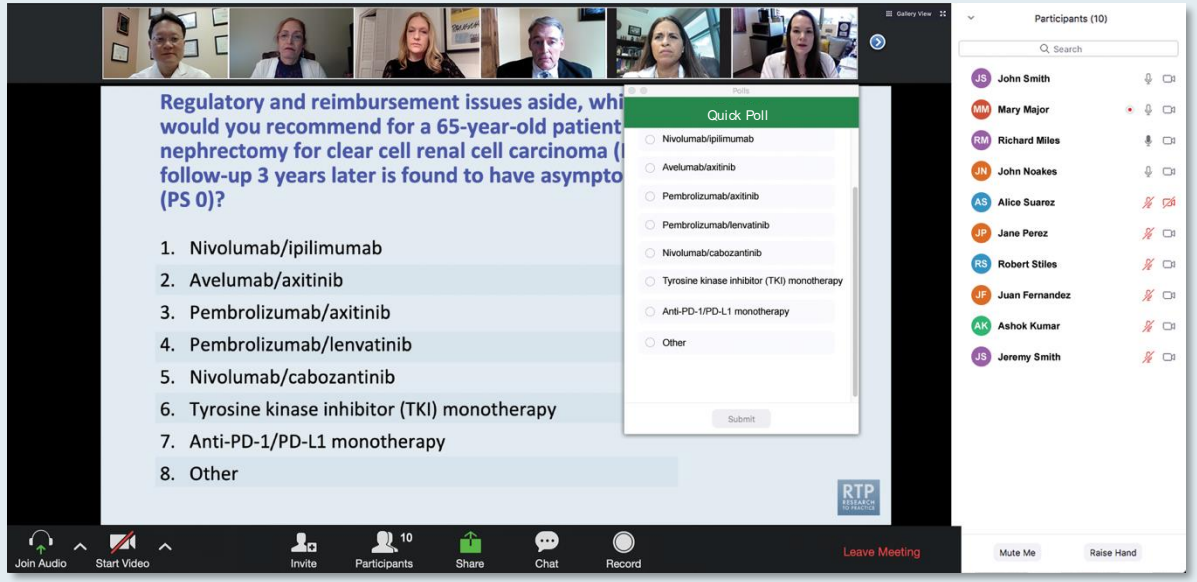

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Agenda

Introduction: Welcome GU Oncology Fellows!

Module 1: Prostate Cancer — Dr Aggarwal

Module 2: Urothelial Bladder Cancer — Dr Galsky

Module 3: Renal Cell Carcinoma — Dr Zhang

Agenda

Introduction: Welcome GU Oncology Fellows!

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Module 3: Renal Cell Carcinoma — Dr Zhang

FDA Approves Capivasertib with Abiraterone and Prednisone for PTEN-Deficient Androgen Pathway Modulation-Naïve or Androgen Pathway Modulation-Sensitive Prostate Cancer

Press Release: June 12, 2026

"On June 12, 2026, the Food and Drug Administration approved capivasertib in combination with abiraterone and prednisone for adults with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer (previously referred to as metastatic hormone-sensitive prostate cancer) that is PTEN-deficient as detected by an FDA-authorized test.

Efficacy was evaluated in CAPItello-281 (NCT04305496), a randomized, double-blind, placebo-controlled, multicenter trial that enrolled 1,012 adults with newly diagnosed, PTEN-deficient mAPMN/S prostate cancer. Tumor PTEN deficiency status was prospectively determined by central testing using the immunohistochemistry-based VENTANA PTEN (SP218) RxDx Assay; PTEN deficiency was defined as ≥ 90% of viable malignant cells with no specific cytoplasmic staining. Patients were randomized 1:1 to receive either capivasertib with abiraterone or placebo with abiraterone. Abiraterone was administered with either prednisone or prednisolone.

The major efficacy outcome measure was investigator-assessed radiographic progression-free survival (rPFS). Overall survival (OS) was an additional efficacy outcome measure."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-capivasertib-abiraterone-and-prednisone-pten-deficient-androgen-pathway-modulation

RTP RESEARCH TO PRACTICE

FDA Approves Durvalumab in Combination with Bacillus Calmette-Guérin for High-Risk Non-Muscle-Invasive Bladder Cancer

Press Release: May 28, 2026

"On May 28, 2026, the Food and Drug Administration approved durvalumab in combination with Bacillus Calmette-Guerin (BCG) for the treatment of adult patients with BCG-naïve, high-risk non-muscle invasive bladder cancer (NMIBC).

Efficacy was evaluated in the POTOMAC study (NCT03528694), a randomized, open-label, multicenter trial that enrolled 1,018 patients with high-risk NMIBC following transurethral resection of bladder tumor. High-risk NMIBC was defined as having one of the following: T1 tumor, Grade 3/high-grade tumor, carcinoma in situ (CIS), or multiple, recurrent, and large tumors. Patients were randomized (1:1:1) to receive either durvalumab every four weeks for 13 cycles plus BCG induction and maintenance, BCG induction and maintenance, or an additional investigational combination regimen.

The major efficacy outcome measure was investigator-assessed disease-free survival (DFS). DFS was defined as the time from the date of randomization until the date of first recurrence of high-risk NMIBC, persistent CIS, muscle invasive bladder cancer, metastatic disease, or death."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-combination-bacillus-calmette-guerin-high-risk-non-muscle-invasive-bladder

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Perioperative Durvalumab with Neoadjuvant Enfortumab Vedotin Demonstrated Statistically Significant and Clinically Meaningful Improvements in Event-Free Survival and Overall Survival for Muscle-Invasive Bladder Cancer in the Phase III VOLGA Trial

Press Release: May 14, 2026

"High-level results from a planned interim analysis of the VOLGA Phase III trial showed perioperative treatment with durvalumab in combination with neoadjuvant enfortumab vedotin (EV) demonstrated statistically significant and clinically meaningful improvements in event-free survival (EFS) and overall survival (OS) in patients with muscle-invasive bladder cancer (MIBC) versus standard of care. Patients were ineligible for or had declined cisplatin-based chemotherapy. Patients in the comparator arm had a radical cystectomy (surgery to remove the bladder) with or without approved adjuvant treatment.

Perioperative durvalumab plus tremelimumab in combination with neoadjuvant EV demonstrated a statistically significant and clinically meaningful improvement in EFS and a favourable trend for OS; however, the OS data were not statistically significant at this planned interim analysis and will be formally reassessed at a subsequent analysis."

https://www.astrazeneca.com/media-centre/press-releases/2026/imfinzi-ev-improves-efs-os-in-bladder-cancer.html

RTP RESEARCH TO PRACTICE

FDA Approves Pembrolizumab or Pembrolizumab and Berahyaluronidase Alfa-pmph, Each with Enfortumab Vedotin, for Muscle-Invasive Bladder Cancer

Press Release: July 10, 2026

"On July 10, 2026, the Food and Drug Administration approved pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph each in combination with enfortumab vedotin-ejfv as neoadjuvant treatment (before surgery) followed by adjuvant treatment after cystectomy (surgery to remove the bladder) for adults with muscle invasive bladder cancer (MIBC). This extends the prior approval for the regimen in this setting from patients who are cisplatin-ineligible to all patients with MIBC who are candidates for cystectomy.

Efficacy was evaluated in KEYNOTE-B15/EV-304 (NCT04700124), an open-label, randomized, active-controlled, multicenter trial in 808 patients with previously untreated MIBC who were candidates for radical cystectomy with pelvic lymph node dissection and were eligible for cisplatin-based chemotherapy. Patients were randomized (1:1) to receive neoadjuvant pembrolizumab and enfortumab vedotin-ejfv followed by surgery followed by adjuvant pembrolizumab and enfortumab vedotin-ejfv or to neoadjuvant gemcitabine and cisplatin followed by surgery.

The major efficacy outcome measure was event-free survival (EFS) assessed by blinded independent central review. Overall survival (OS) was an additional efficacy outcome. The trial demonstrated statistically significant improvements in EFS and OS in patients treated with perioperative pembrolizumab and enfortumab vedotin-ejfv compared with neoadjuvant gemcitabine and cisplatin."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-or-pembrolizumab-and-berahyaluronidase-alfa-pmph-each-enfortumab-vedotin

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FDA Approves Atezolizumab for Adjuvant Treatment of Muscle-Invasive Bladder Cancer in Patients with Molecular Residual Disease

Press Release: May 15, 2026

"On May 15, 2026, the Food and Drug Administration approved atezolizumab and atezolizumab and hyaluronidase-tqjs as adjuvant treatments for adults with muscle invasive bladder cancer (MIBC) after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test.

Efficacy was evaluated in IMvigor011 (NCT04660344), a multi-center, randomized, double-blind, placebo-controlled trial enrolling 250 patients with MIBC who had radical cystectomy with lymph node dissection and in whom MRD was detected by serial ctDNA MRD evaluation of blood during the subsequent 12 months, starting at least 6 weeks after cystectomy. Patients were randomized (2:1) to receive either atezolizumab 1680 mg or placebo intravenously every four weeks. Treatment continued for up to 12 cycles or one year (whichever occurred first) unless there was disease recurrence or unacceptable toxicity.

The major efficacy outcome measure was investigator-assessed disease-free survival (DFS). Overall survival (OS) was an additional efficacy outcome measure."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-adjuvant-treatment-muscle-invasive-bladder-cancer-patients-molecular

RTP RESEARCH TO PRACTICE

FDA Approves Belzutifan and Pembrolizumab for Adjuvant Treatment of Renal Cell Carcinoma

Press Release: June 12, 2026

"On June 12, 2026, the Food and Drug Administration approved belzutifan in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the adjuvant treatment of adults with renal cell carcinoma with a clear cell component (ccRCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

Efficacy was evaluated in LITESPARK-022 (NCT05239728), a multicenter, double-blind, randomized trial in 1,841 patients with prior nephrectomy for ccRCC who were at intermediate-high or high risk of recurrence, or who had resected metastases with no evidence of disease. Patients were randomized (1:1) to receive belzutifan in combination with pembrolizumab as adjuvant therapy or placebo in combination with pembrolizumab until disease recurrence or unacceptable toxicity or for up to 54 weeks of belzutifan or 12 months of pembrolizumab.

The major efficacy outcome measure was investigator-assessed disease-free survival (DFS), defined as time to recurrence, metastasis, or death."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-belzutifan-pembrolizumab-adjuvant-treatment-renal-cell-carcinoma

RTP RESEARCH TO PRACTICE

Year in Review
GU Cancers

Prostate Cancer	Urothelial Bladder Cancer	Renal Cell Carcinoma
• **mAPMN or mAPMS** - PARPi (niraparib, talazoparib) - AKTi (capivasertib) - Radiopharmaceuticals (lutetium-177) • **ADT intensification** **PROTEUS trial**	• **EV/pembrolizumab** • **Anti-HER2 (T-DXd)** • **ctDNA** • **Intravesical therapy** • **Immunotherapy (durvalumab) + BCG for non-muscle-invasive disease**	• **Adjuvant belzutifan** • **Belzutifan after IO for metastatic disease**

Hope S Rugo, MD

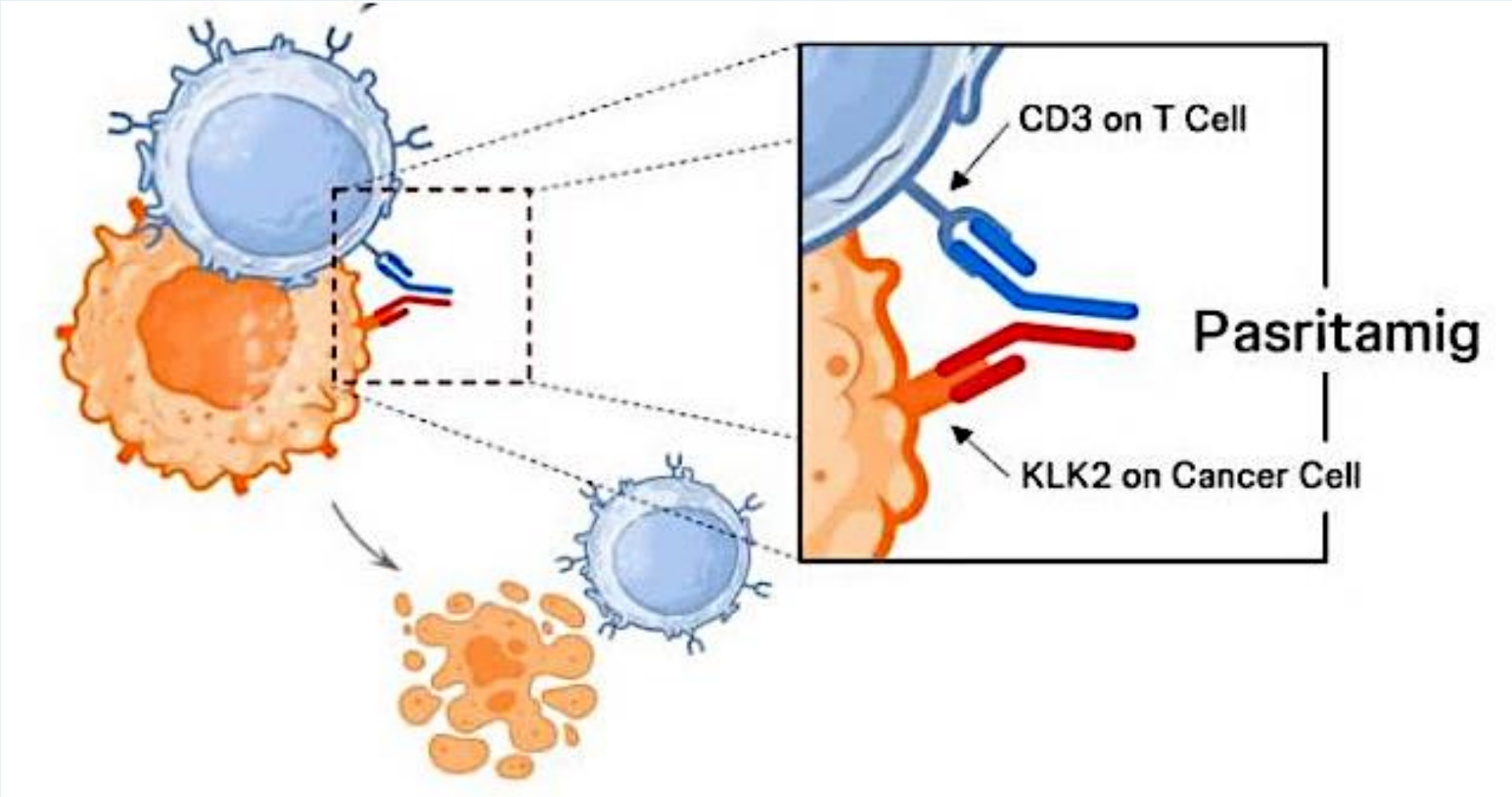
Virginia Kaklamani, MD, DSc

TPS5139

KLK2-PASenger: A Phase 3 Randomized, Open-label Study of Pasritamig, a T-cell-engager, Targeting Human Kallikrein 2 with Docetaxel versus Docetaxel in Metastatic Castration-resistant Prostate Cancer

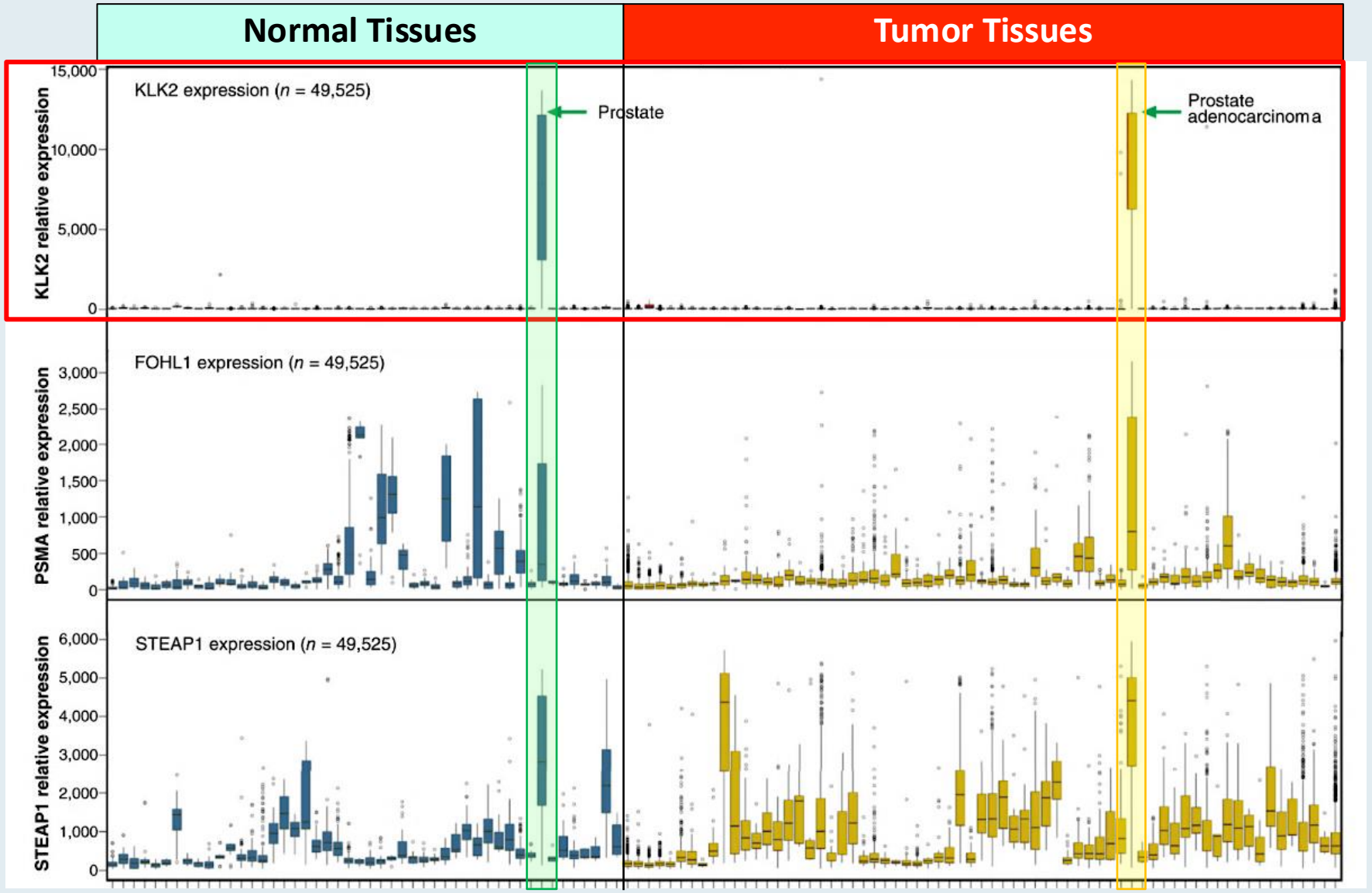
McKay R et al. ASCO 2026;Abstract TPS5139.

Pasritamig Mechanism of Action



McKay R et al. ASCO 2026;Abstract TPS5139.

KLK2 Is Highly Expressed on Prostate Cells (Normal and Malignant)



Shen F et al. *Clin Cancer Res* 2025 November 3;31(21):4543-56.

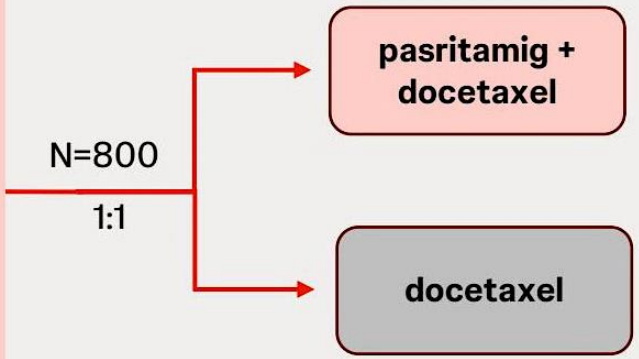
Phase III KLK2-PASenger

Key Eligibility

- Histologically confirmed adenocarcinoma of the prostate
- Evidence of metastatic disease on conventional imaging and PSA or radiographic progression at screening
- Progression on 1-2 novel ARPI for any stage of prostate cancer
- No prior treatment with T-cell redirecting therapies, chemotherapy, or radiopharmaceutical therapy
- No significant comorbidities that could interfere with study participation.

Study design

Figure 3: A global, randomized, open-label, phase 3 study evaluates the efficacy and safety of PAS + DOCE versus DOCE alone in adult chemo-naïve participants (≥18 years) with mCRPC (NCT07225946).



Primary endpoint: rPFS by BICR per PCWG3 and RECIST v1.1 criteria.

Key secondary endpoints:

- OS
- Time to symptomatic progression
- Time to subsequent therapy
- Time to skeletal-related event

Stratification factors:

- sites of metastases (on conventional imaging)
- LDH
- ECOG PS
- prior PARP inhibitor use

- PAS is administered in the outpatient setting at a target dose of 300 mg IV Q6W with two step-up doses of 3.5 mg IV on day 1 and 18 mg IV on day 8.
- DOCE is planned for 10 doses in both arms unless limited by toxicity despite optimal supportive care.
- Pre-medications including dexamethasone are administered in both treatment arms
- Participants in the DOCE alone arm will also receive continuous prednisone per label.

APMR = androgen pathway modulation-resistant; ARPI = androgen receptor pathway inhibitors; CD3 = cluster of differentiation 3; DOCE = docetaxel; KLK2 = human kallikrein 2; mCRPC = metastatic castration-resistant prostate cancer; PAS = pasritamig; PCWG= Prostate Cancer Clinical Trials Working Group; PARP = poly ADP-ribose polymerase; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen; rPFS = radiographic progression free survival; RECIST 1.1 = Response Evaluation Criteria in Solid Tumors 1.1

McKay R et al. ASCO 2026;Abstract TPS5139.

Agenda

Introduction: Welcome GU Oncology Fellows!

Module 1: Prostate Cancer — Dr Aggarwal

Module 2: Urothelial Bladder Cancer — Dr Galsky

Module 3: Renal Cell Carcinoma — Dr Zhang

UCSF Helen Diller Family Comprehensive Cancer Center

Post-ASCO 2026 Webinar: Prostate Cancer

Rahul Aggarwal MD
Professor of Medicine
University of California San Francisco

Outline

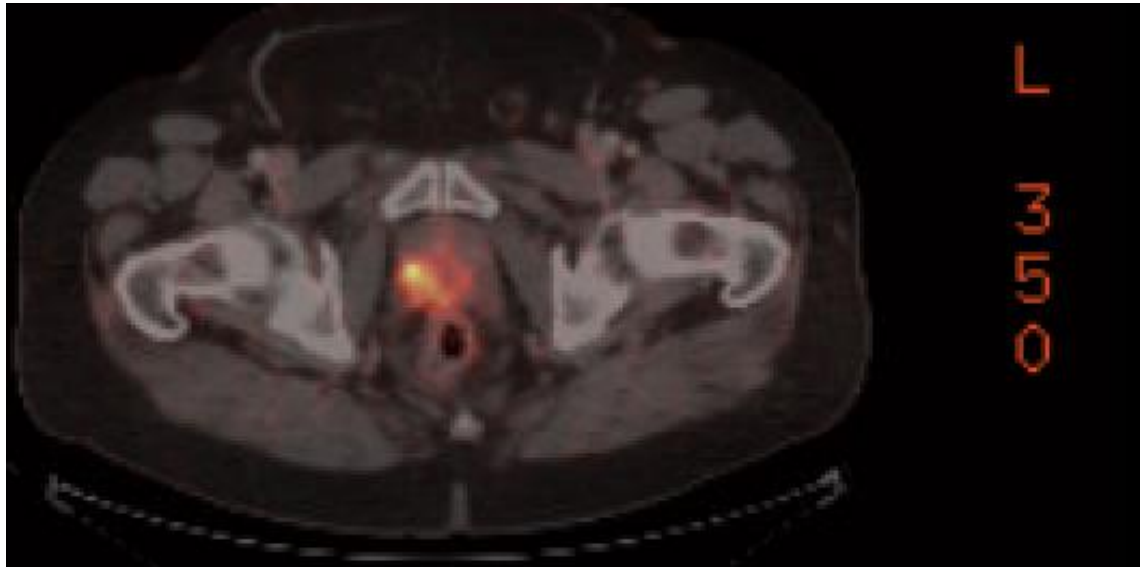
- Androgen pathway inhibition in hormone-sensitive prostate cancer
- Novel triplets in metastatic hormone sensitive prostate cancer
- Updates in PSMA-targeted radioligand therapy

Outline

- Androgen pathway inhibition in hormone-sensitive prostate cancer
  - Taplin ME et al. Final Analysis of the PROTEUS phase 3 study ASCO 2026; Abstract LBA1
  - Freedland S et al. EMBARK: Testosterone recovery to > 250 ng/dL following treatment suspension. ASCO 2026; Abstract 5088
  - Choudhury A et al. Phase 2 trial of ADT interruption (A-DREAM / Alliance A032101) ASCO 2026; Abstract 5004

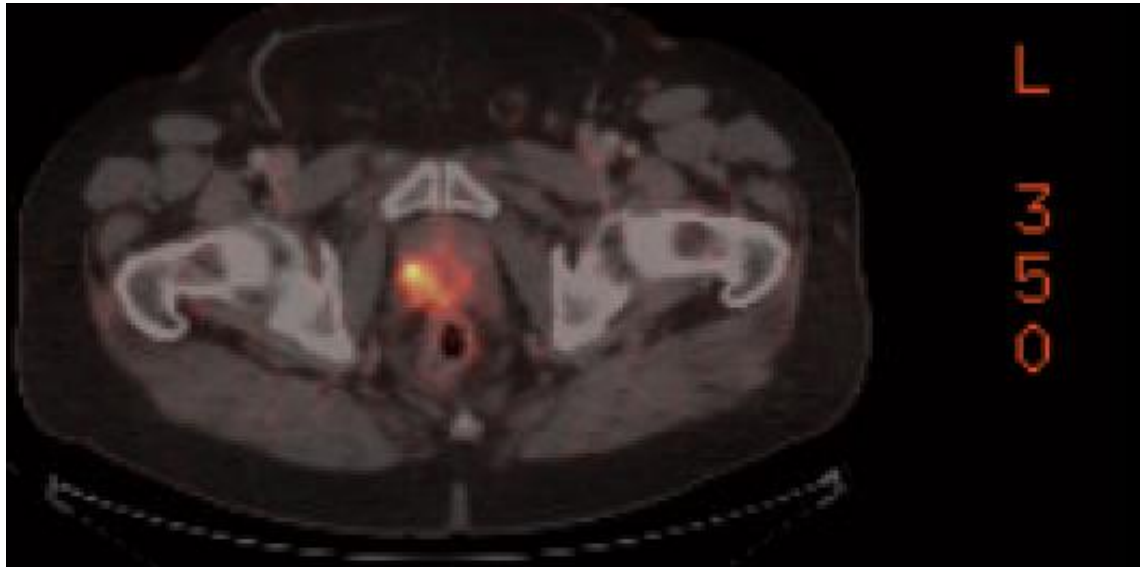
Case #1: High-risk localized prostate cancer

- 64 y/o M presented with elevated screening PSA of 16.4 ng/mL (prior PSA of 3.3 in 2023)
- No significant urinary symptoms
- TRUS biopsy with Gleason 4+5 prostate cancer noted in 9/13 cores
- Staging PSMA PET with uptake in prostate gland and bilateral pelvic nodes



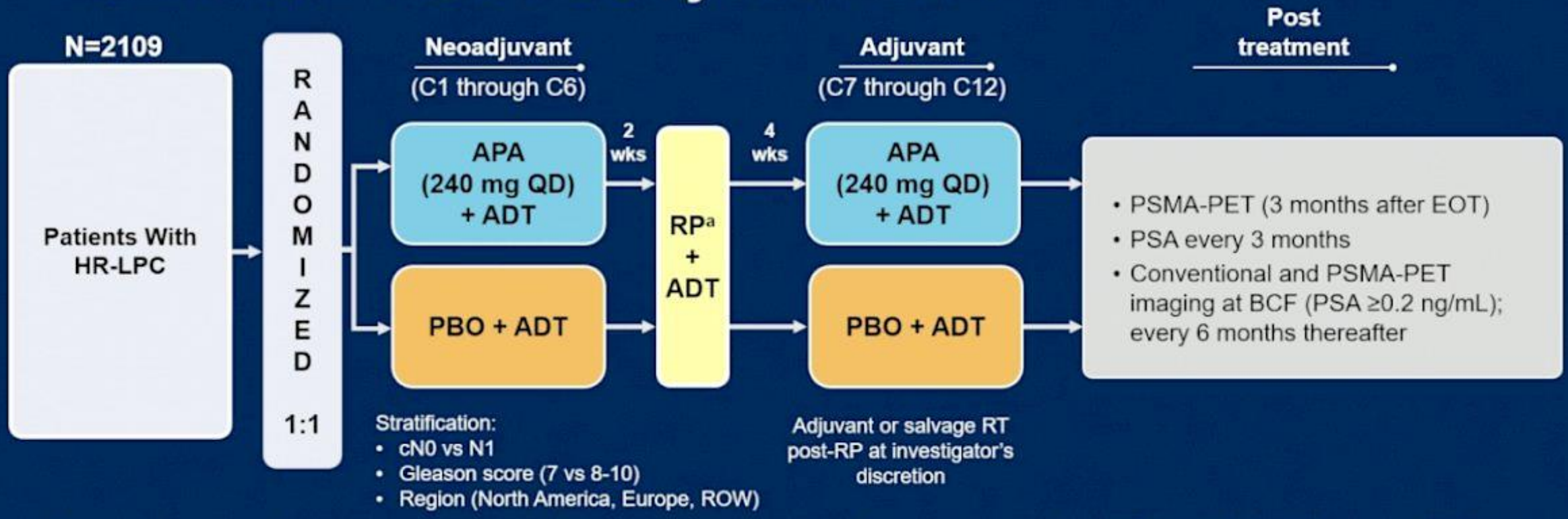
Case #1: High-risk localized prostate cancer

- Patient opted to receive ADT + abiraterone/prednisone for 24 months in combination with radiation to the prostate + pelvis



- Future state: Multi-modal treatment with upfront surgery?
  - Multimodal treatment with peri-operative ADT + apalutamide with radical prostatectomy (PROTEUS regimen)

PROTEUS: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study in HR-LPC

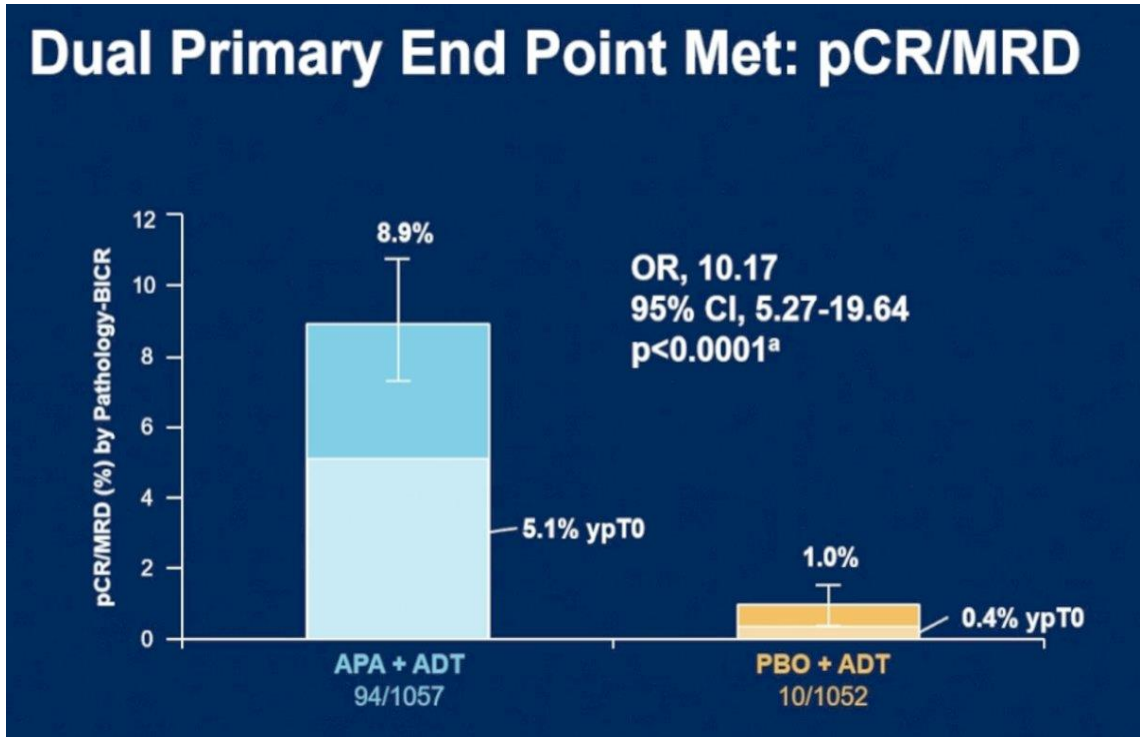


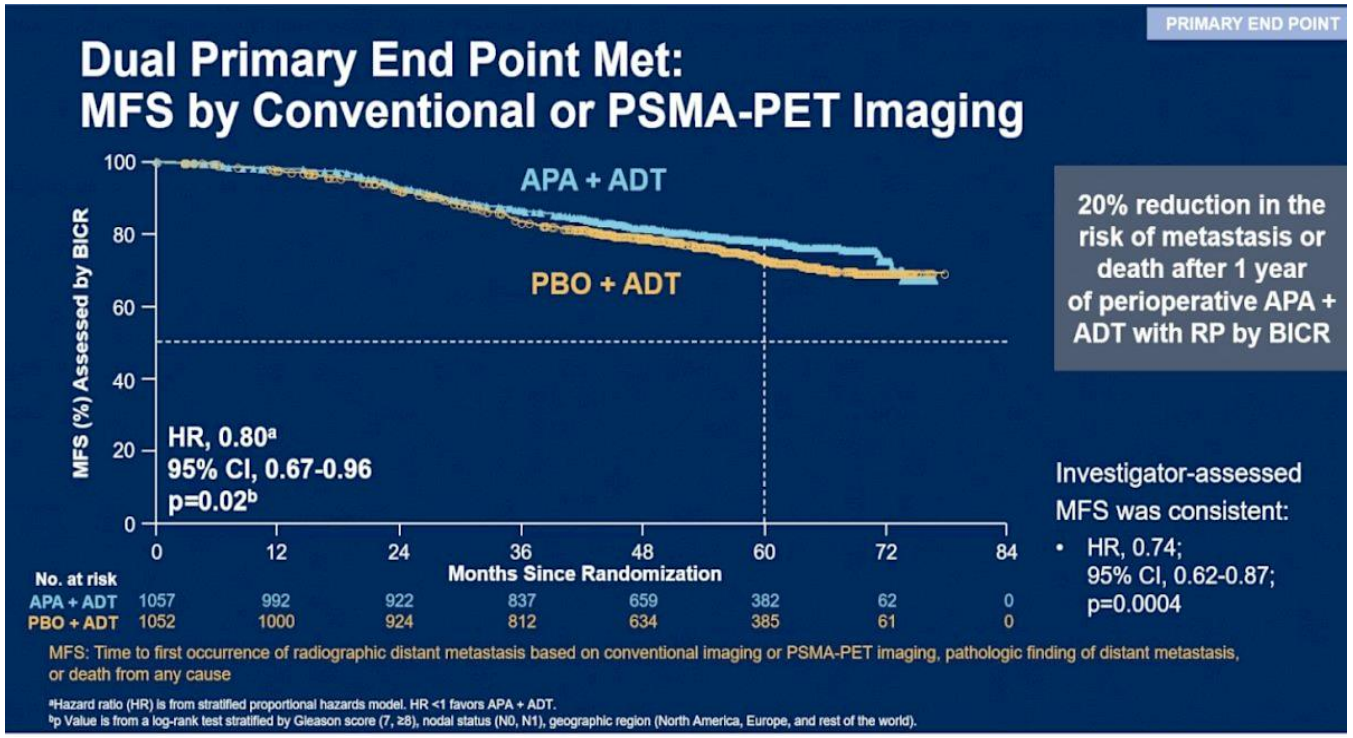
- To complement these data, a substudy is ongoing to further inform on the role of APA + ADT + RP versus RP alone

Patients randomized from July 15, 2019, to June 30, 2022.
Protocol Amendment 7 for including PSMA-PET into MFS assessment (April 14, 2022).

APA, apalutamide; BCF, biochemical failure; C, cycle; EOT, end of treatment; PBO, placebo; PSA, prostate-specific antigen; PSMA-PET, prostate-specific membrane antigen positron emission tomography; QD, daily; ROW, rest of the world; RT, radiation therapy.
[a]APA/PBO is stopped 2 weeks prior to planned RP and then resumed 4 weeks after RP. Cardiovascular risk prophylaxis and venous thromboembolism prophylaxis given based on risk.

PROTEUS: Primary Endpoints





Taplin ME et al. ASCO 2026

PROTEUS: Safety Results

Frequency of Treatment-Related Adverse Events

	Safety Population, n (%)	APA + ADT (n=1050)	PBO + ADT (n=1050)
All grades	Treatment-related AE	1000 (95.2)	985 (93.8)
Grade 3/4	Treatment-related AEs	289 (27.5)	198 (18.9)
	Treatment-related AEs leading to dose reduction[a]	118 (11.2)	24 (2.3)
	Treatment-related AEs leading to dose interruption[a]	126 (12.0)	46 (4.4)
All grades	Treatment-related AEs leading to death[b]	7 (0.7)	1 (0.1)

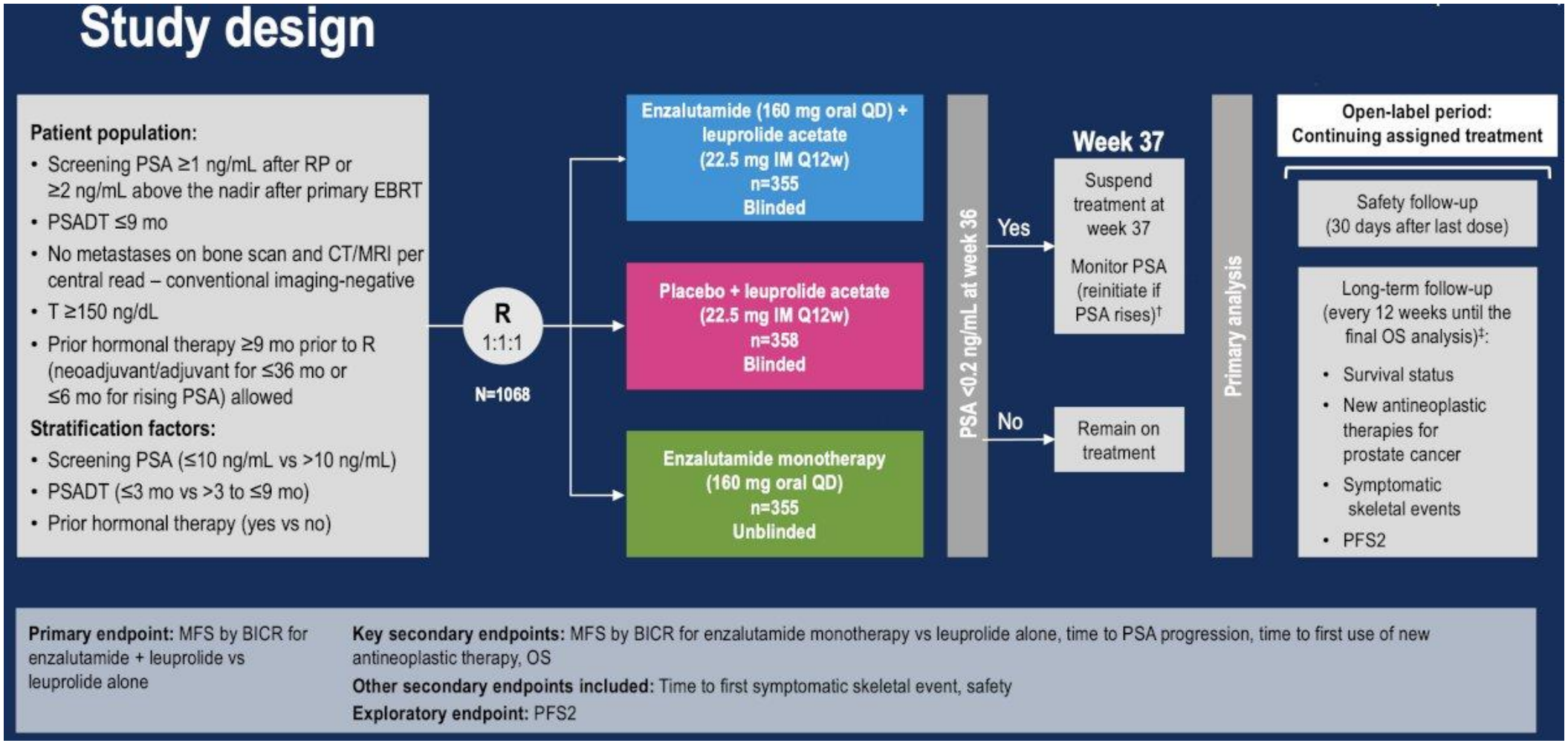
Treatment-Emergent Adverse Events of Special Interest

Special Interest Category, n (%)	APA + ADT (n=1050)		PBO + ADT (n=1050)	
	All Grades	Grade ≥3	All Grades	Grade ≥3
≥1 TEAE of special interest	398 (37.9)	90 (8.6)	214 (20.4)	23 (2.2)
Skin rash	346 (33.0)	62 (5.9)	161 (15.3)	3 (0.3)
Fall	34 (3.2)	6 (0.6)	29 (2.8)	5 (0.5)
Ischemic heart disease	25 (2.4)	13 (1.2)	22 (2.1)	9 (0.9)
Nonpathological fracture	22 (2.1)	6 (0.6)	19 (1.8)	5 (0.5)
Cerebrovascular disorders	8 (0.8)	5 (0.5)	13 (1.2)	6 (0.6)
Seizure	2 (0.2)	2 (0.2)	1 (0.1)	0
Fatigue	291 (27.7)	4 (0.4)	281 (26.8)	1 (0.1)

TEAE, treatment-emergent AE.
TEAEs are those that occurred on or after the first dose of study drug through the last dose of study treatment plus 30 days or prior to the start of subsequent therapy, whichever is earlier, or any AE that is considered treatment related regardless of the start date of the event. Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. The event with the worst toxicity grade is used. If a patient has all adverse events with missing toxicity grades, the patient is only counted in the total column.

Taplin ME et al. ASCO 2026

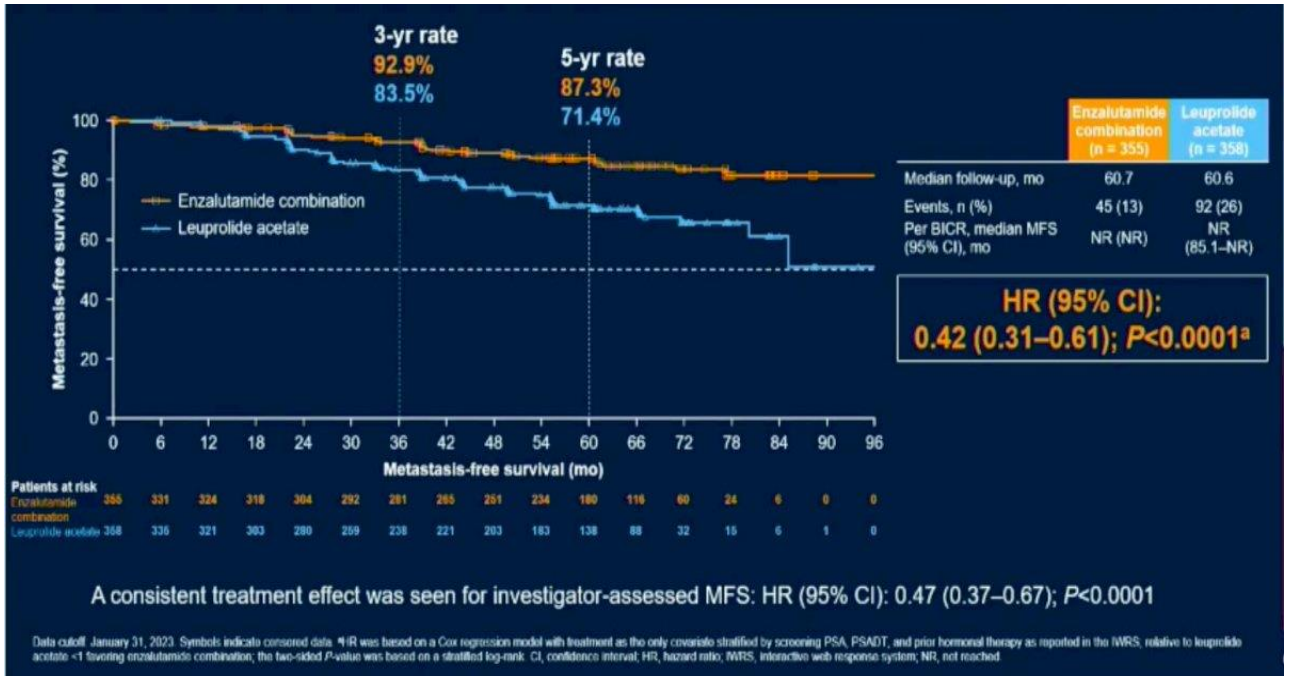
EMBARK: Phase 3 study in biochemical relapse



Freedland S et al. AUA 2023

EMBARK: Primary Efficacy Results

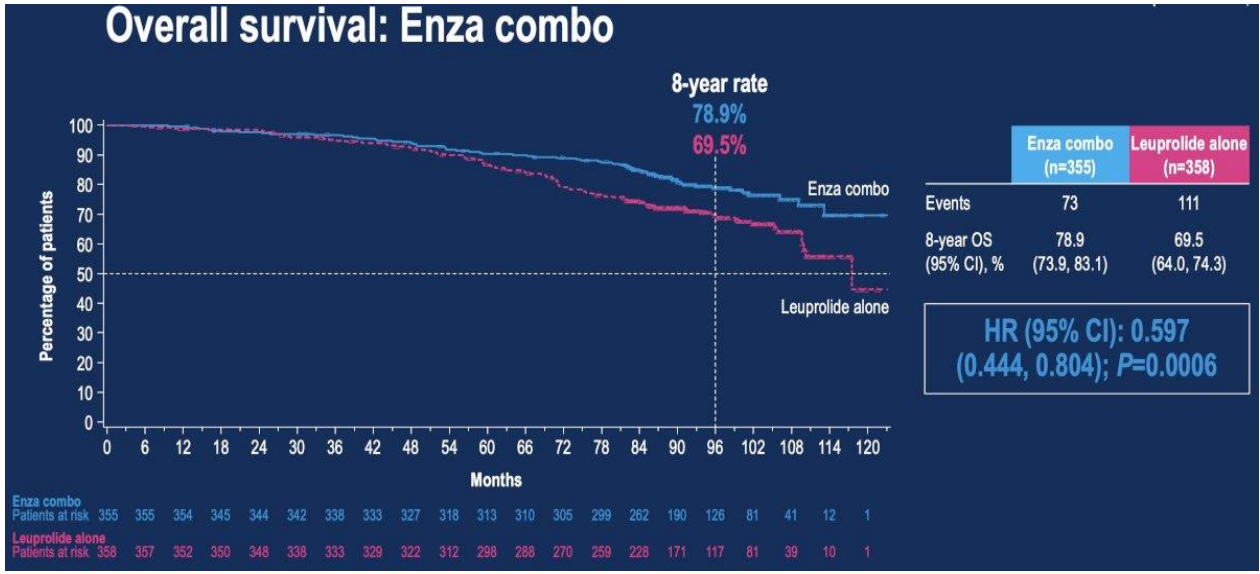
Metastasis-free survival



A consistent treatment effect was seen for investigator-assessed MFS: HR (95% CI): 0.47 (0.37–0.67); *P*<0.0001

Data cutoff: January 31, 2023. Symbols indicate censored data. aHR was based on a Cox regression model with treatment as the only covariate stratified by screening PSA, PSADT, and prior hormonal therapy as reported in the IWRS, relative to leuprolide acetate <1 favoring enzalutamide combination; the two-sided *P*-value was based on a stratified log-rank. CI, confidence interval; HR, hazard ratio; IWRS, interactive web response system; NR, not reached.

Overall survival



Freedland S et al. AUA 2023

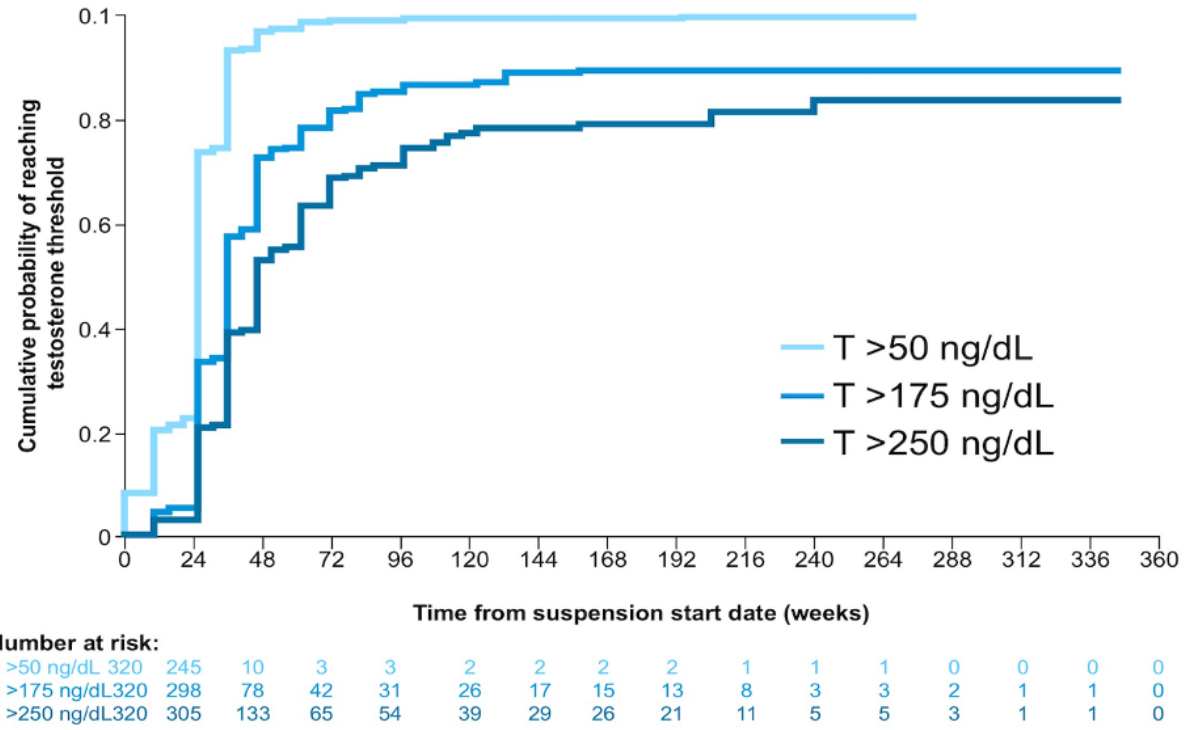
EMBARK: Testosterone recovery following treatment break

90% of patients in combination arm had treatment cessation at 37 weeks

Table 1. Time to testosterone recovery in patients with treatment suspension

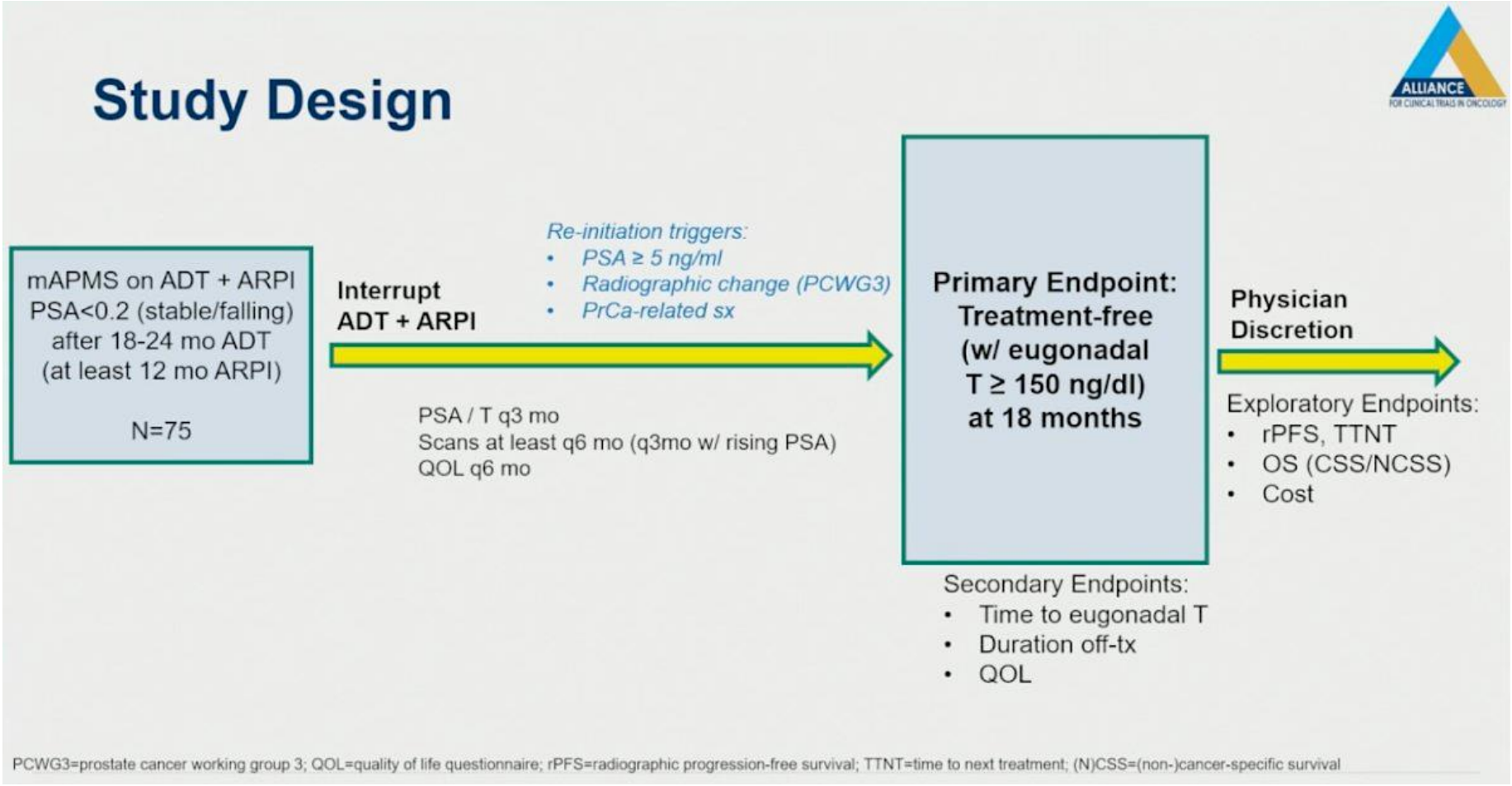
	Enzalutamide combination (n=320)
Patients who reached T recovery (>250 ng/dL), n (%)	108 (33.8)
Time to T recovery (>250 ng/dL), months†	
Median (range)	5.6 (0.0–22.1)
Mean (SD)	6.8 (2.87)

Figure 2. Cumulative probability of reaching testosterone thresholds among patients with treatment suspension after 37 weeks of enzalutamide + leuprolide



Freedland S et al. ASCO 2026

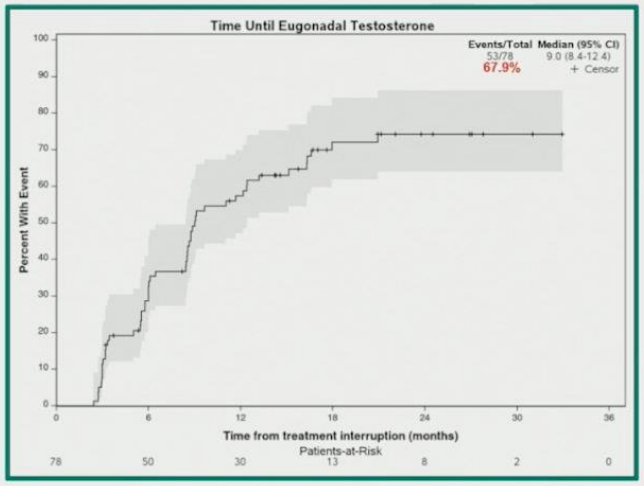
A-DREAM: Treatment interruption in metastatic HSPC with optimal PSA nadir



Choudhury A et al. ASCO 2026

A-DREAM: Treatment interruption in metastatic HSPC with optimal PSA nadir

Testosterone Recovery and Patient Disposition



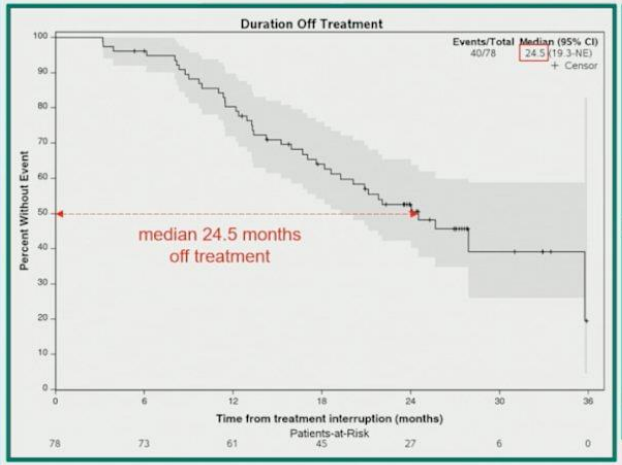
Testosterone recovery (≥150) by 18 months	**52 (66.7%)**
Treatment-free for 18 months	**45 (57.7%)**
Treatment-free for 18 months with T recovery (**primary endpoint**)	**32 (41.0%)***

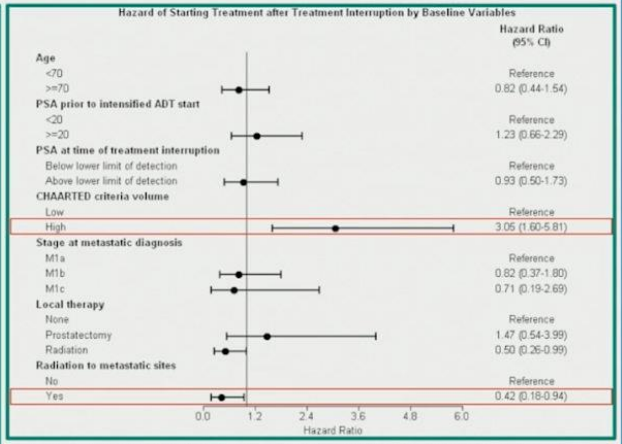
At 26.9 months median follow-up:

Did not interrupt treatment	**0 (0.0%)**
Continuing on treatment interruption	**30 (38.5%)**
Resumed ADT+initial ARPI after meeting resumption criteria per protocol	**29 (37.2%)**
Resumed ADT+initial ARPI prior to meeting resumption criteria	**5 (6.4%)**
Withdrawal before starting another treatment	**6 (7.7%)**
Death before starting another treatment	**1 (1.3% - MI)**
Started non-protocol treatment	**7 (9.0%)**
Radiation therapy	4 (5.1%)
Different ARPI	2 (2.6%)
Carboplatin+etoposide	1 (1.3%)

*80% CI 33.1-48.9%, one-sided p 0.0249

Duration Off Treatment





Low volume disease and prior RT to mets were associated with lower likelihood of requiring cancer-directed therapy (including ADT+ARPI resumption) after treatment interruption

Choudhury A et al. ASCO 2026

Outline

- Androgen pathway inhibition in hormone-sensitive prostate cancer
- Novel triplets in metastatic hormone sensitive prostate cancer
- Updates in PSMA-targeted radioligand therapy

Tailored Approach to Metastatic HSPC

Emerging Therapeutic Strategies

Metastatic Hormone Sensitive Prostate Cancer

Favorable Factors

- Low Volume by metabolic imaging
- PSA Nadir ≤ 0.2 ng/mL
- *PTEN/TP53/RB1* wild type
- *SPOP* mutant

Intermittent ADT + ARPI + Local Treatment + Metastasis-Directed Treatment (if oligometastatic)

Adverse Factors

- High volume
- PSA Nadir > 0.2 ng/mL
- *PTEN/TP53/RB1* mutant
- *BRCA2* mutant

Continuous ADT + ARPI backbone PLUS

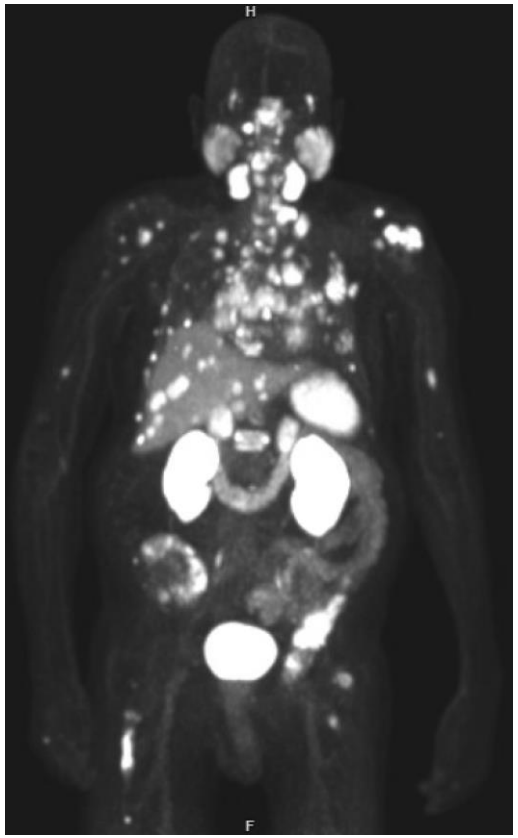
Docetaxel (adverse factors) OR Capivasertib (PTEN loss) OR Niraparib (BRCA2)

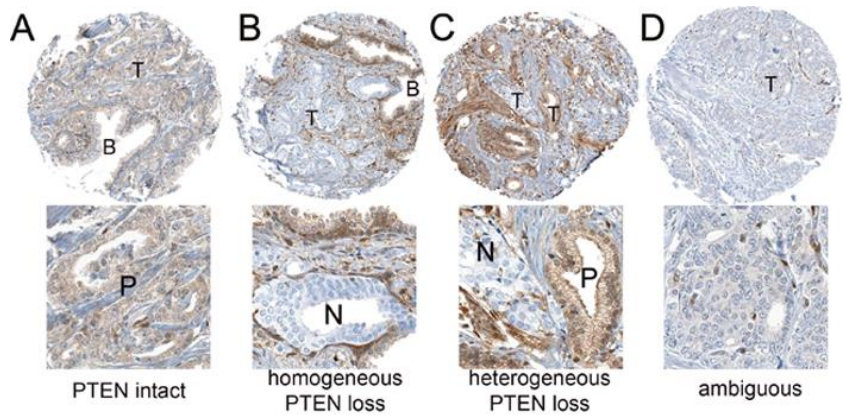
Outline

- Novel triplets in metastatic hormone sensitive prostate cancer
  - Phase III CAPItello-281 trial in PTEN-deficient mHSPC
  - Agarwal N, et al. TALAPRO-3 in mHSPC with HRR gene alterations. ASCO 2026; Abstract LBA5007
  - Phase III AMPLITUDE trial of niraparib plus abiraterone/prednisone in BRCA2-altered mHSPC

Case #2: PTEN-deficient mHSPC

- 57 y/o M presented with urinary obstructive symptoms for the past 3 months along with low back pain
- TRUS biopsy with Gleason 4+5 prostate cancer noted in 9/13 cores
- NGS (UCSF500): **PTEN deletion**, TP53 mutation, MSS, TMB 2.1 mut/MB
- PTEN IHC staining showed loss of expression in 95% of tumor
- PSMA PET with multifocal osseous uptake, uptake in primary tumor, hepatic and pulmonary metastases





CAPItello-281 Study Design

A global, multicentre, randomized, double-blind, Phase 3 study

Patients with PTEN deficient *de novo* mHSPC

- PTEN deficiency: (diagnostic cut-off of **≥90%** of viable malignant cells with **no specific cytoplasmic staining** by IHC)*
  - i.e. ≤10% of cells expressing PTEN by IHC

Of ~6,200 patients submitting tumour tissue **97%** had a valid IHC result and **25%** were **PTEN deficient**

1,012 patients (R 1:1)

Capivasertib	400 mg BID 4 days on, 3 days off
Abiraterone/pred + ADT	1000 mg/5 mg QD + ADT
Placebo	400 mg BID 4 days on, 3 days off
Abiraterone/pred + ADT	1000 mg/5 mg QD + ADT

Primary endpoint

- **Investigator assessed rPFS**

Secondary endpoints

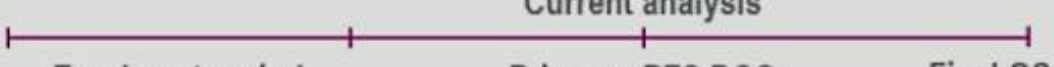
- Overall survival
- Time to first subsequent therapy
- Symptomatic skeletal-event free survival
- Time to pain progression
- Time to castration resistance
- Time to PSA progression

Exploratory *post-hoc* PTEN deficiency subgroups

Stratification factors:†

- M1 volume (CHAARTED criteria) and visceral mets
- Geography

Study timeline

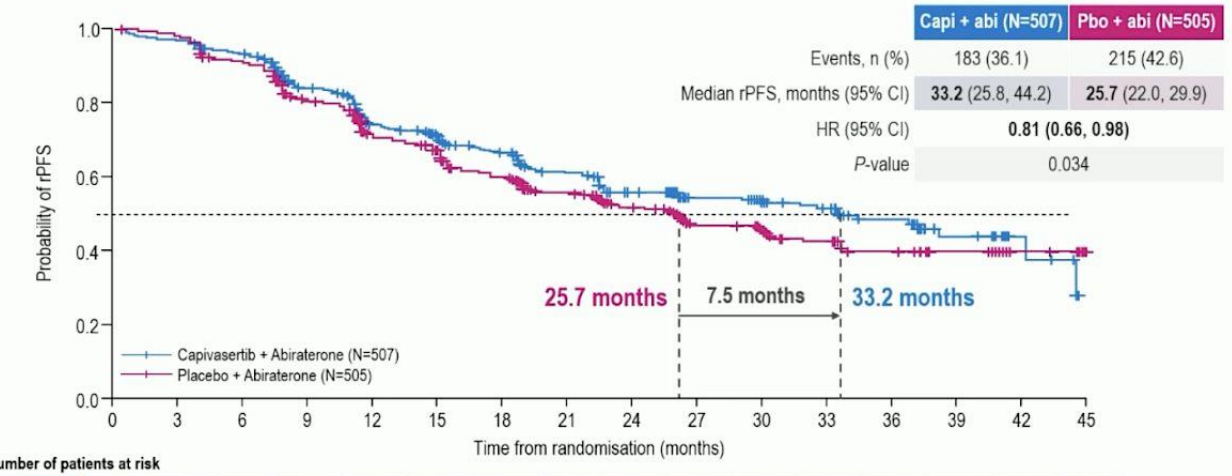


Enrolment period	Primary rPFS DCO	Final OS DCO
13 July 2020–5 Feb 2024	7 Oct 2024 Median rPFS follow-up:‡ ~18 mo	Planned for 522 deaths (52.2% maturity)

Fizazi K et al. ESMO 2025

CAPItello-281 Primary Results

CAPItello-281 Primary endpoint: investigator-assessed rPFS

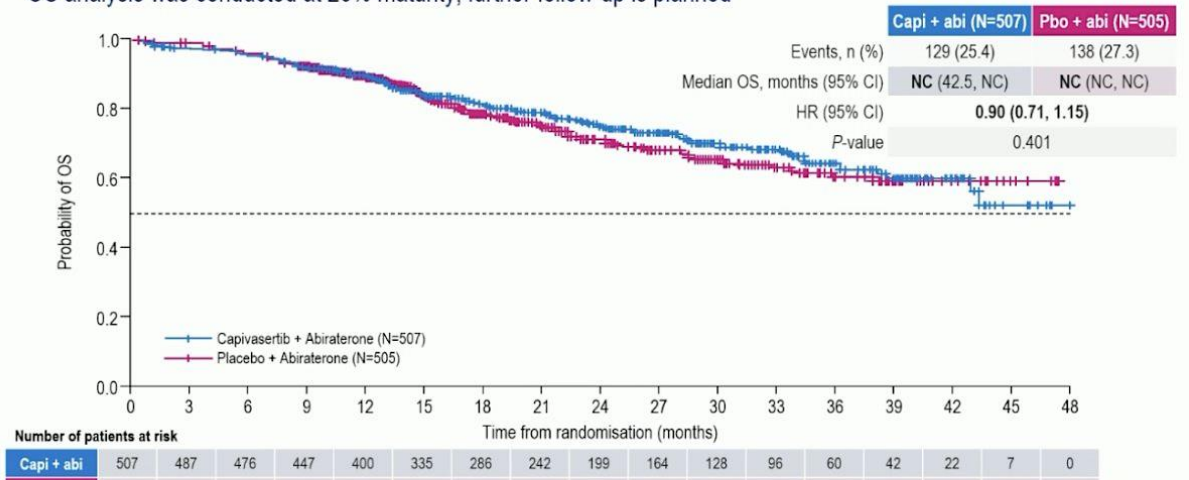


Number of patients at risk

Capi + abi	507	460	435	353	282	233	217	165	123	93	69	62	41	21	6	0
Pbo + abi	505	479	440	359	276	215	198	154	113	83	59	51	37	23	8	0

CAPItello-281: Interim OS

OS analysis was conducted at 26% maturity, further follow-up is planned



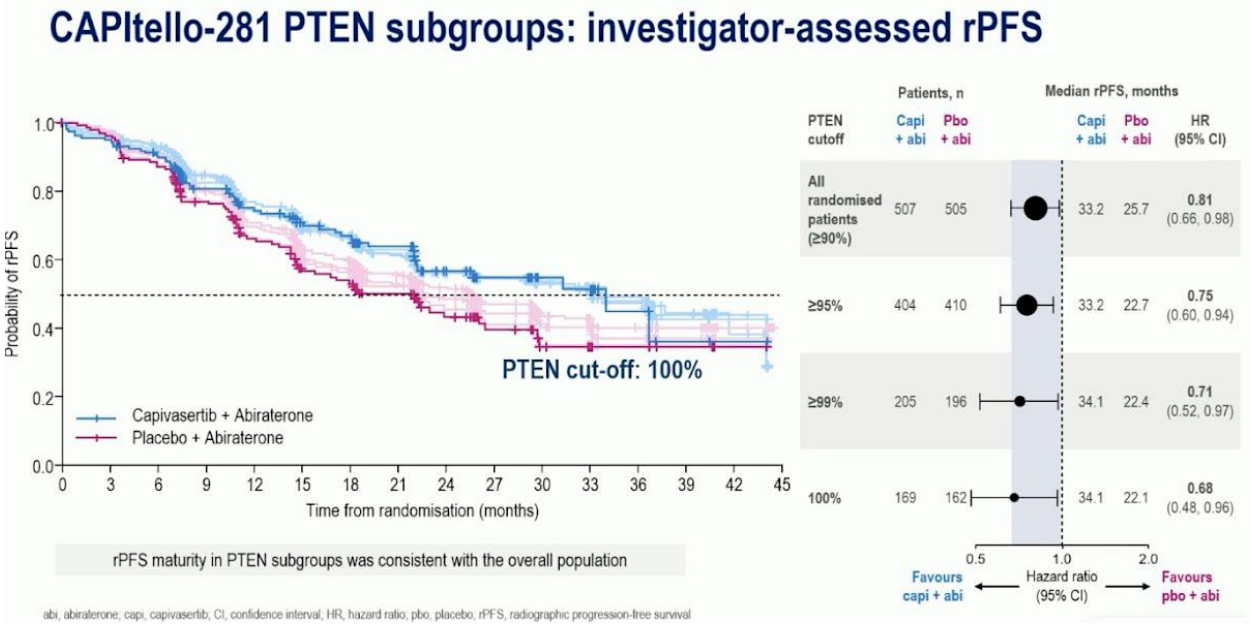
Number of patients at risk

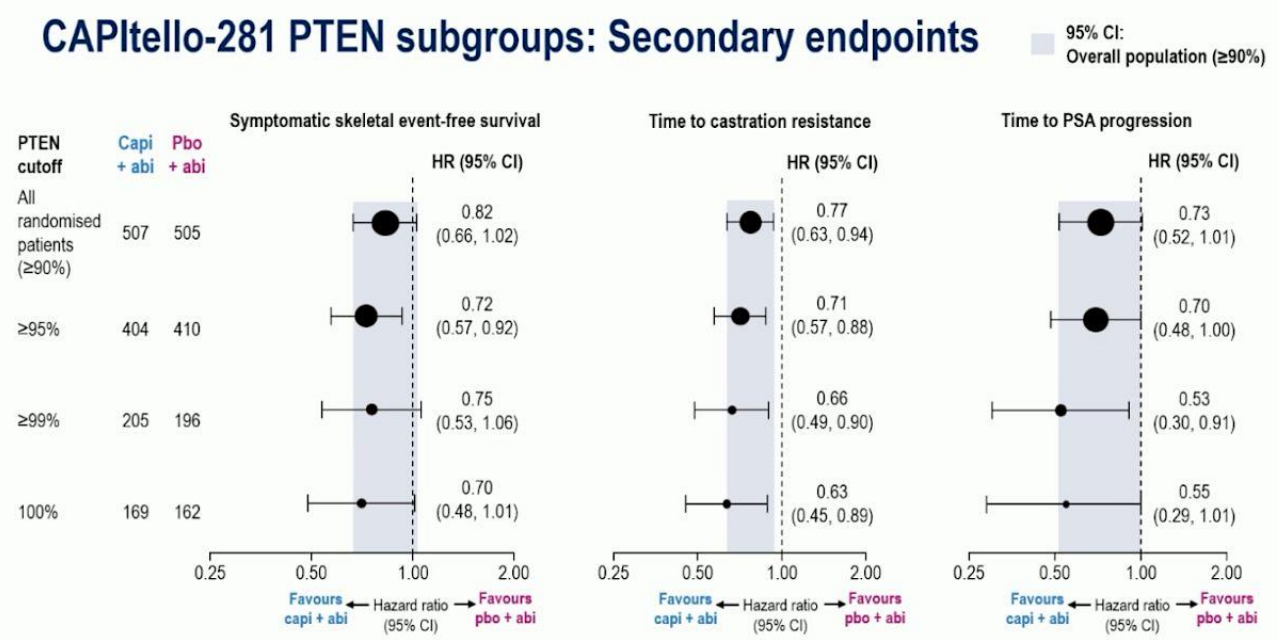
Capi + abi	507	487	476	447	400	335	286	242	199	164	128	96	60	42	22	7	0
Pbo + abi	505	494	479	449	388	330	273	227	188	153	113	88	56	33	19	7	0

A stratified log-rank test was used to calculate two-sided P values. HRs and 95% CIs were calculated using a stratified Cox proportional-hazards model.
CI, confidence interval; HR, hazard ratio; NC, not calculable; OS, overall survival; pbo, placebo

Fizazi K et al. ESMO 2025

CAPItello-281 Primary Results



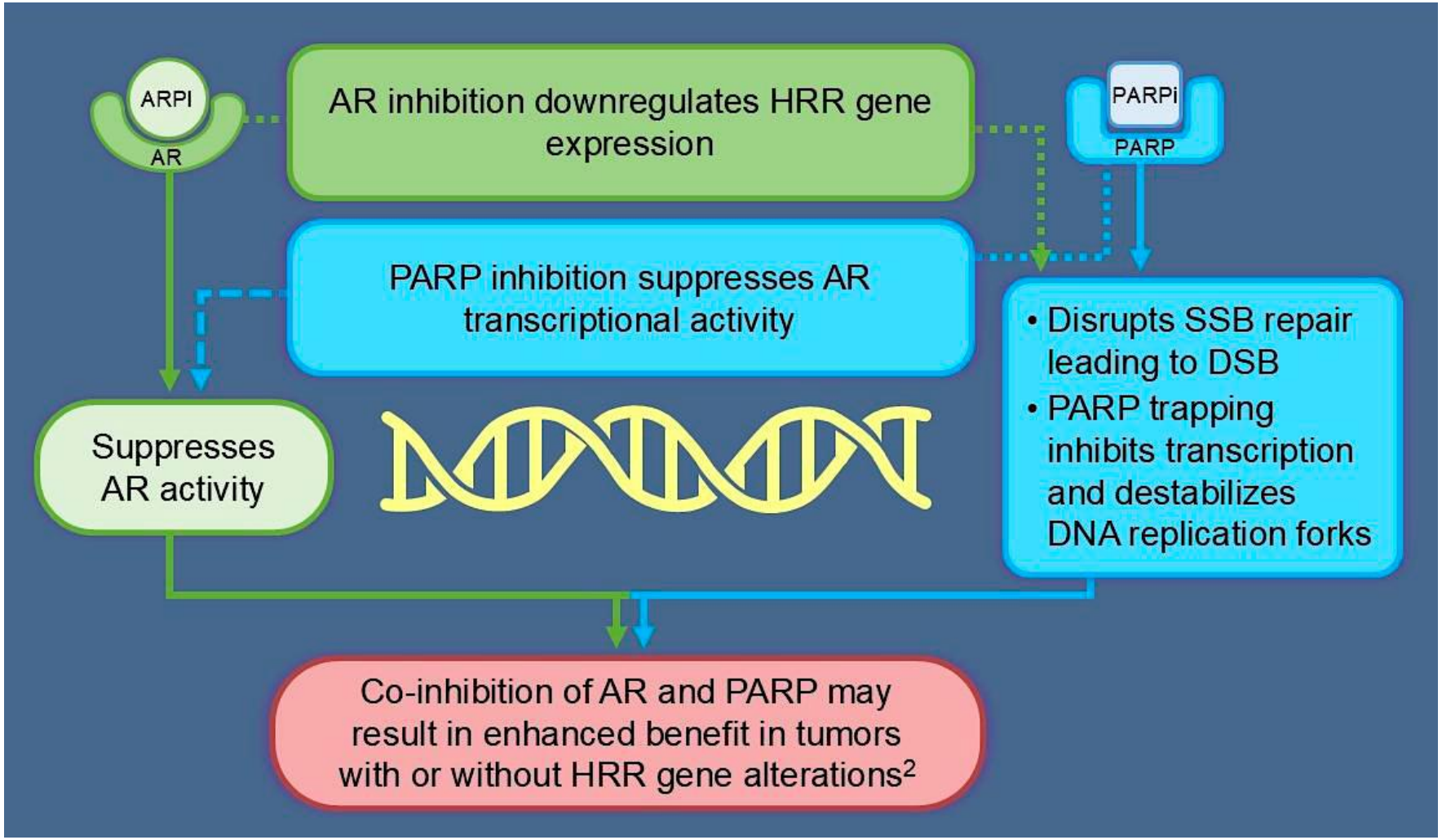


FDA approves capivasertib with abiraterone and prednisone for PTEN-deficient androgen pathway modulation-naïve or -sensitive prostate cancer

On June 12, 2026, the Food and Drug Administration approved capivasertib (Truqap, AstraZeneca) in combination with abiraterone and prednisone for adults with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer (previously referred to as metastatic hormone-sensitive prostate cancer) that is PTEN-deficient as detected by an FDA-authorized test.

Fizazi K et al. ESMO 2025

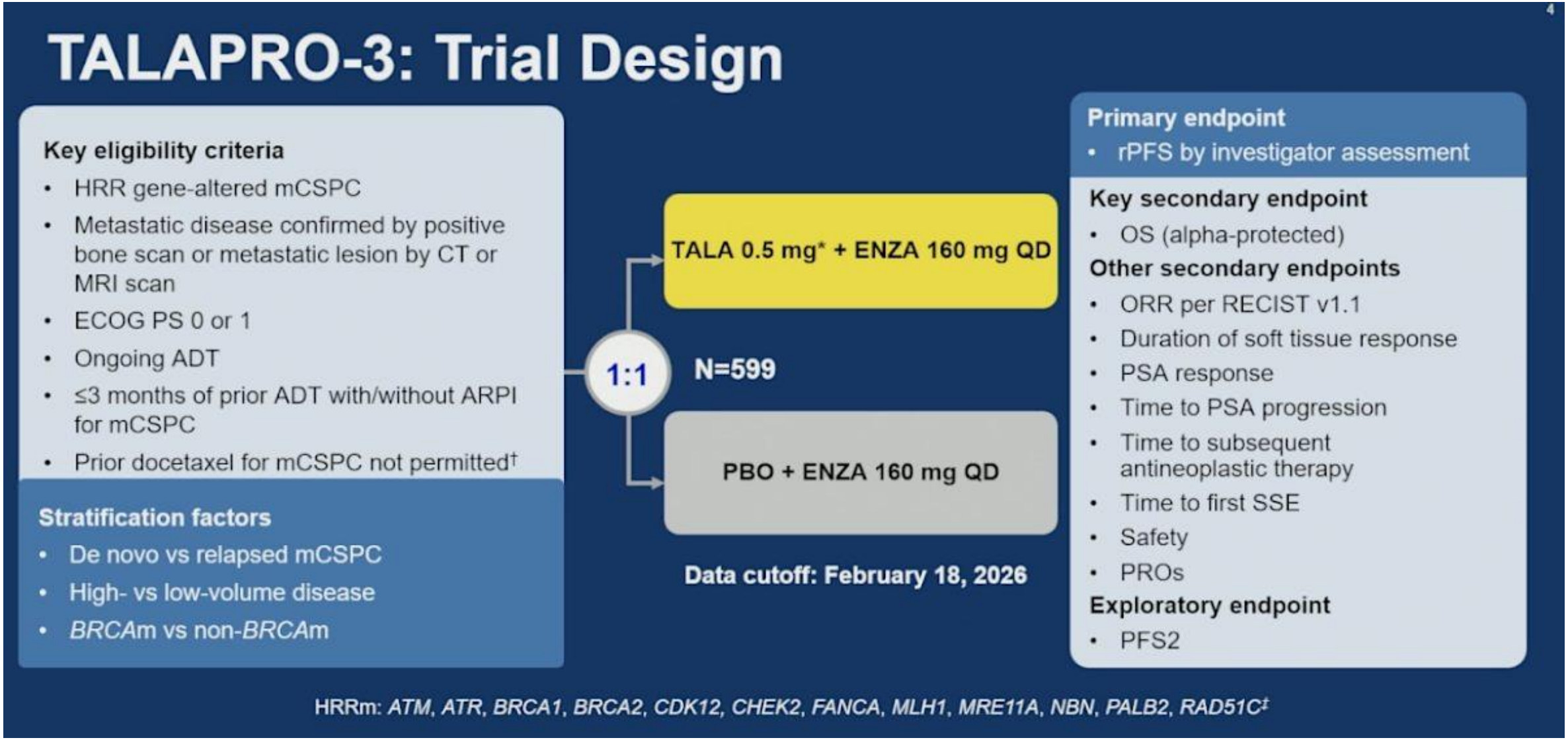
Rationale for the Combination of Androgen Pathway + PARP inhibition in Prostate Cancer



Summary of the Phase 3 Trial Data of ARPI + PARPi in First-line mCRPC

Trial	MAGNITUDE	PROPEL	TALAPRO-2
Experimental arm	Abiraterone + niraparib	Abiraterone + olaparib	Enzalutamide + talazoparib
Sample size (total)	656 patients	796 patients	805 patients
Hazard ratio rPFS **(BRCA-mutant)**	0.53 (0.36, 0.79)	0.23 (0.12, 0.43)	0.23 (0.10, 0.53)
Hazard ratio OS **(BRCA-mutant)**	0.93 (0.72-1.20)	0.29 (0.14, 0.56)	0.50 (0.32, 0.78)
FDA Label	BRCA-mutated mCRPC	BRCA-mutated mCRPC	HRR-altered mCRPC

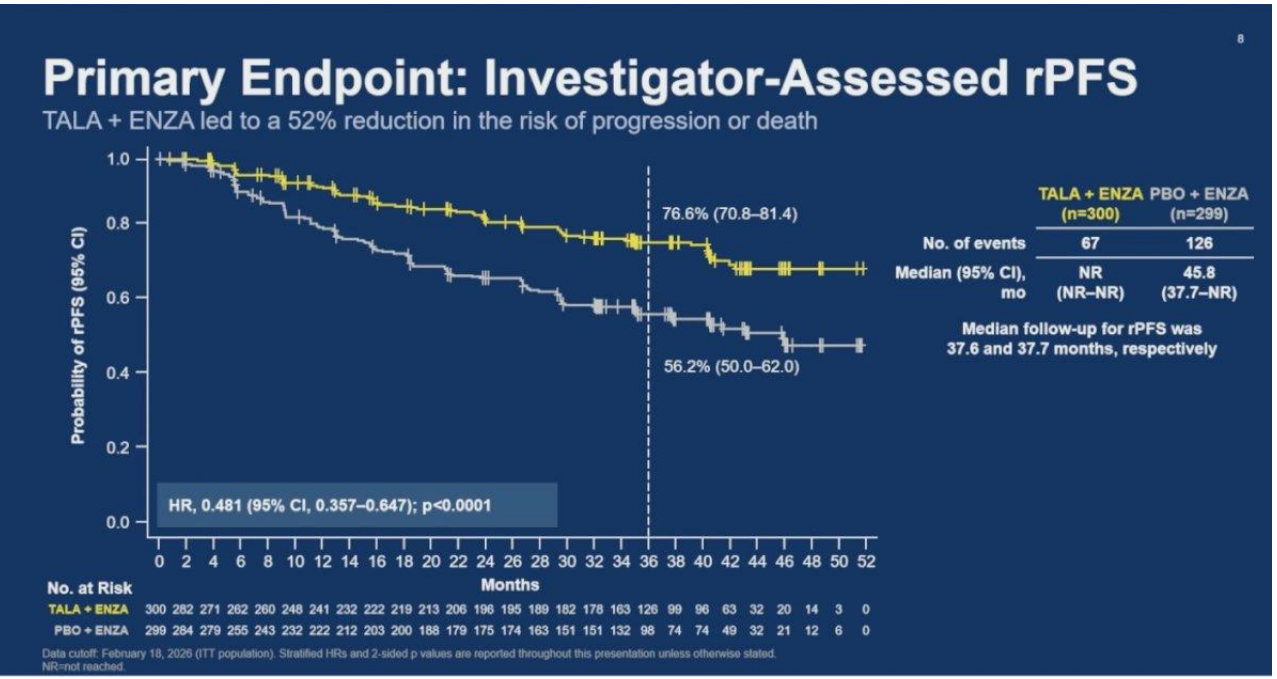
TALAPRO-3: Trial Design

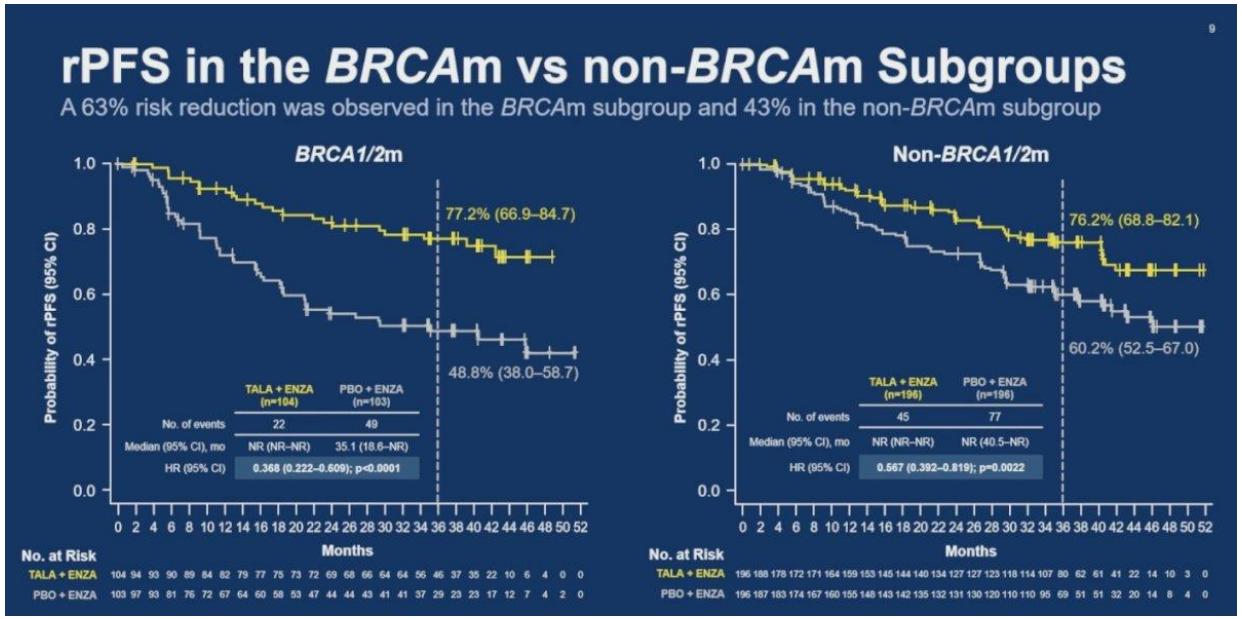


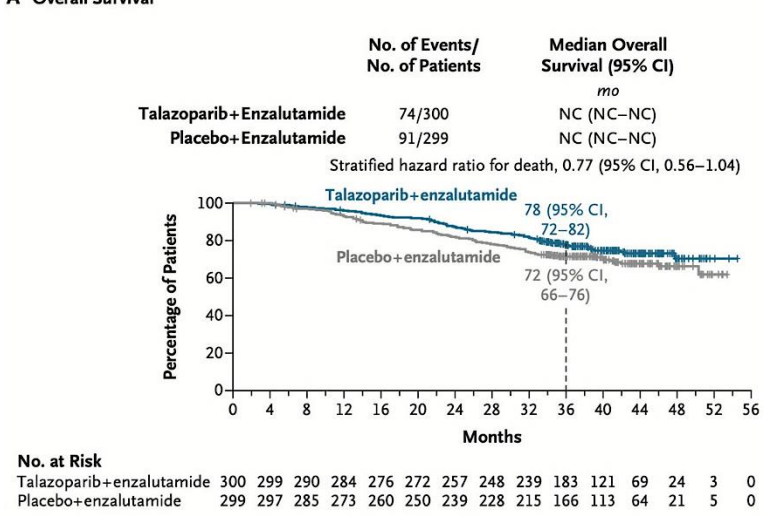
Agarwal N, et al. ASCO 2026

TALAPRO-3: Results

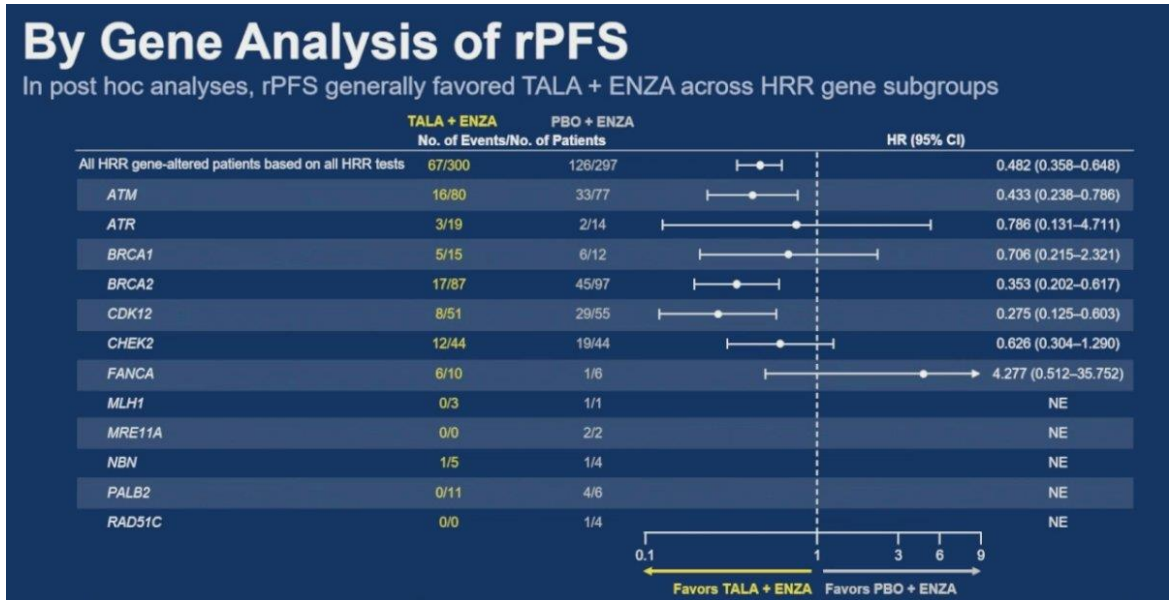
Agarwal N et al. ASCO 2026







Agarwal N et al. *N Engl J Med* 2026; May 30 (online ahead of print).



TALAPRO-3: Results

Summary of TEAEs

TEAE		TALA + ENZA (n=299)	PBO + ENZA (n=295)
Any TEAE		297 (99)	286 (97)
SAEs		126 (42)	93 (32)
Grade 3–4 TEAEs		**235 (79)**	**121 (41)**
Grade 5 TEAEs		8 (3)	9 (3)
Treatment-related*		2 (<1)	0
AE resulting in dose interruption of:	TALA or PBO†	207 (69)	90 (31)
	ENZA‡	140 (47)	85 (29)
AE resulting in dose reduction of:	TALA or PBO†	178 (60)	22 (7)
	ENZA‡	53 (18)	25 (8)
AE resulting in permanent drug discontinuation of:	**TALA or PBO†**	**56 (19)**	**29 (10)**
	ENZA‡	**32 (11)**	**26 (9)**
Median duration of treatment, mo (range)	TALA or PBO	35.0 (0.5–54.5)	32.9 (0.1–52.9)
	ENZA	35.9 (0.9–54.5)	32.9 (0.1–52.9)
Median relative dose intensity,% (range)	TALA or PBO	71.6 (23.0–142.9)	100 (52.6–142.9)
	ENZA	99.5 (33.9–100)	100 (35.7–101.6)

Most Common (≥15%) All-Cause TEAEs

Agarwal N et al. ASCO 2026

AMPLITUDE: Randomized, Double-Blind, Placebo-Controlled Trial in HRRm mCSPC

First and final rPFS analysis and first interim analysis of time to symptomatic progression and overall survival. Median follow-up: 30.8 months

Key inclusion criteria:

- mCSPC[a]
- Alteration in ≥1 HRR eligible gene: *BRCA1*, *BRCA2*, *BRIP1*, *CDK12*, *CHEK2*, *FANCA*, *PALB2*, *RAD51B*, *RAD54L*[b]
- ECOG PS 0-2

Key exclusion criteria:

- Any prior
  - PARPi
  - ARPI other than AAP

Prior allowed treatments in mCSPC:

- ADT ≤6 months
- Docetaxel ≤6 cycles[c]
- AAP ≤45 days
- Palliative RT

Randomized 1:1 (N=696)

Nira (200 mg QD) + **AAP** (1000 mg QD + 5 mg QD) + **ADT** (n=348)

PBO + **AAP** (1000 mg QD + 5 mg QD) + **ADT** (n=348)

Primary end point

- rPFS by investigator review

Key secondary end points

- Time to symptomatic progression
- OS
- Safety

Stratification factors:

- *BRCA2* vs *CDK12* vs all other alterations
- Prior docetaxel (yes vs no)
- Disease volume (high vs low)

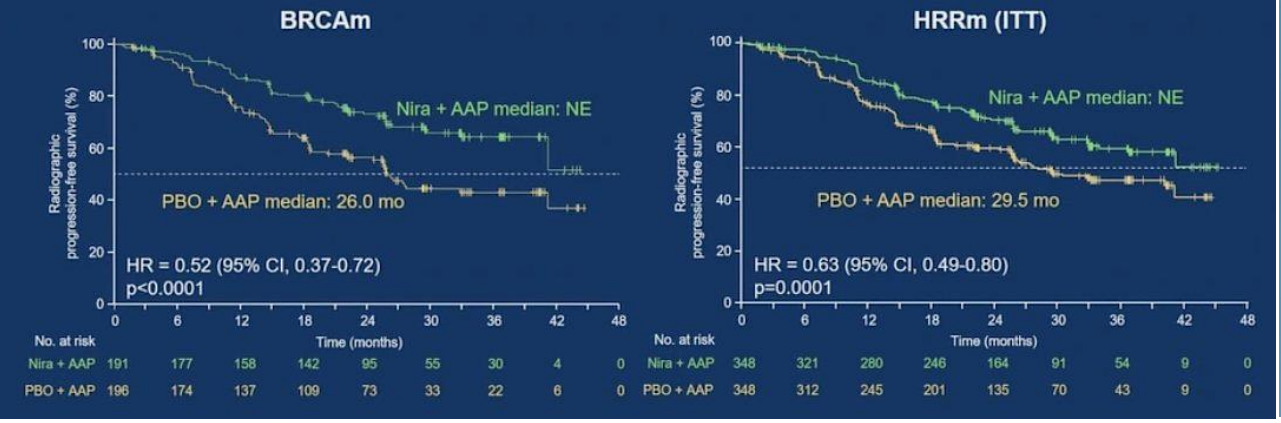
Clinical data cutoff: January 7, 2025

[a]Patients with lymph node–only disease are not eligible. [b]HRR gene panel was fixed prior to trial initiation based on MAGNITUDE trial and external data from the published literature. [c]Last dose ≤3 months prior to randomization.
ECOG PS, Eastern Cooperative Oncology Group performance status; Nira, niraparib; OS, overall survival; PBO, placebo; RT, radiotherapy; QD, once daily.

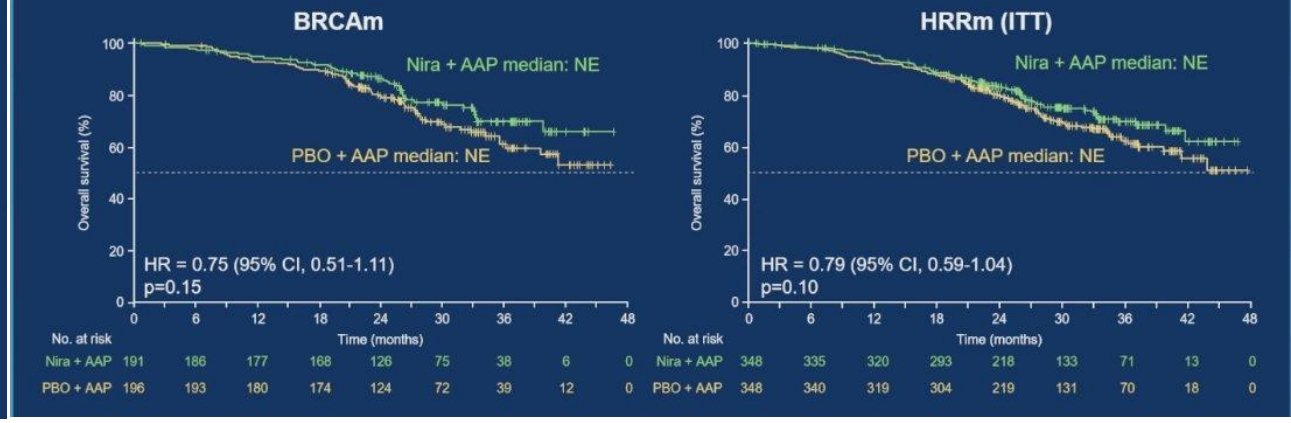
Attard G et al. ASCO 2025

AMPLITUDE Primary Results

Primary End Point: Radiographic Progression-Free Survival

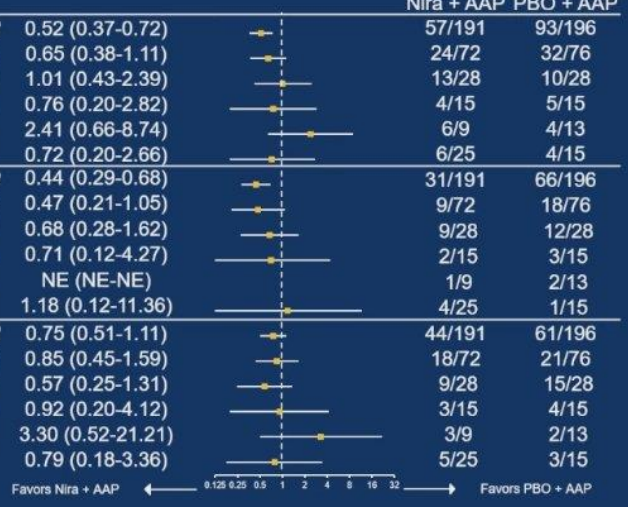


Secondary End Point: Overall Survival (First Interim Analysis)



Subgroup Analysis by BRCA and non-BRCA Alterations

End Point	Subgroup	HR (95% CI)	Events/N Nira + AAP	Events/N PBO + AAP
rPFS	*BRCA1/2*	0.52 (0.37-0.72)	57/191	93/196
	CHEK2	0.65 (0.38-1.11)	24/72	32/76
	CDK12	1.01 (0.43-2.39)	13/28	10/28
	FANCA	0.76 (0.20-2.82)	4/15	5/15
	PALB2	2.41 (0.66-8.74)	6/9	4/13
	Other	0.72 (0.20-2.66)	6/25	4/15
Time to symptomatic progression	*BRCA1/2*	0.44 (0.29-0.68)	31/191	66/196
	CHEK2	0.47 (0.21-1.05)	9/72	18/76
	CDK12	0.68 (0.28-1.62)	9/28	12/28
	FANCA	0.71 (0.12-4.27)	2/15	3/15
	PALB2	NE (NE-NE)	1/9	2/13
	Other	1.18 (0.12-11.36)	4/25	1/15
OS	*BRCA1/2*	0.75 (0.51-1.11)	44/191	61/196
	CHEK2	0.85 (0.45-1.59)	18/72	21/76
	CDK12	0.57 (0.25-1.31)	9/28	15/28
	FANCA	0.92 (0.20-4.12)	3/15	4/15
	PALB2	3.30 (0.52-21.21)	3/9	2/13
	Other	0.79 (0.18-3.36)	5/25	3/15



Adverse Events of Special Interest

Selected categories of TEAEs of interest, n (%)		Nira + AAP (n=347) All grades	Nira + AAP (n=347) Grade ≥3	PBO + AAP (n=348) All grades	PBO + AAP (n=348) Grade ≥3
Patients with ≥1 AE of interest		306 (88)	217 (63)	261 (75)	132 (38)
Hematologic	**Anemia**	**179 (52)**	**101 (29)**	**83 (24)**	**16 (5)**
	Neutropenia	76 (22)	33 (10)	28 (8)	7 (2)
	Thrombocytopenia	66 (19)	24 (7)	20 (6)	1 (<1)
	MDS	1 (<1)	1 (<1)	0	0
Cardiovascular	**Hypertension**	**155 (45)**	**93 (27)**	**113 (33)**	**64 (18)**
	Arrhythmia	68 (20)	19 (5)	28 (8)	11 (3)
	Cardiac failure	20 (6)	9 (3)	6 (2)	4 (1)
Other	Hypokalemia	92 (27)	40 (12)	70 (20)	38 (11)
	Hepatotoxicity	46 (13)	8 (2)	71 (20)	19 (5)

- Other common AEs of any grade: constipation (35% vs 16%), nausea (31% vs 14%), fatigue (26% vs 18%), and arthralgia (21% vs 21%) in the Nira +AAP vs placebo + AAP arms, respectively

Attard G et al. ASCO 2025

Outline

- Androgen pathway inhibition in hormone-sensitive prostate cancer
- Novel triplets in metastatic hormone sensitive prostate cancer
- Updates in PSMA-targeted radioligand therapy

Outline

- Updates in PSMA-targeted radioligand therapy
  - Saad F et al. Subgroup analyses from PSMAddition ASCO 2026; Abstract 5020
  - Emmett L et al. AcTION: Phase 1 study of [225Ac]-Ac-PSMA-617 in mCRPC ASCO 2026; Abstract 5010

Case #3: Taxane-naïve mCRPC

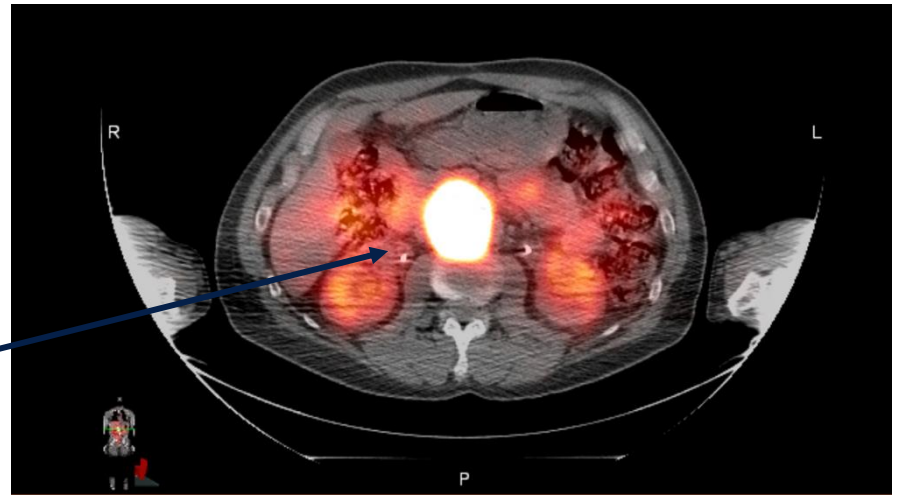
- 52 y/o M presented in 2024 with urinary obstruction, hydronephrosis
- 12/2024: TURP/TURBT with Gleason 5+5 prostate adenocarcinoma, TP53 mutation, MSS, TMB low
- PSA 50
- PSMA PET with extensive bulky adenopathy, bulky primary tumor
- Received ADT + abi/pred + docetaxel triplet for mHSPC
- Nadir PSA 0.7, subsequent transition to mCRPC after 10 months
- CT-guided biopsy of RP node: Prostate adenocarcinoma, + NKX.3, negative NE markers
- Starts Lu-PSMA-617 in March 2026

Case #3: Taxane-naïve mCRPC

- Received two doses of Lu-PSMA-617 to date in March and May 2026 with **complete PSA and radiographic response by SPECT/CT imaging**

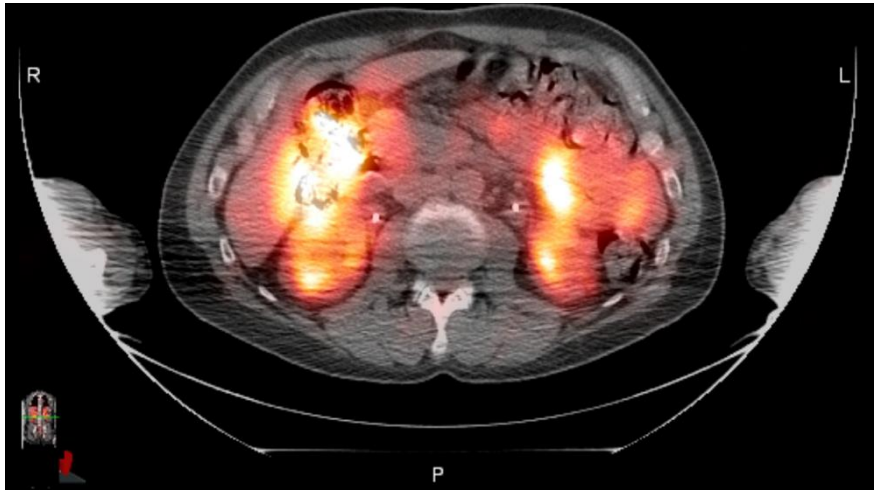
- Currently on treatment break with serial assessment of PSA and cross-sectional imaging every 12 weeks

Pre-treatment



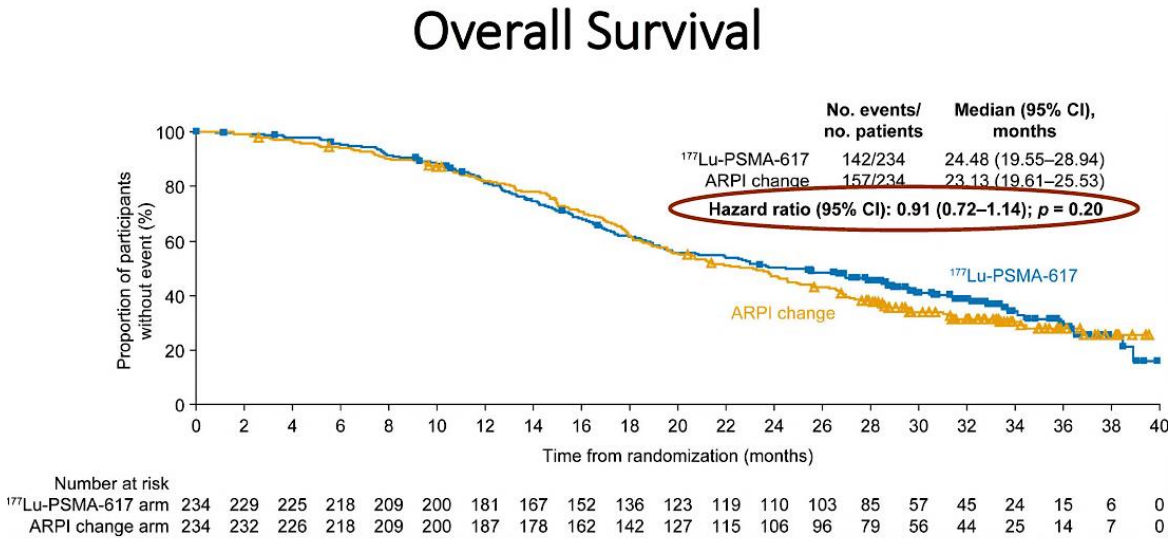
PET bulky RP node

Following cycle 2



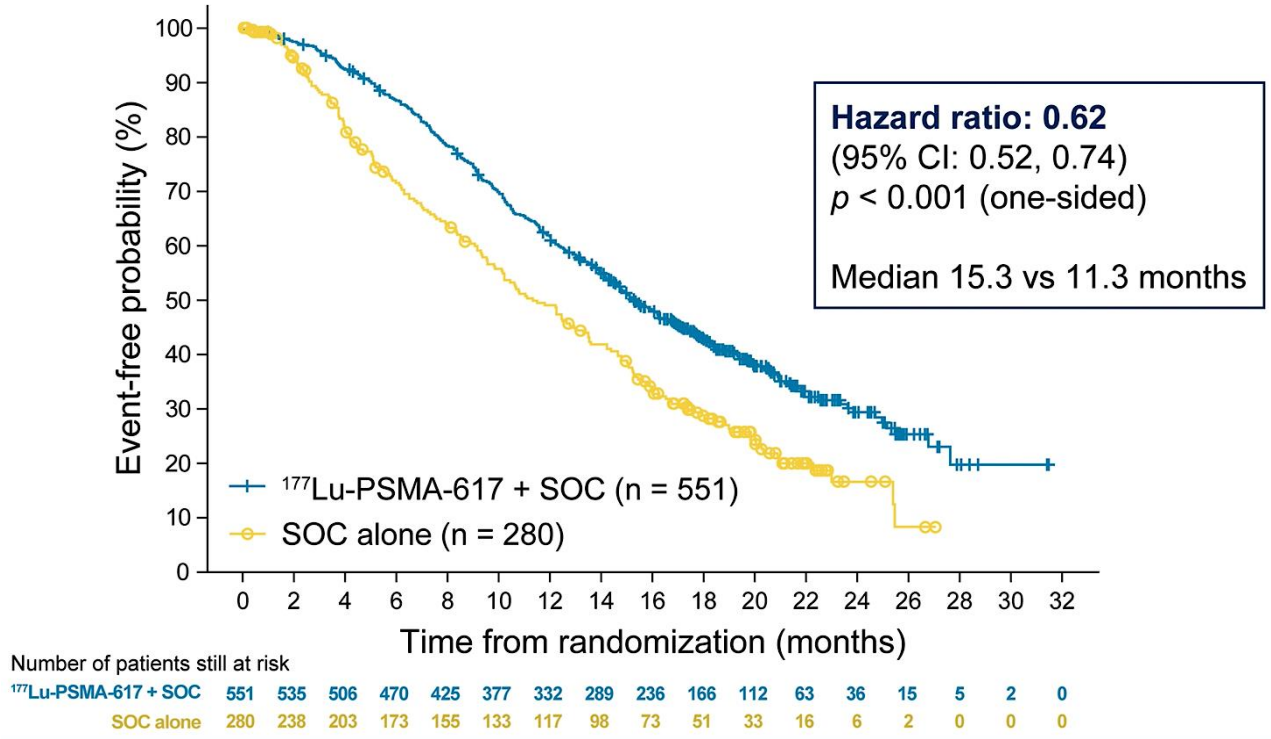
Lu-PSMA-617 in pre- and post-taxane mCRPC

Pre-taxane: PSMAfore



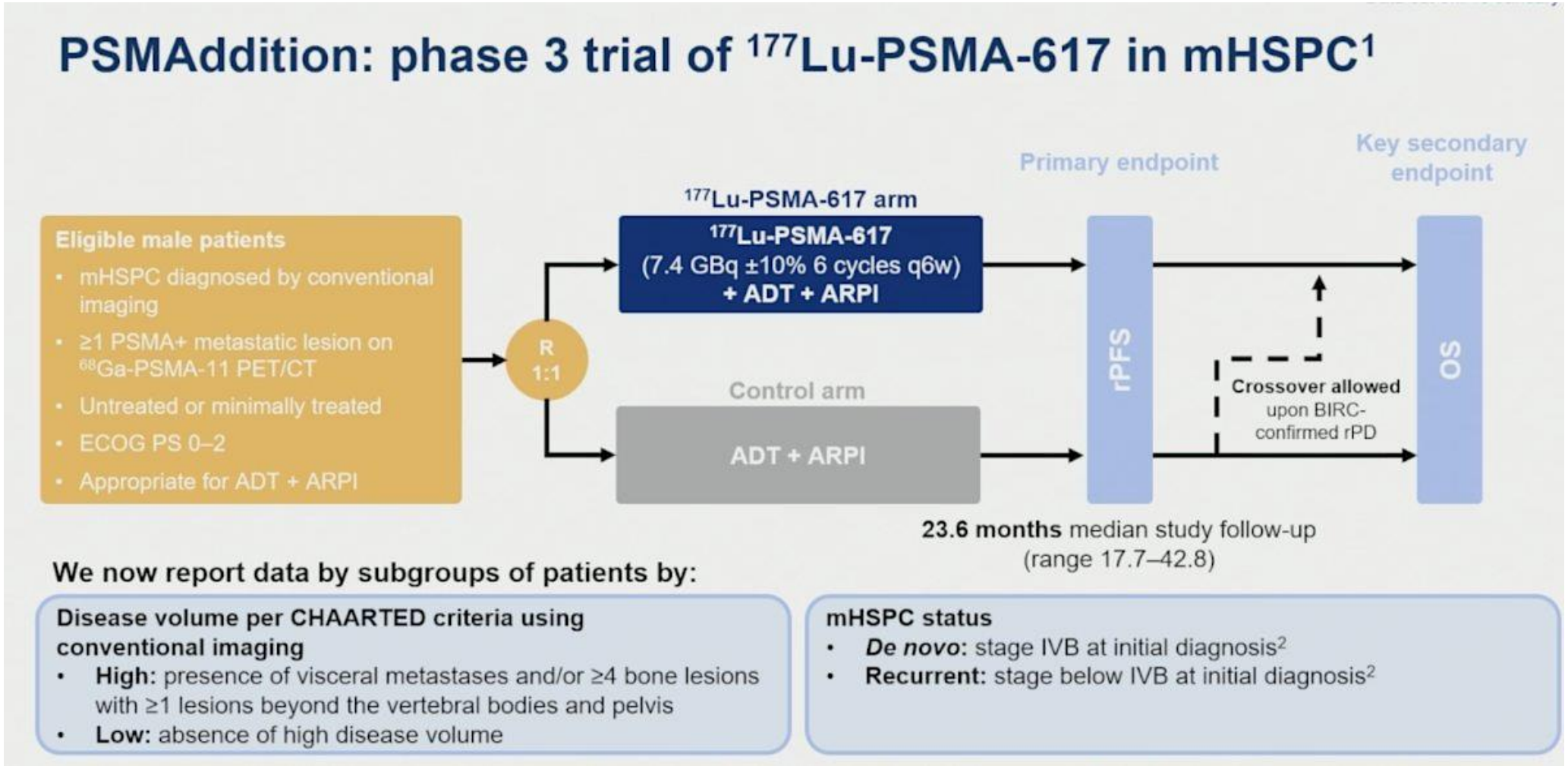
57% of patients in control arm crossed over to receive Lu-PSMA-617
Cross-over adjusted (IPCW) hazard ratio for OS = 0.59 (0.38, 0.91)

Post-taxane: VISION



Fizazi K et al. Ann Oncol 2025; Morris M et al. ASCO 2021

PSMAddition Subgroup Analyses



Saad F et al. ASCO 2026

PSMAddition Subgroup Analyses

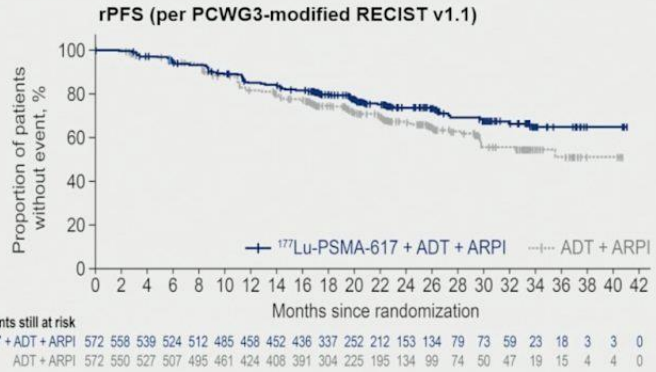
Data cut-off: 13 January 2025

PSMAddition: key results from second interim analysis[1]

rPFS primary endpoint (met)[1]

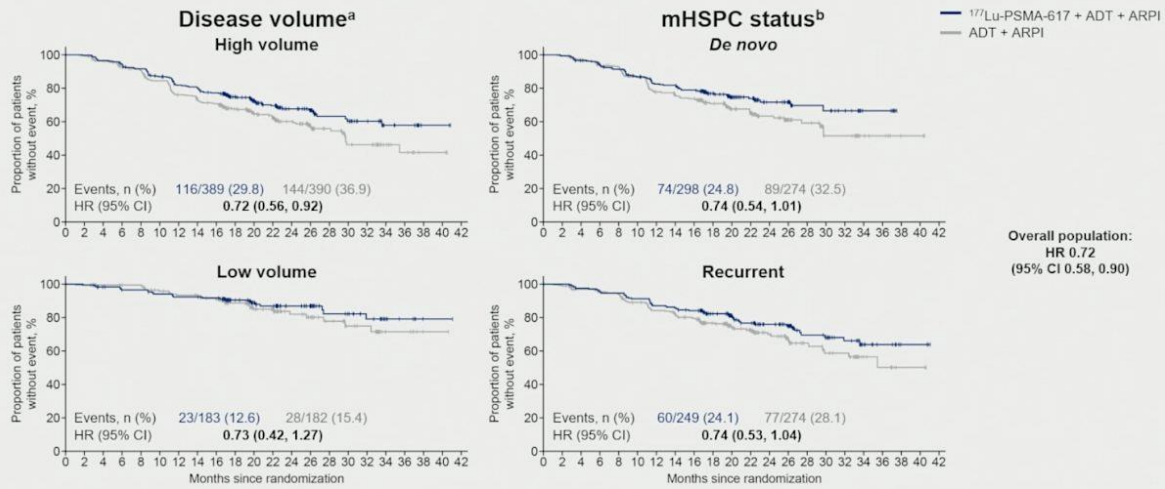
- Significantly improved rPFS with ^{177}Lu-PSMA-617 + ADT + ARPI versus ADT + ARPI at IA2

	^{177}Lu-PSMA-617 + ADT + ARPI n = 572	ADT + ARPI n = 572
Median rPFS (95% CI) – months	NR (NE–NE)	NR (29.7–NE)
HR (95% CI)[a]	0.72 (0.58, 0.90) p = 0.002	



We now present data by subgroups of patients by disease volume and recurrent/*de novo* mHSPC

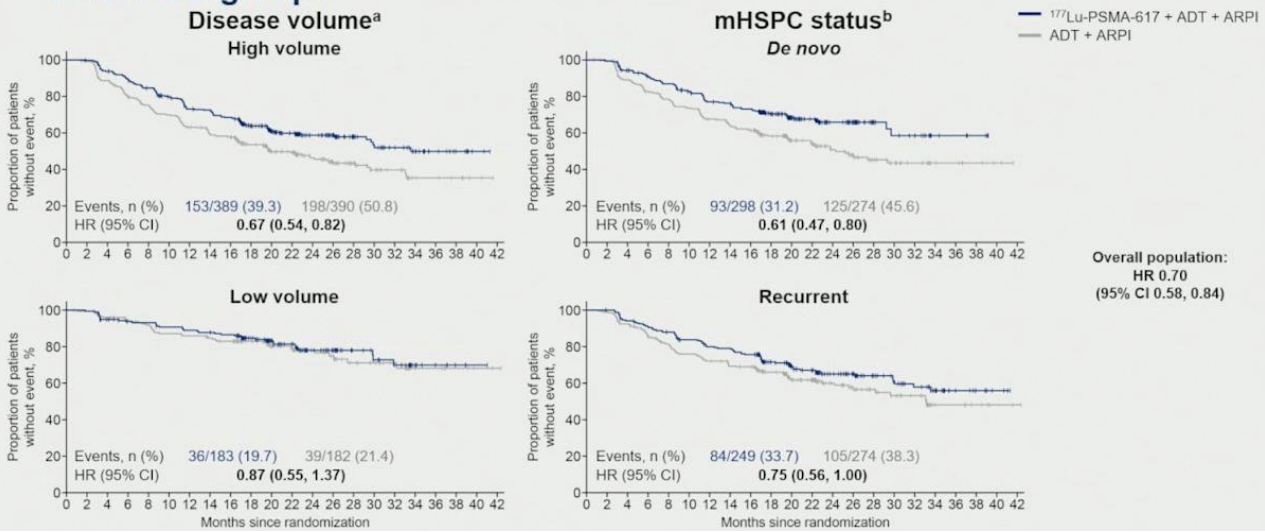
Consistent rPFS benefit with ^{177}Lu-PSMA-617 across subgroups



rPFS per PCWG3-modified RECIST v1.1 (primary endpoint). [a]Per CHAARTED criteria using conventional imaging. [b]Subgroup not prespecified; *de novo*: stage IVB at initial diagnosis (*AJCC Cancer Staging Manual* 8th edition). ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor; mHSPC, metastatic hormone-sensitive prostate cancer; rPFS, radiographic progression-free survival

Data cut-off: 13 January 2025

Consistent time to mCRPC benefit with ^{177}Lu-PSMA-617 across subgroups



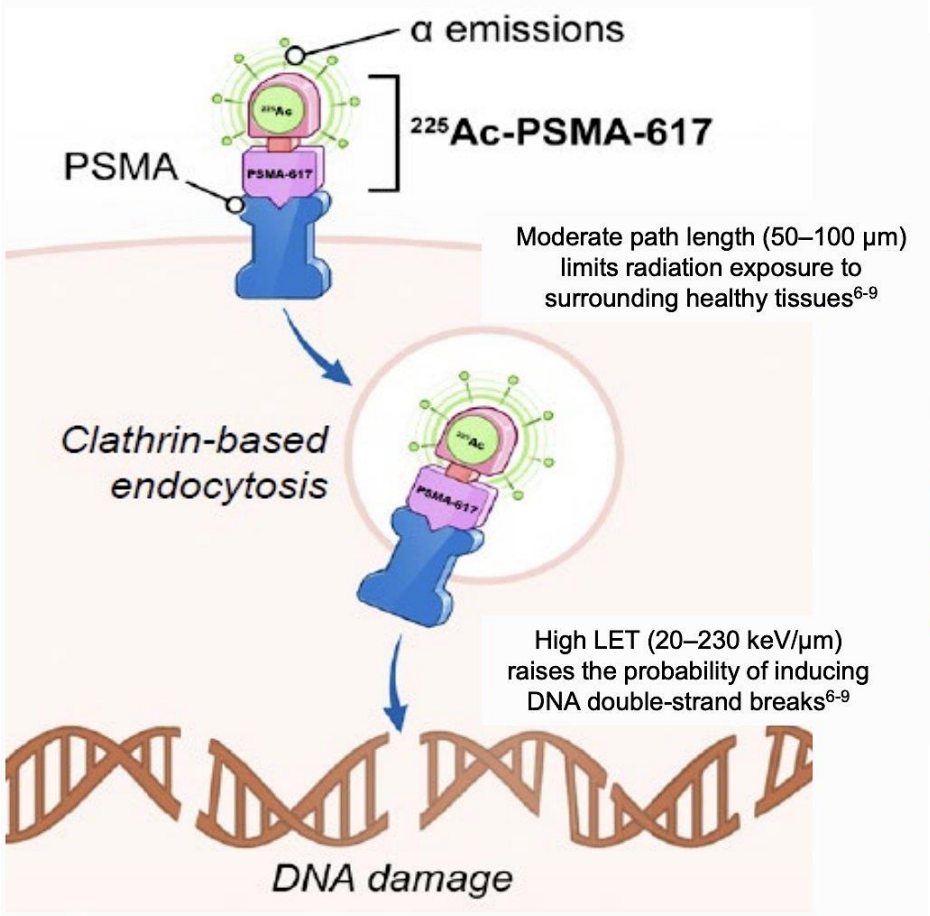
Data cut-off: 13 January 2025

HRs for patient-reported outcomes were generally similar in all patients and subgroups

	HR (95% CI)[a]	Events, n/N (%) ^{177}Lu-PSMA-617 + ADT + ARPI	Events, n/N (%) ADT + ARPI
Time to FACT-P total score worsening[b]			
All patients	1.14 (0.98, 1.33)	348/572 (60.8)	304/572 (53.1)
High disease volume	1.13 (0.94, 1.37)	237/389 (60.9)	209/390 (53.6)
Low disease volume	1.16 (0.88, 1.53)	111/183 (60.7)	95/182 (52.2)
De novo mHSPC	1.13 (0.90, 1.41)	180/298 (60.4)	144/274 (52.6)
Recurrent mHSPC	1.16 (0.92, 1.46)	155/249 (62.2)	149/274 (54.4)
Time to EQ-5D-5L utility score worsening[b]			
All patients	1.13 (0.97, 1.31)	353/572 (61.7)	312/572 (54.5)
High disease volume	1.04 (0.87, 1.25)	239/389 (61.4)	222/390 (56.9)
Low disease volume	1.34 (1.01, 1.77)	114/183 (62.3)	90/182 (49.5)
De novo mHSPC	1.17 (0.93, 1.45)	182/298 (61.1)	143/274 (52.2)
Recurrent mHSPC	1.09 (0.87, 1.37)	155/249 (62.2)	156/274 (56.9)
Time to BPI-SF pain intensity worsening[b]			
All patients	1.02 (0.87, 1.18)	339/572 (59.3)	326/572 (57.0)
High disease volume	0.98 (0.82, 1.18)	232/389 (59.6)	229/390 (58.7)
Low disease volume	1.09 (0.83, 1.44)	107/183 (58.5)	97/182 (53.3)
De novo mHSPC	1.06 (0.85, 1.31)	174/298 (58.4)	154/274 (56.2)
Recurrent mHSPC	0.97 (0.78, 1.22)	153/249 (61.4)	159/274 (58.0)

[a]Stratified Cox proportional hazards model. [b]Composite of time to worsening, clinical progression, or death. BPI-SF, Brief Pain Inventory-Short Form; FACT-P, Functional Assessment of Cancer Therapy – Prostate; mHSPC, metastatic hormone-sensitive prostate cancer

AcTION Phase 1 Trial of 225Ac-PSMA-617



Open-label Phase 1 dosage-escalation/expansion

Patient population

- ≥18 years
- Confirmed mCRPC
- ECOG 0-2
- Positive ^{68}Ga-PSMA-11 PET/CT scan

Group A
- Prior taxane + ARPI
- Naive to ^{177}Lu-PSMA RLT

Group B
- No prior taxane or ARPI
- Naive to ^{177}Lu-PSMA RLT

Group C
- Prior ^{177}Lu-PSMA RLT
- No prior taxane or ARPI required

Endpoints

Primary
- RP2D

Secondary
- Safety/tolerability
- Confirmed PSA50
- RECIST v1.1
- HRQOL

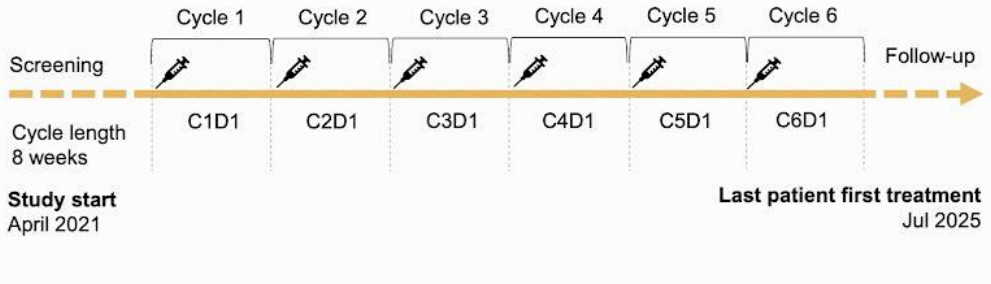
Dosage and treatment schedule

Screened N=134

Total treated: N=101

Dosage escalation (N=58)
4 and 6 MBq: ≥3 patients
8 and 10 MBq: 6 patients each

Dosage expansion (N=43)
8 and 10 MBq:
Up to 10 additional patients



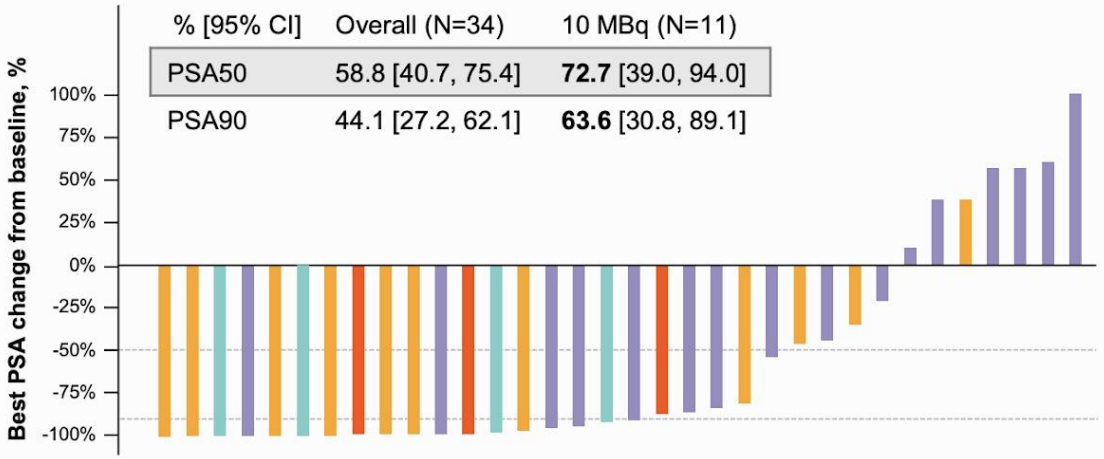
Emmett L et al. ASCO 2026

AcTION Phase 1 Trial of 225Ac-PSMA-617

	Group A (N=34) Prior taxane+ARPI		Group B (N=27) Taxane/ARPI-naive		Group C (N=40) Prior ^{177}Lu-PSMA RLT	
Category, n (%)	**All grades**	**Grades ≥3**	**All grades**	**Grades ≥3**	**All grades**	**Grades ≥3**
Any TEAE	34 (100.0)	17 (50.0)	26 (96.3)	4 (14.8)	39 (97.5)	13 (32.5)
Any TRAEs	34 (100.0)	8 (23.5)	26 (96.3)	3 (11.1)	39 (97.5)	6 (15.0)
TEAEs leading to dosage reduction[a]	5 (14.7)	2 (5.9)	3 (11.1)	3 (11.1)	5 (12.5)	4 (10.0)
TEAEs leading to discontinuation	1 (2.9)	1 (2.9)	0	0	4 (10.0)	2 (5.0)
TEAEs reported in >25% of patients in any group						
Dry mouth	33 (97.1)	0	26 (96.3)	0	36 (90.0)	0
Fatigue	18 (52.9)	0	4 (14.8)	0	27 (67.5)	0
Anemia	9 (26.5)	6 (17.6)	4 (14.8)	4 (14.8)	16 (40.0)	6 (15.0)
Nausea	9 (26.5)	0	3 (11.1)	0	16 (40.0)	1 (2.5)
Decreased appetite	7 (20.6)	0	8 (29.6)	0	8 (20.0)	0
Weight decreased	6 (17.6)	1 (2.9)	8 (29.6)	0	8 (20.0)	1 (2.5)
Other selected TEAEs						
Dry eye	3 (8.8)	0	3 (11.1)	0	6 (15.0)	0
Lymphopenia	1 (2.9)	1 (2.9)	0	0	0	0
Neutropenia	4 (11.8)	0	0	0	6 (15.0)	1 (2.5)
Thrombocytopenia	2 (5.9)	0	2 (7.4)	1 (3.7)	5 (12.5)	0
Renal impairment	1 (2.9)	1 (2.9)	0	0	3 (7.5)	1 (2.5)

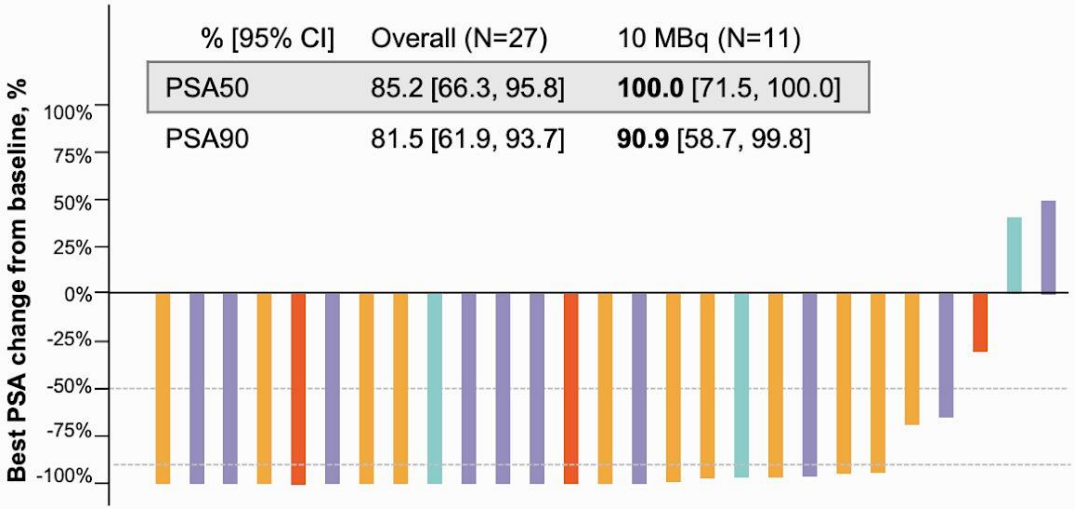
Group A (Prior taxane + ARPI; N=34)

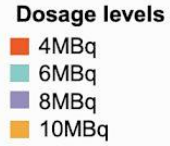
% [95% CI]	Overall (N=34)	10 MBq (N=11)
PSA50	58.8 [40.7, 75.4]	**72.7** [39.0, 94.0]
PSA90	44.1 [27.2, 62.1]	**63.6** [30.8, 89.1]



Group B (Taxane/ARPI-naive; N=27)

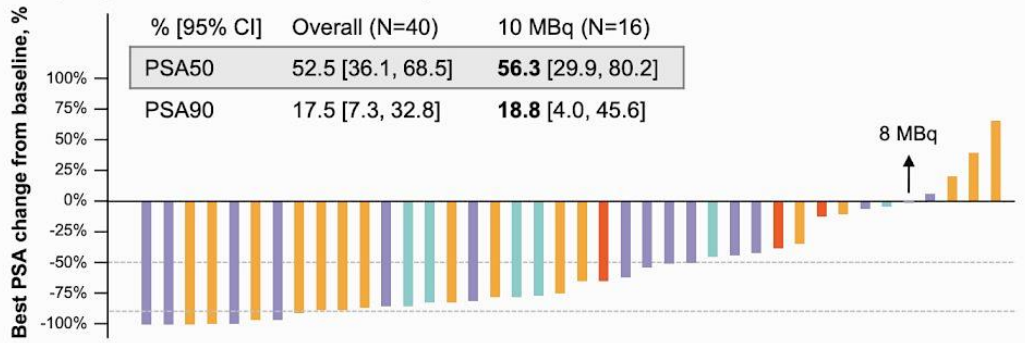
% [95% CI]	Overall (N=27)	10 MBq (N=11)
PSA50	85.2 [66.3, 95.8]	**100.0** [71.5, 100.0]
PSA90	81.5 [61.9, 93.7]	**90.9** [58.7, 99.8]





Group C (Prior ^{177}Lu-PSMA RLT; N=40)

% [95% CI]	Overall (N=40)	10 MBq (N=16)
PSA50	52.5 [36.1, 68.5]	**56.3** [29.9, 80.2]
PSA90	17.5 [7.3, 32.8]	**18.8** [4.0, 45.6]



Agenda

Introduction: Welcome GU Oncology Fellows!

Module 1: Prostate Cancer — Dr Aggarwal

Module 2: Urothelial Bladder Cancer — Dr Galsky

Module 3: Renal Cell Carcinoma — Dr Zhang

Post ASCO 2026: Urothelial Cancer

Matthew D. Galsky, MD FASCO

Lillian and Henry Stratton Professor of Medicine

Icahn School of Medicine at Mount Sinai

Director, Genitourinary Medical Oncology

Deputy Director

The Tisch Cancer Center at Mount Sinai

Phase 3 Trials of BCG + IO in BCG-Naïve Patients With NMIBC

POTOMAC

Eligibility Criteria

- High-grade Ta, T1 and/or CIS
- Multiple and recurrent and large with largest tumor ≥3 cm

Treatment

- **Durvalumab** 1500 mg IV Q4Wk x 13 cycles

ALBAN

Eligibility Criteria

- High-grade Ta, T1 and/or CIS

Treatment

- **Atezolizumab** 1200 mg IV Q3Wk x 18 cycles

CREST

Eligibility Criteria

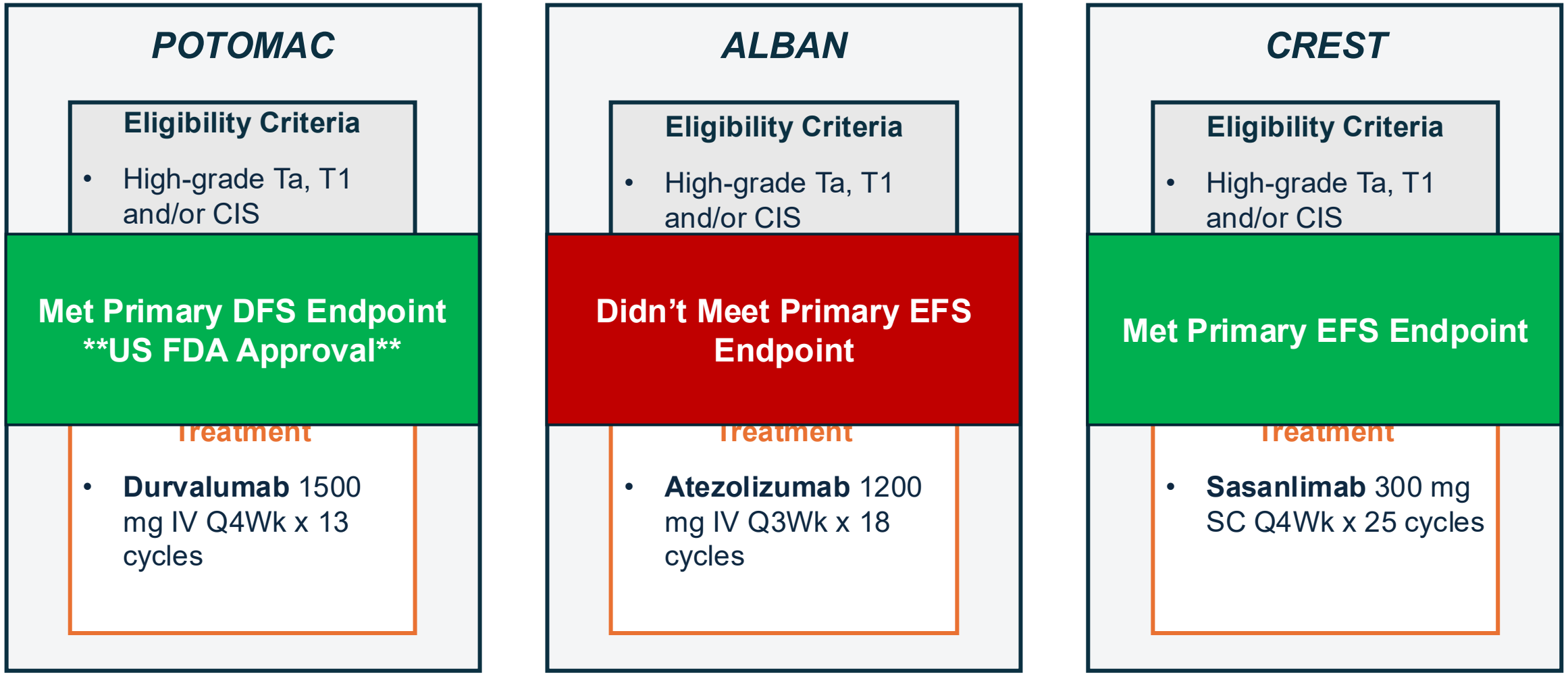
- High-grade Ta, T1 and/or CIS

Treatment

- **Sasanlimab** 300 mg SC Q4Wk x 25 cycles

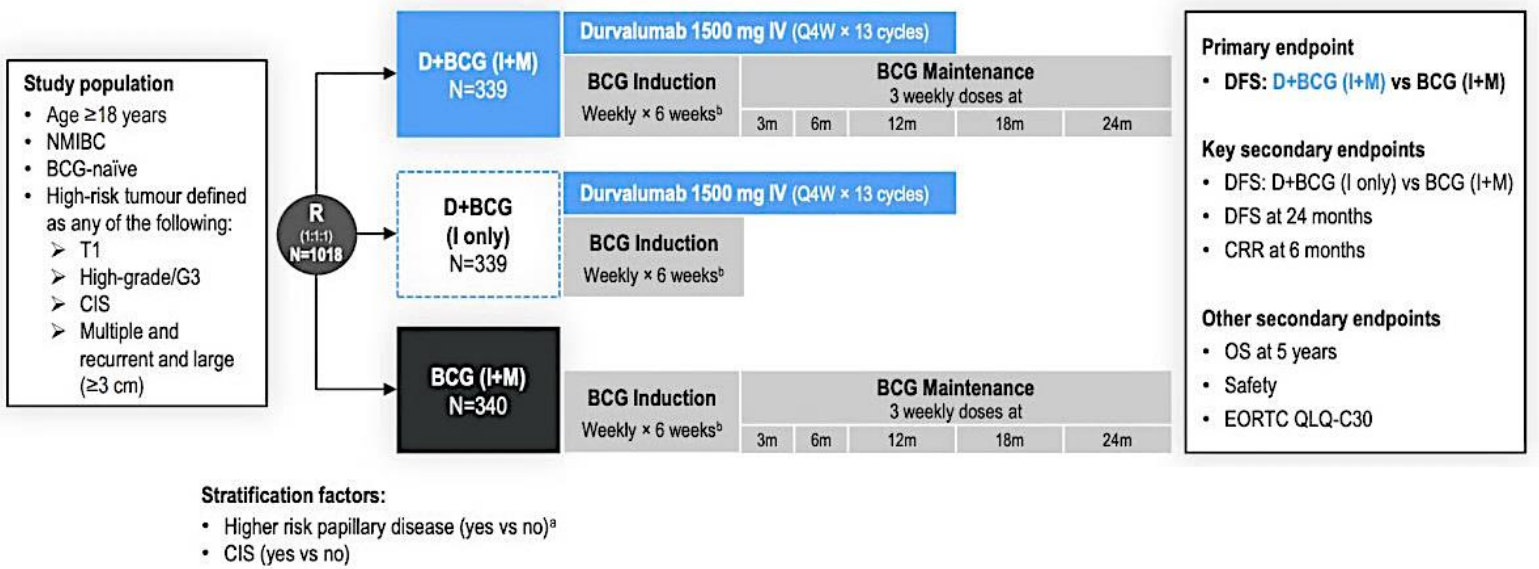
1. Roupret et al. *Ann Oncol*; 2025. 2. De Santis et al. *Lancet*. 2025. 3. Shore et al. *Nat Med*. 2025

Phase 3 Trials of BCG + IO in BCG-Naïve Patients With NMIBC



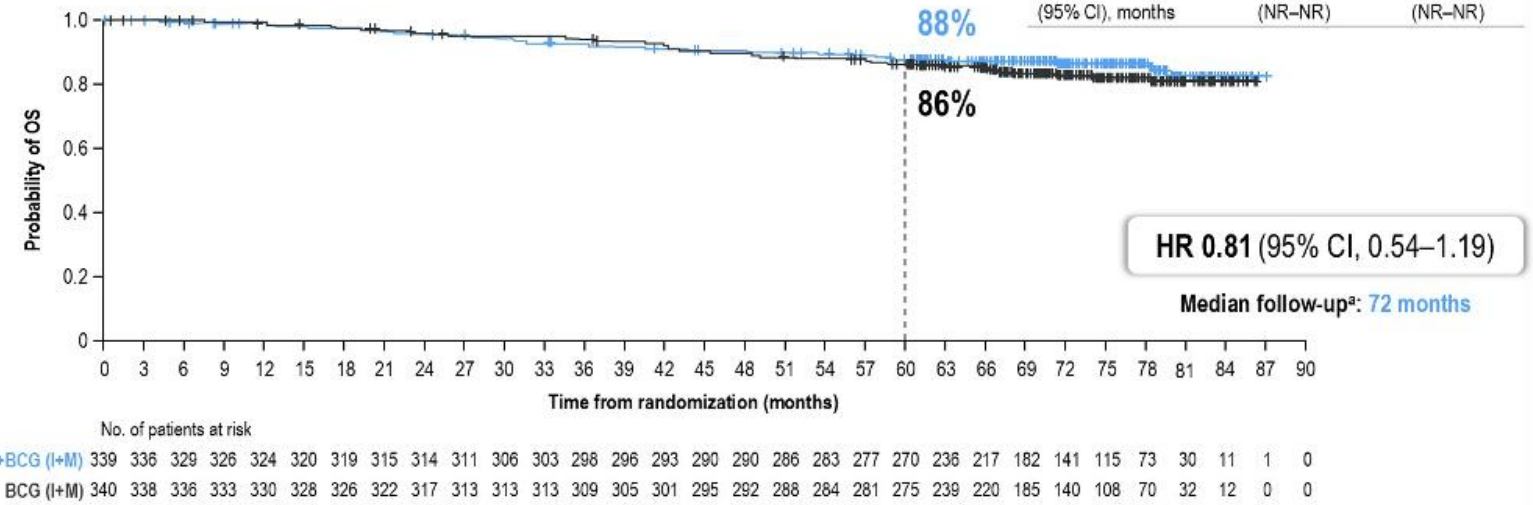
1. Roupret et al. *Ann Oncol*; 2025. 2. De Santis et al. *Lancet*. 2025. 3. Shore et al. *Nat Med*. 2025

POTOMAC: OS data and QoL



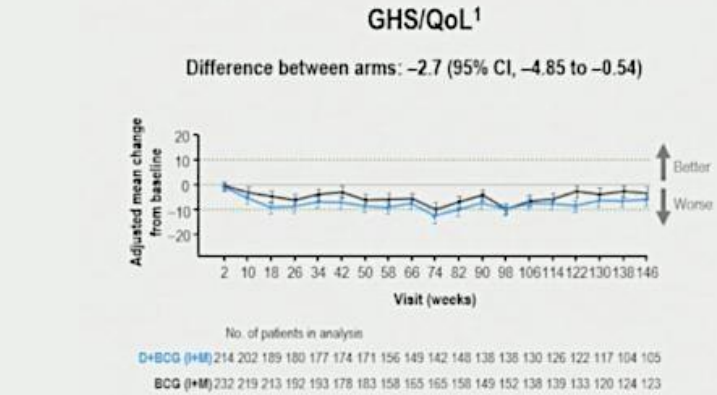
Stratification factors:
- Higher risk papillary disease (yes vs no)[a]
- CIS (yes vs no)

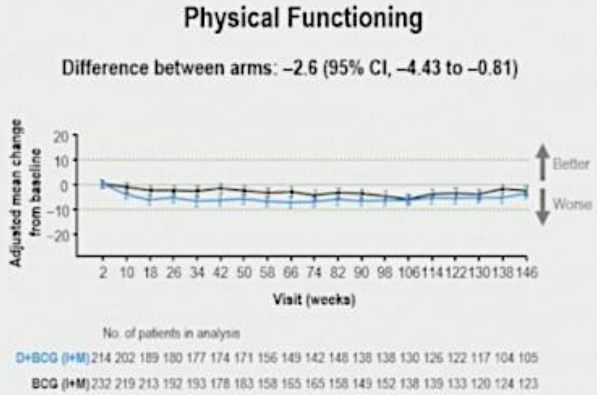
	D+BCG (I+M) N=339	BCG (I+M) N=340
Deaths, n (%)	45 (13)	56 (16)
Median OS (95% CI), months	NR (NR–NR)	NR (NR–NR)

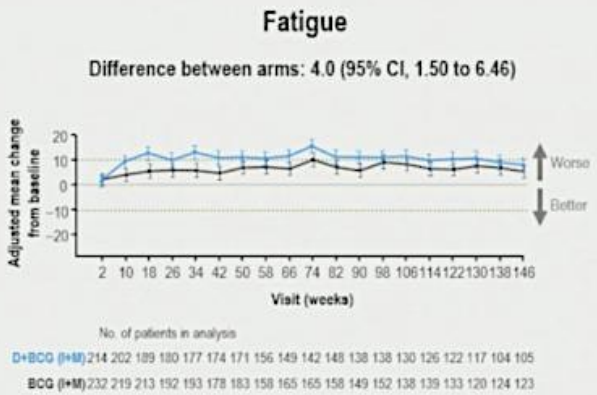


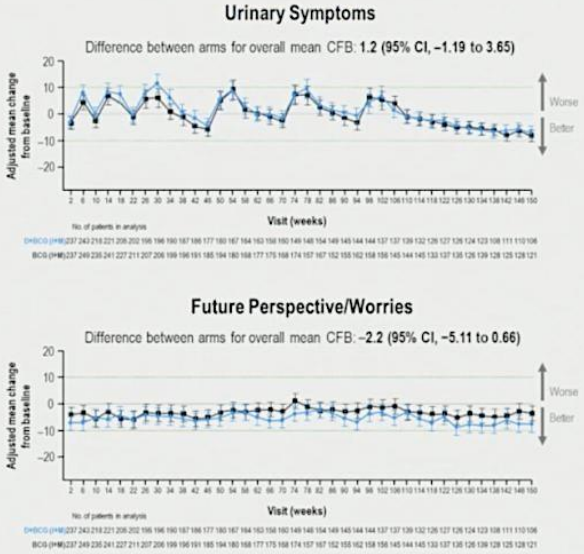
De Santis M et al. ASCO 2026: Abstract 4624

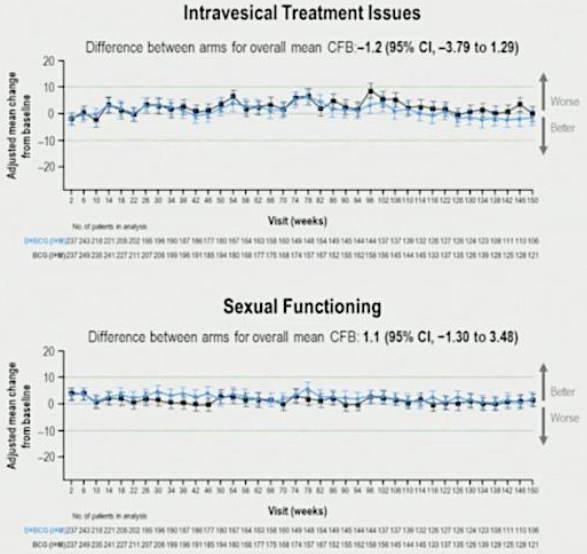
POTOMAC: OS data and QoL

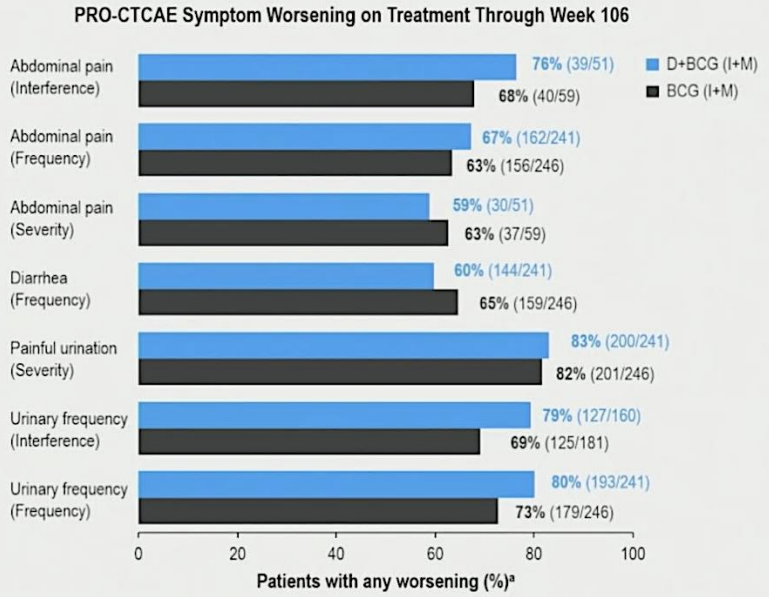






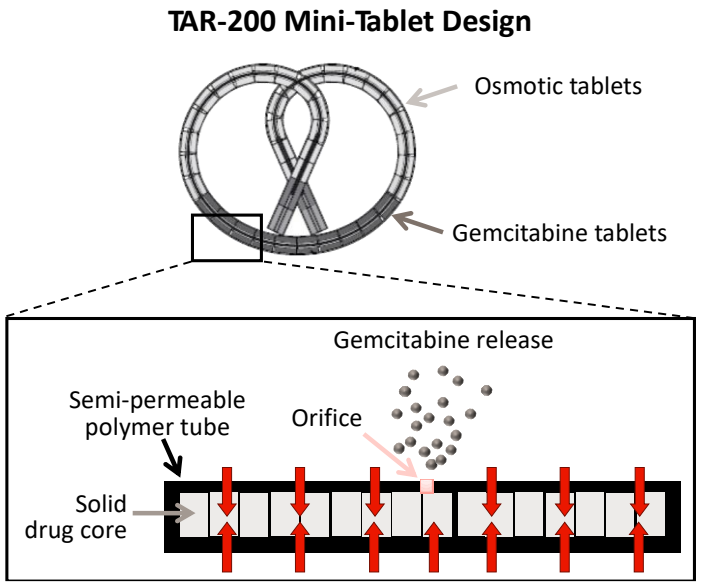


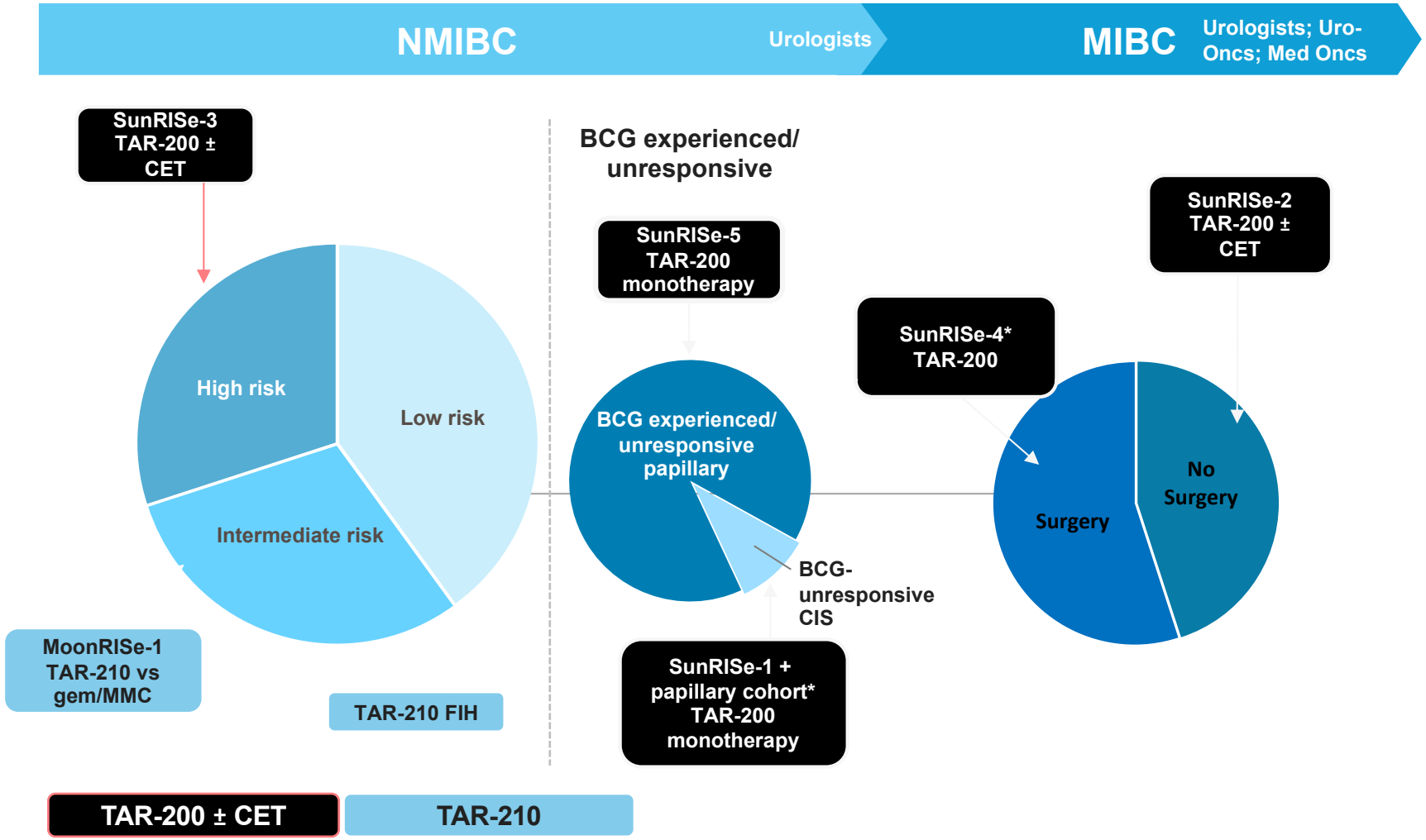




De Santis M et al. ASCO 2026: Abstract 4624

TAR-200 in Bladder Cancer





Phase 2b SunRISe-1 Study: Cohort 2 BCG-Unresponsive HR NMIBC CIS ± Papillary Disease

NCT04640623

Population:
- Aged ≥18 years
- Histologically confirmed HR NMIBC CIS (with or without papillary disease)
- ECOG PS of 0-2
- Persistent or recurrent disease within 12 months of completion of BCG
- Unresponsive to BCG[1,2] and not receiving RC

Population:
- Papillary-only HR NMIBC (no CIS)[a]

R

TAR-200 + Cetrelimab[b]
Cohort 1 (N=53)[c]
Cohort 1 was closed

TAR-200 Monotherapy
***Cohort 2* (N=85)**
Enrollment completed

Cetrelimab[b] Monotherapy
Cohort 3 (N=28)
Cohort 3 was closed

TAR-200 Monotherapy
Cohort 4 (N=52)
Enrollment completed

TAR-200 dosing:
Q3W (indwelling) for the first 24 weeks; then Q12W through Week 96

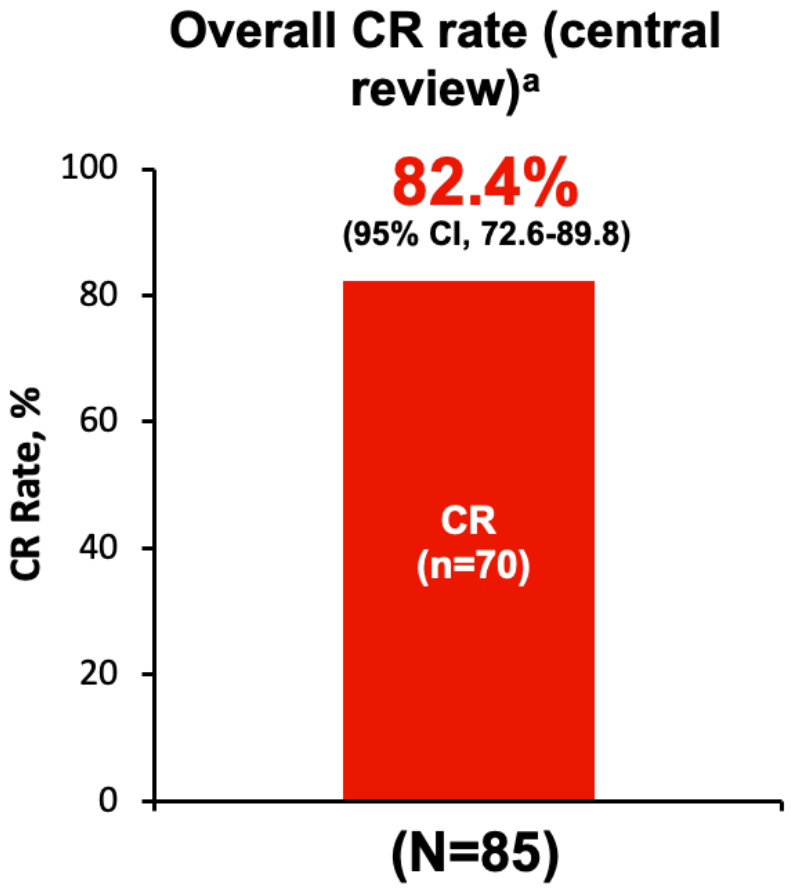
Cohorts 1-3:
Primary end point
- Overall CR rate

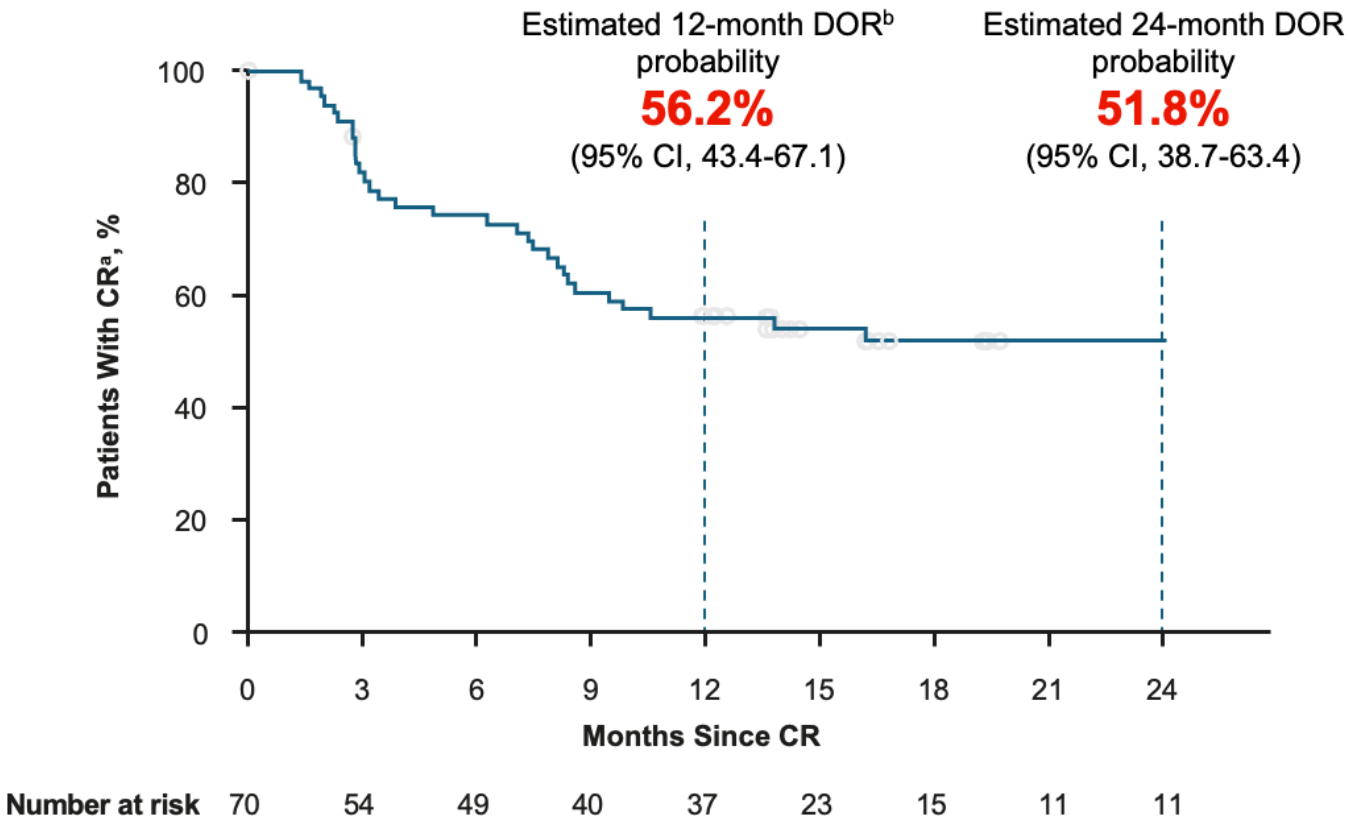
Key secondary end points
- Duration of response
- Overall survival
- Safety
- Tolerability
- HRQoL

Cohort 4:
Primary end point
- DFS

Daneshmand, S et al. TAR-200 for Bacillus Calmette-Guérin–Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer: Results From the Phase IIb SunRISe-1 Study. J Clin Oncol 43, 3578-3588(2025).

TAR-200 Monotherapy in BCG-Unresponsive HR NMIBC CIS ± Papillary Disease





Daneshmand, S et al. TAR-200 for Bacillus Calmette-Guérin–Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer: Results From the Phase IIb SunRISe-1 Study. J Clin Oncol 43, 3578-3588(2025).

TAR-210 erdafitinib intravesical delivery first-in-human phase 1 trial

Molecular eligibility

- *FGFR* alterations: flexible molecular eligibility strategy used
  - Local or central fresh/archival **tissue-based** testing by NGS or PCR or
  - Central **urine cell-free DNA** NGS testing

HR-NMIBC (cohort 1)

- Recurrent, high-grade Ta/T1, papillary only, no CIS
- BCG-experienced/unresponsive and not undergoing RC
- TURBT with complete resection of all visible disease prior to treatment

IR NMIBC (cohort 3)

- Recurrent, history of low-grade only Ta/T1 disease
- **Visible target lesions** prior to treatment (chemoablation design)

Part 1: dose escalation

BOIN

TAR-210-D
≈ 4 mg/day

TAR-210-B
≈ 2 mg/day

- Placement every 3 months

Part 2: dose expansion

- Expansion of both dose levels

Response assessed every 3 months with continued treatment for up to 1 year if recurrence free (cohort 1) or CR (cohort 3)

Interim results: Cohort 1

- **90% estimated 12-month RFS rate**[a] (n = 21)
  - Median RFS was not estimable
  - 2 of 21 patients recurred
  - Median duration of follow-up was 8.9 months
- No difference was observed in RFS between the TAR-210 dose levels

Interim results: Cohort 3

31 patients were evaluable for response[b]

90% CR rate, with 28/31 patients achieving a CR at week 12

- Overall, **100% of patients achieved a clinical response**; 3 patients had a non-CR/non-PD response

Consistent CR rate across both doses

86% (24/28) of CRs are ongoing at time of clinical cutoff

NCT06319820

Phase 3 MoonRISe-1 underway: TAR-210 vs IV chemo in *FGFR*-altered IR NMIBC

NCT06919965

Phase 3 MoonRISe-3 underway: TAR-210 vs IV chemo in BCG-treated, *FGFR*-altered Papillary only HR NMIBC

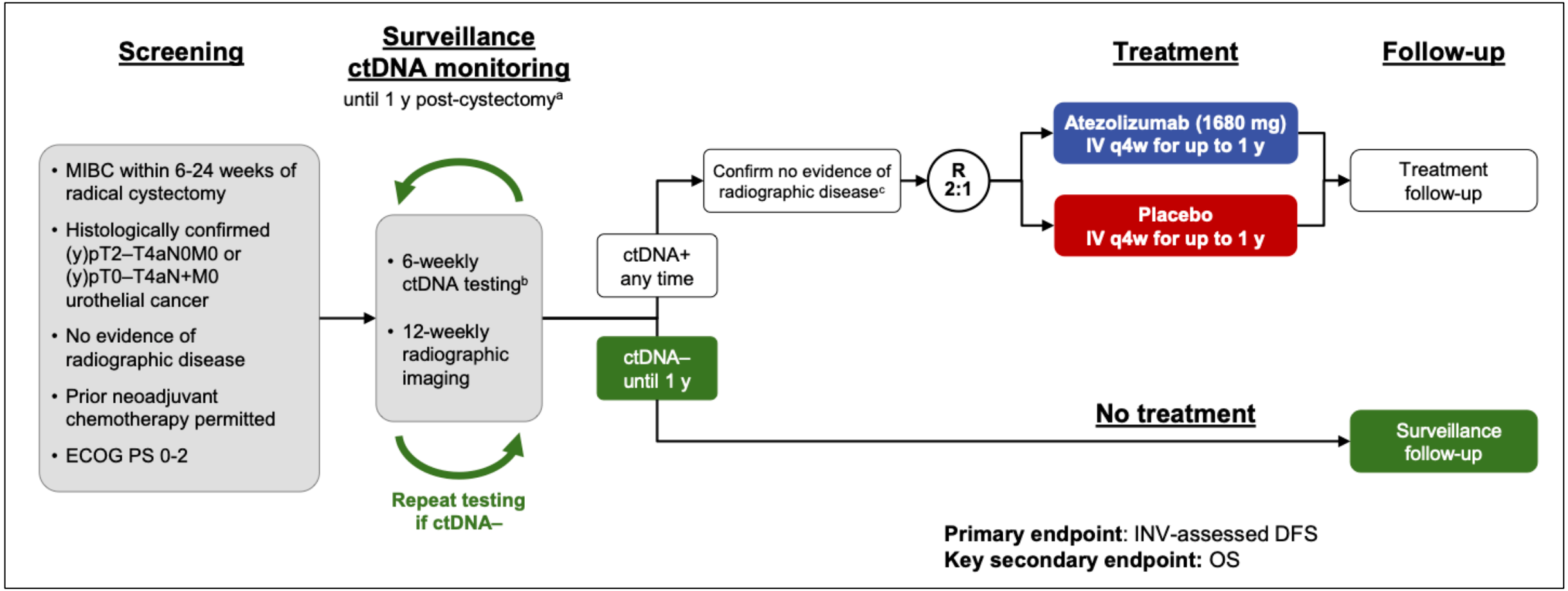
- BOIN, Bayesian Optimal Interval; CR, complete response; HR, high risk; IR, intermediate-risk; NGS, next-generation sequencing; NMIBC, nonmuscle-invasive bladder cancer; PCR, polymerase chain reaction; RC, radical cystectomy.

1. Liu S and Yuan Y. *J R Stat Soc Ser C Appl Stat*. 2015;64:507–523. 2. Yuan Y et al. *Clin Cancer Res*. 2016;22:4291–4301. 3. Vilaseca A et al. Presentation at the American Urological Association Annual Meeting; May 3–6, 2024; San Antonio, TX. Abstract 1343

Evolution of Systemic Therapy for MIBC

Grossman, NEJM, 2003; James, NEJM, 2012; Bajorin, NEJM, 2021; Powles NEJM, 2024; Vulsteke, NEJM, 2026; Galsky, ASCO GU, 2026

IMvigor 011 Phase 3 Trial



Powles T et al. *N Engl J Med.* 2025 Oct 20.

IMvigor 011 Phase 3 Trial

ctDNA+ at initial test

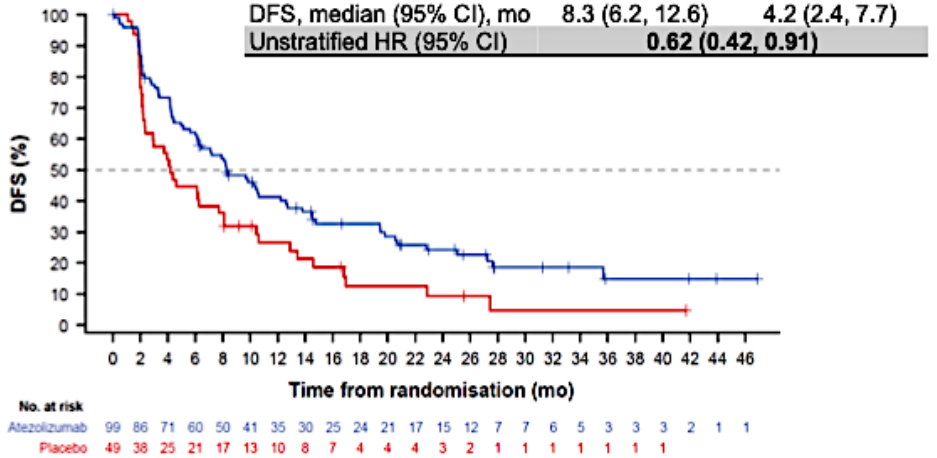
(148/250; 59.2%)

ctDNA+ at subsequent test

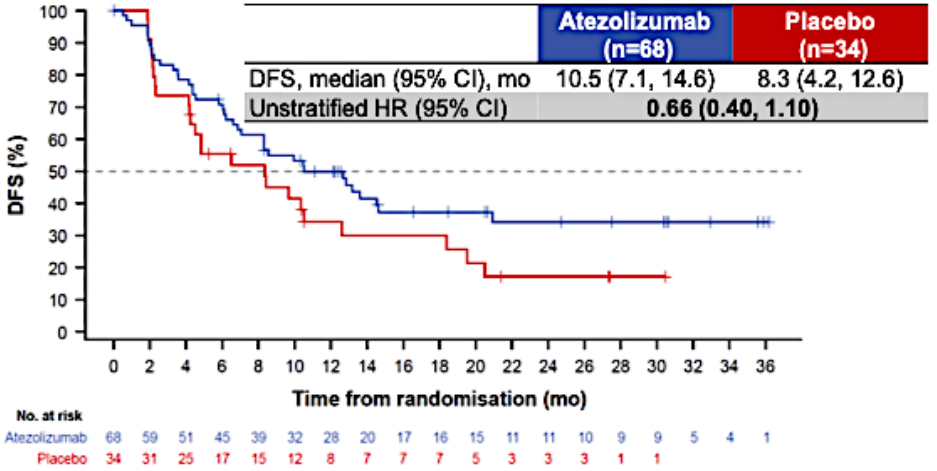
(102/250; 40.8%)

INV-assessed DFS

	Atezolizumab (n=99)	Placebo (n=49)
DFS, median (95% CI), mo	8.3 (6.2, 12.6)	4.2 (2.4, 7.7)
Unstratified HR (95% CI)	0.62 (0.42, 0.91)	

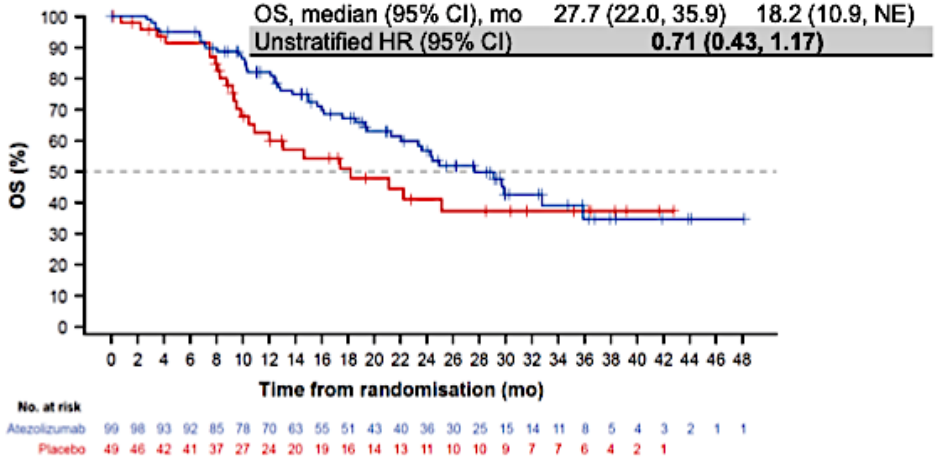


	Atezolizumab (n=68)	Placebo (n=34)
DFS, median (95% CI), mo	10.5 (7.1, 14.6)	8.3 (4.2, 12.6)
Unstratified HR (95% CI)	0.66 (0.40, 1.10)	

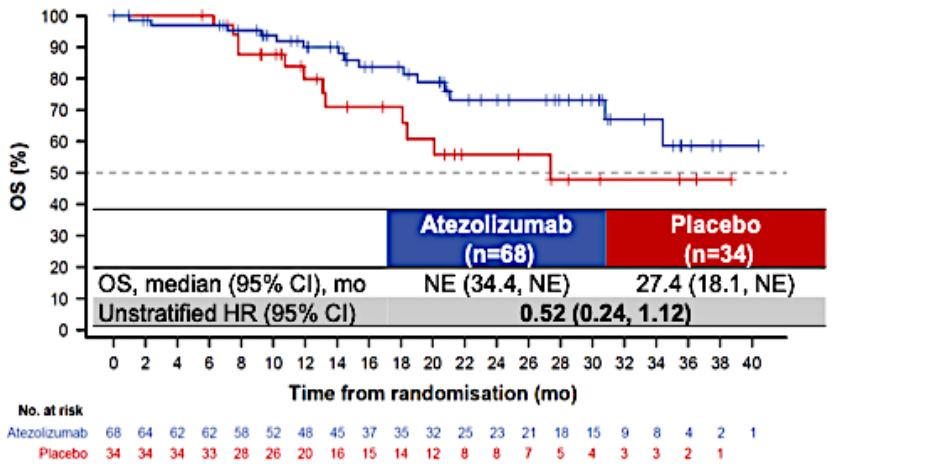


OS

	Atezolizumab (n=99)	Placebo (n=49)
OS, median (95% CI), mo	27.7 (22.0, 35.9)	18.2 (10.9, NE)
Unstratified HR (95% CI)	0.71 (0.43, 1.17)	

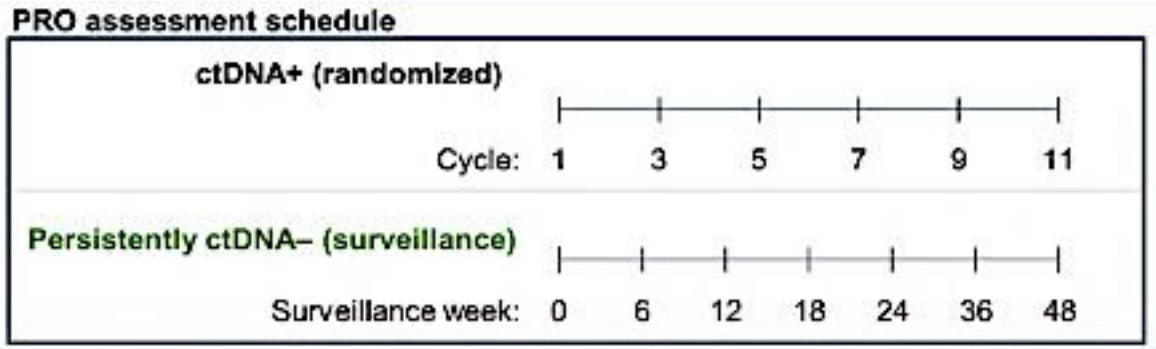


	Atezolizumab (n=68)	Placebo (n=34)
OS, median (95% CI), mo	NE (34.4, NE)	27.4 (18.1, NE)
Unstratified HR (95% CI)	0.52 (0.24, 1.12)	

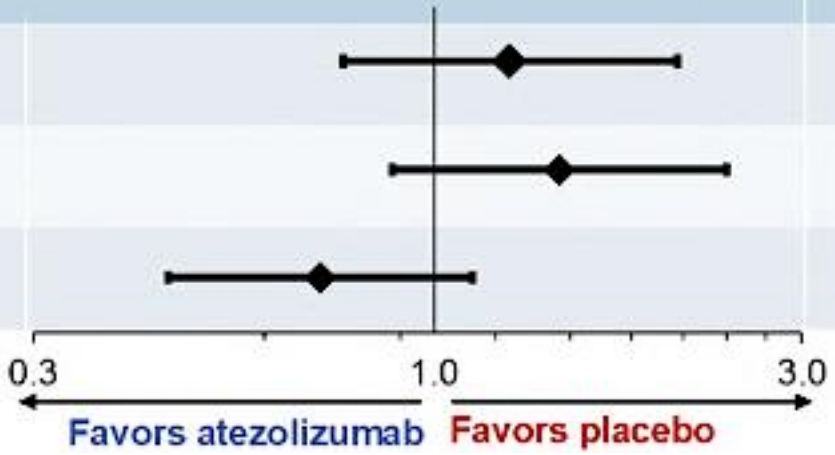


Powles T et al. *N Engl J Med.* 2025 Oct 20.

IMvigor 011 Phase 3 Trial: PROs



Measure	Median (95% CI), months: Atezolizumab	Placebo	Stratified HR (95% CI)
Time to confirmed deterioration[a,b]			
Physical functioning	25.1 (18.5, NE)	NE (19.4, NE)	1.25 (0.76, 2.07)
Role functioning	18.5 (12.2, NE)	NE (19.4, NE)	1.45 (0.88, 2.40)
GHS/QoL	35.4 (19.3, NE)	16.5 (10.9, NE)	0.71 (0.45, 1.12)



Bellmunt J et al. ASCO 2026;Abstract 4627

Contemporary perioperative trials in cisplatin-ineligible patients

Keynote-905/EV 303

(NCT03924895) (N = 857)

Treatment

Pembro → RC → Pembro (Arm A)

RC Alone (Arm B)

EVP → RC → EVP (Arm C)

Key Eligibility Criteria

Patients with MIBC who are cisplatin ineligible or refusant

Primary & Secondary Endpoints

Primary: EFS up to 7.7 yrs (Arms B+C)

Secondary: EFS up to 7.7 yrs (Arms A+B), OS up to 7.7 yrs (Arms B+C)

MET PRIMARY ENDPOINT

VOLGA

(NCT04960709) (N = 830)

Treatment

Durva + Treme + EV → RC → Durva + Treme (Arm A)

Durva + EV → RC → Durva (Arm B) **vs**

No systemic therapy → RC (Arm C)

Key Eligibility Criteria

Muscle invasive urothelial carcinoma; cisplatin ineligible or refusant

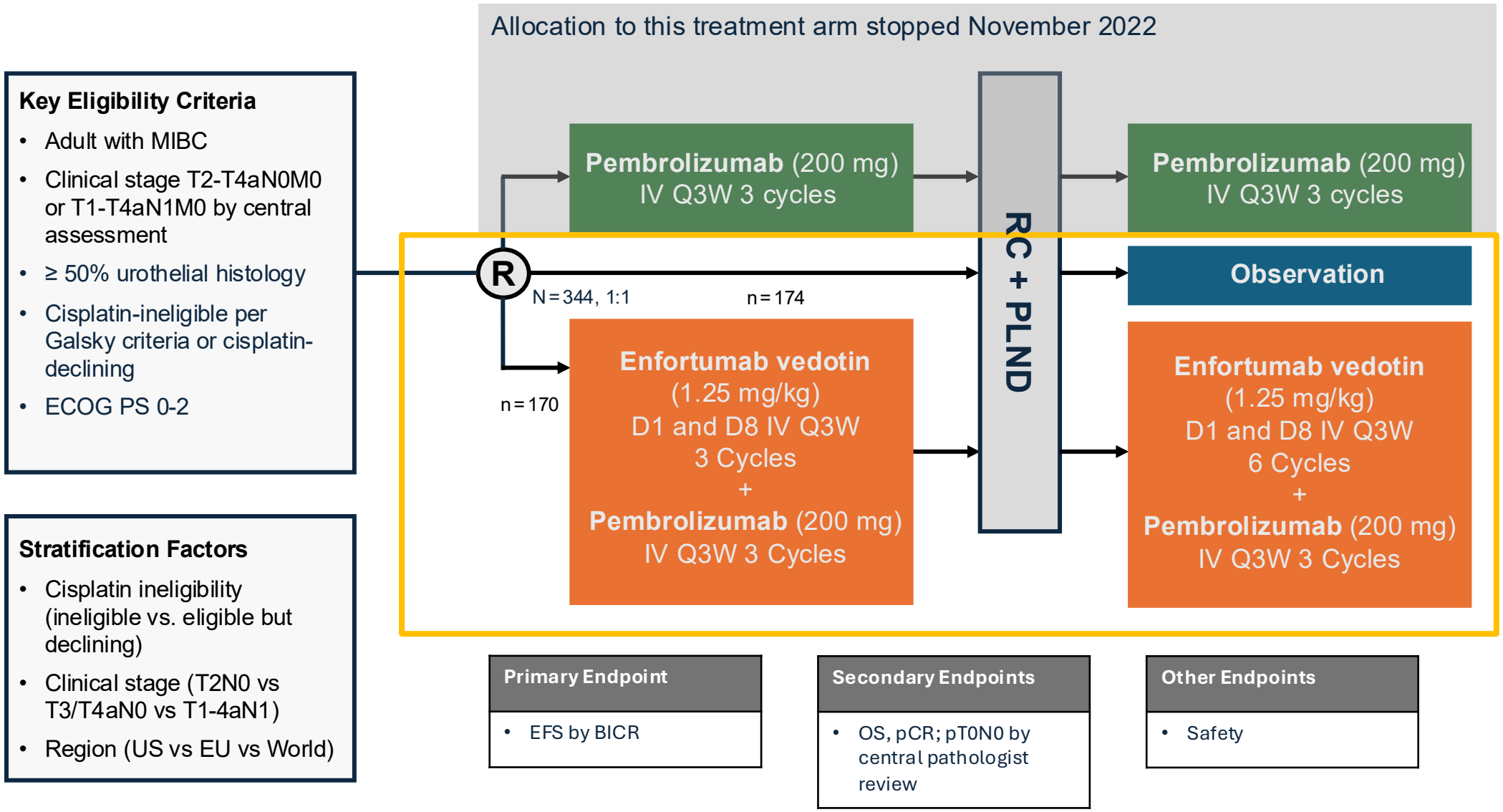
Primary & Secondary Endpoints

Primary: Efficacy of durva + treme + EV relative to surgery alone (pCR and EFS)

Secondary: pCR at time of cystectomy in Arm B vs Arm C

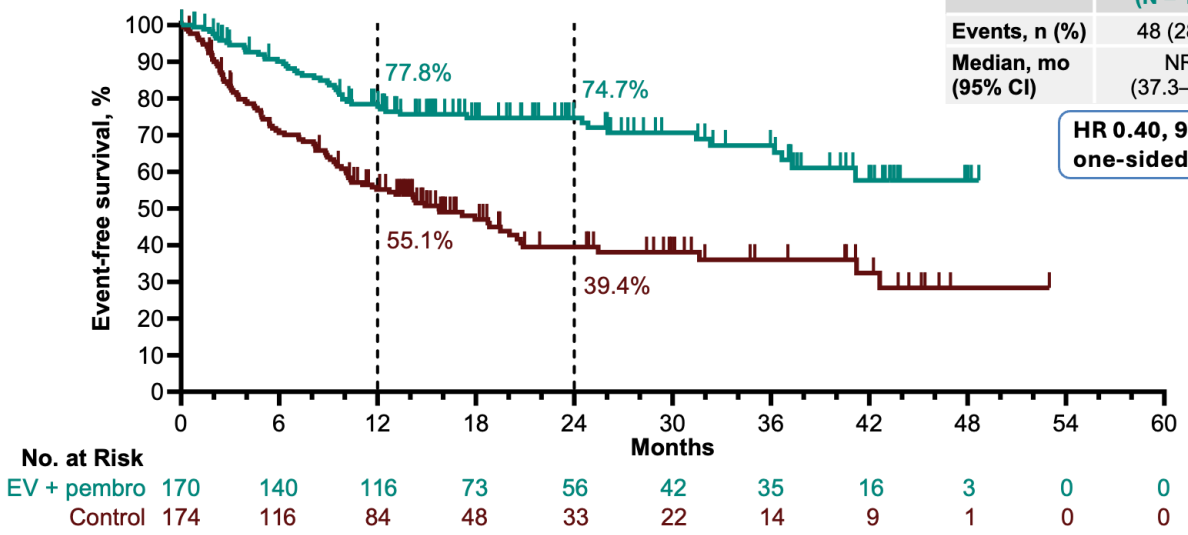
PRESS RELEASE: POSITIVE STUDY

KEYNOTE 905



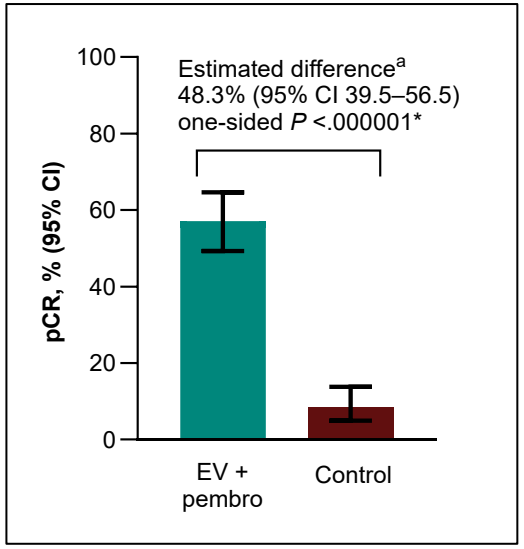
Vulsteke C, et al. *N Engl J Med*. 2026.

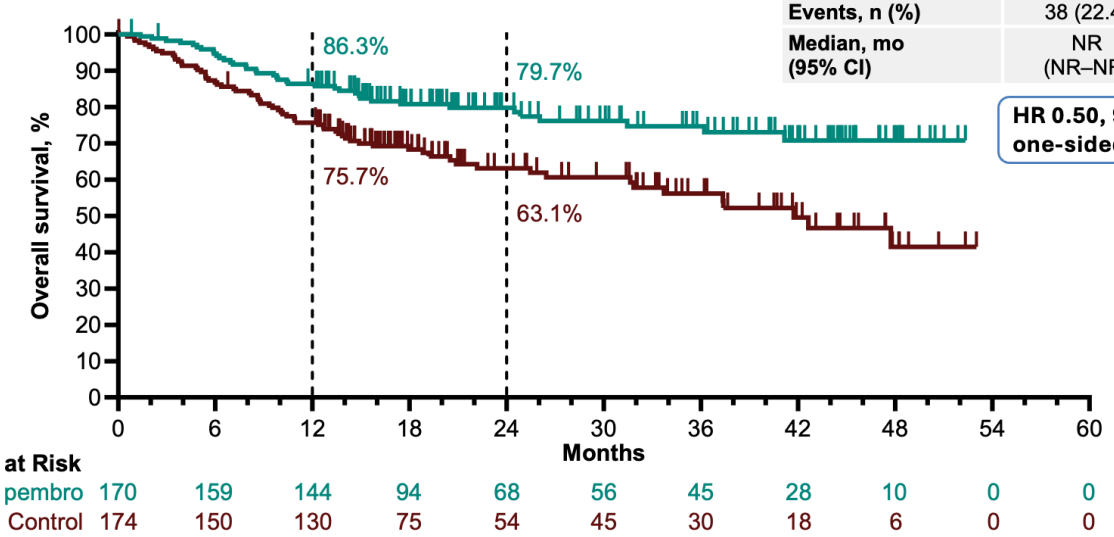
KEYNOTE 905



	EV + pembro (N = 170)	Control (N = 174)
Events, n (%)	48 (28.2)	95 (54.6)
Median, mo (95% CI)	NR (37.3–NR)	15.7 (10.3–20.5)

HR 0.40, 95% CI 0.28–0.57, one-sided *P* <.0001*





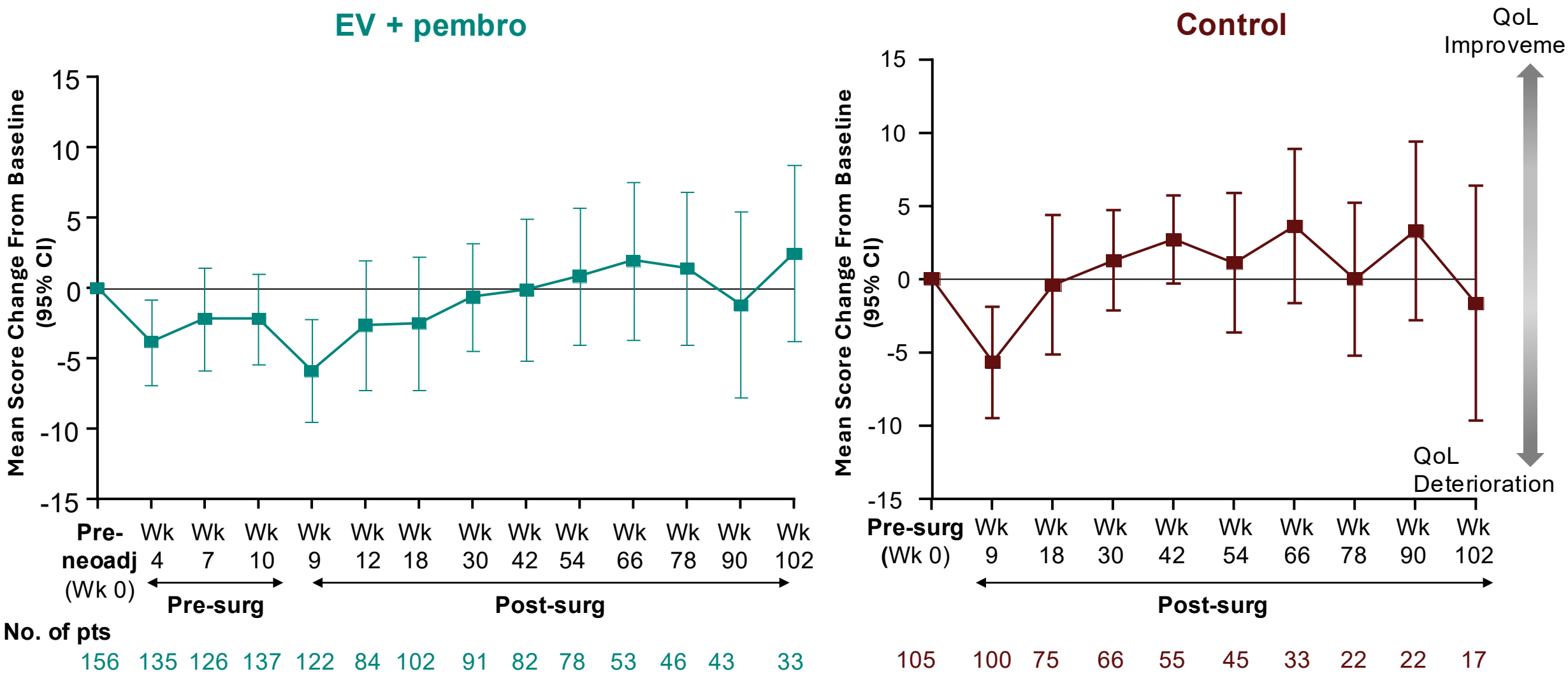
	EV + pembro (N = 170)	Control (N = 174)
Events, n (%)	38 (22.4)	68 (39.1)
Median, mo (95% CI)	NR (NR–NR)	41.7 (31.8–NR)

HR 0.50, 95% CI 0.33–0.74, one-sided *P* =.0002*

Vulsteke C, et al. *N Engl J Med*. 2026.

KEYNOTE 905

Change From Baseline Over Time in EQ-5D-5L VAS



Contemporary perioperative trials in cisplatin-eligible patients

NIAGARA

(NCT03732677)

(N = 1063)

Durvalumab + GemCis → RC → Durvalumab

GemCis → RC

Key Inclusion Criteria

MIBC/Immuno- and Chemotherapy Treatment-Naïve

Primary & Secondary Endpoints

Primary: pCR up to 6 mos, EFS up to 48 mos

Secondary: <P2 at time of cystectomy, EFS at 24 mos

MET PRIMARY ENDPOINT

KeyNote-866

(NCT03924856)

(N = 907)

Pembro + GemCis → RC → Pembro

GemCis → RC

Key Inclusion Criteria

UC/MIBC and RC plus PLND eligible

Primary & Secondary Endpoints

Primary: EFS up to 60 mos

Secondary: pCR and OS up to 72 mos

ACTIVE, NOT RECRUITING

KeyNote-B15

(NCT04700124)

(N = 784)

EVP → RC → EVP

GemCis → RC

Key Inclusion Criteria

UC/MIBC and RC plus PLND eligible

Primary & Secondary Endpoints

Primary: EFS up to 48 mos

Secondary: pCR up to 47 mos, OS up to 68 mos

MET PRIMARY ENDPOINT

Energize

(NCT03661320)

(N = 861)

GemCis → RC, Nivo + GemCis → RC → Nivo, Nivo + GemCis + Linro → RC → Nivo + Linro

Key Inclusion Criteria

MIBC/Treatment-Naive

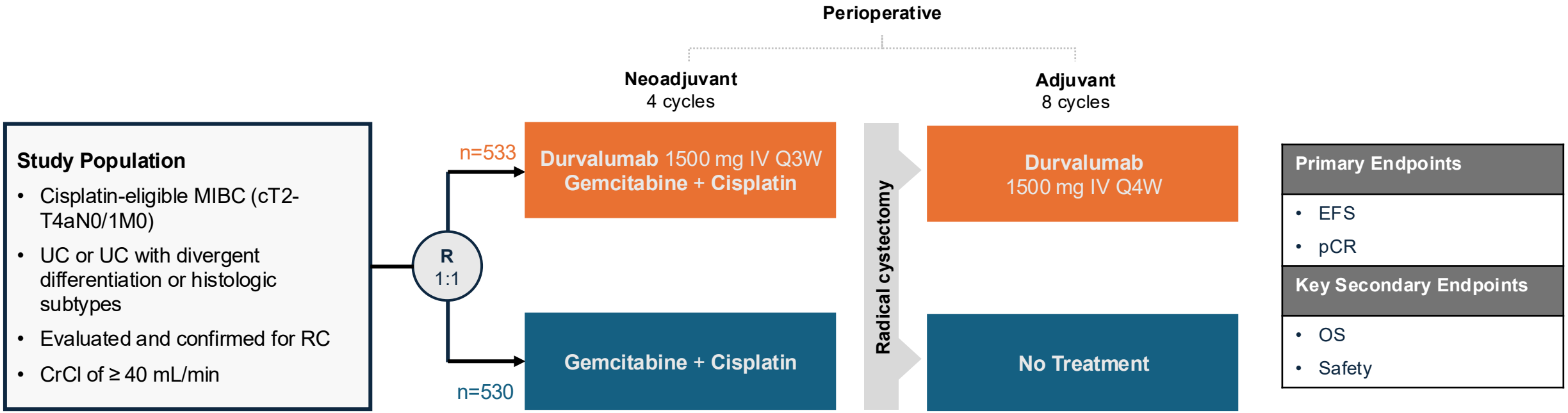
Primary & Secondary Endpoints

Primary: pCR (43 mos), EFS (51 mos)

Secondary: OS (60 mos), AEs and SAEs

ACTIVE, NOT RECRUITING

NIAGARA



Stratification Factors
- Clinical tumor stage (T2N0 vs >T2N0)
- Renal function (CrCl ≥ 60 mL/min vs ≥ 40 to < 60 mL/min)
- PD-L1 status (high vs low/negative expression)

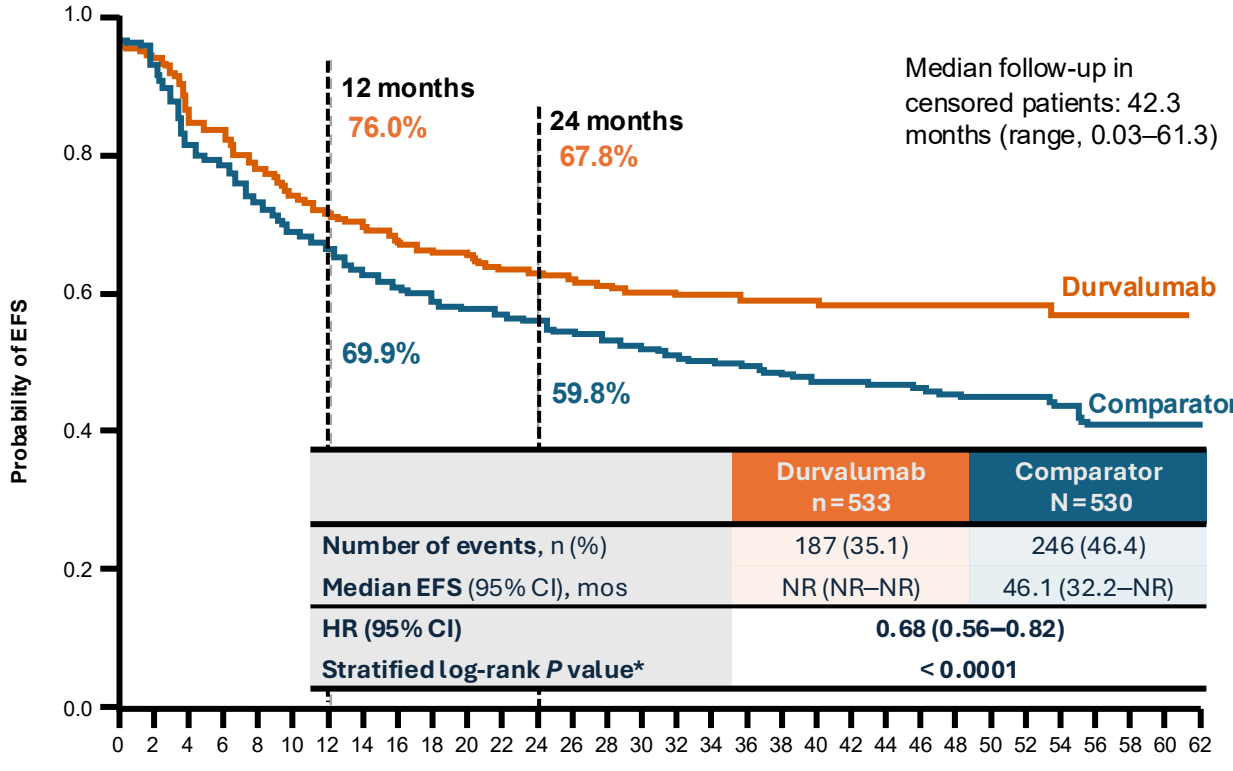
Gemcitabine/Cisplatin Dosing
- CrCl ≥60 mL/min: cisplatin 70 mg/m^2 + gemcitabine 1000 mg/m^2 day 1, then gemcitabine 1000 mg/ m^2 day 8, Q3W for 4 cycles
- CrCl <60 mL/min: split-dose cisplatin 35 mg/m^2 + gemcitabine 1000 mg/m^2 days 1 and 8, Q3W for 4 cycles

EFS was defined as:
- Progressive disease that precluded RC
- Recurrence after RC
- Date of expected surgery in patients who did not undergo RC
- Death from any cause

Powles T, et al. *N Engl J Med*. 2024;391:1773-1786.

NIAGARA

Primary Endpoint: EFS by Blinded Independent Central Review (ITT)

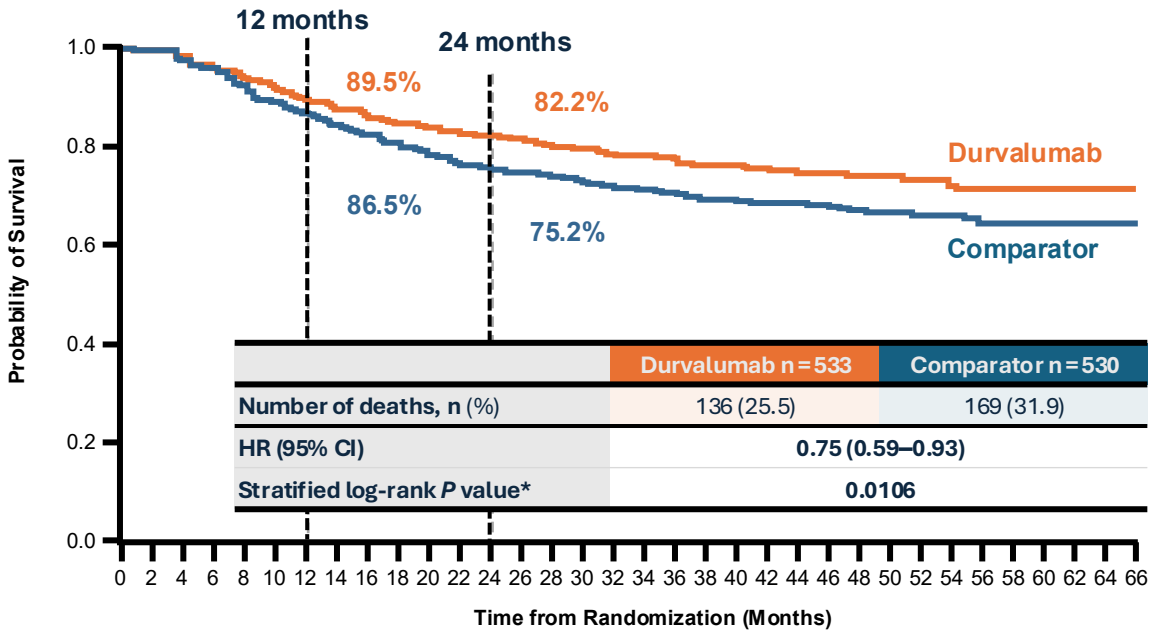


	Durvalumab n = 533	Comparator N = 530
Number of events, n (%)	187 (35.1)	246 (46.4)
Median EFS (95% CI), mos	NR (NR–NR)	46.1 (32.2–NR)
HR (95% CI)	**0.68 (0.56–0.82)**	
Stratified log-rank *P* value*	**< 0.0001**	

No. of patients at risk

Durvalumab	533	519	475	454	424	401	386	370	356	348	344	335	330	321	315	312	282	269	255	214	202	180	141	140	115	86	81	32	20	20	1	0
Comparator	530	498	437	416	381	358	343	328	313	300	296	288	281	273	264	259	228	219	214	177	172	159	132	129	94	69	62	24	18	16	2	0

Overall Survival (ITT)



	Durvalumab n = 533	Comparator n = 530
Number of deaths, n (%)	136 (25.5)	169 (31.9)
HR (95% CI)	**0.75 (0.59–0.93)**	
Stratified log-rank *P* value*	**0.0106**	

No. of patients at risk

Durvalumab	533	528	517	505	492	478	468	457	446	440	434	428	423	418	410	408	400	375	349	321	295	271	238	207	182	152	125	96	68	34	21	7	1	0
Comparator	530	516	507	490	467	450	438	425	413	402	392	383	378	373	368	363	358	334	311	281	259	239	215	194	174	141	113	90	60	38	21	10	2	0

Powles T, et al. *N Engl J Med*. 2024;391:1773-1786.

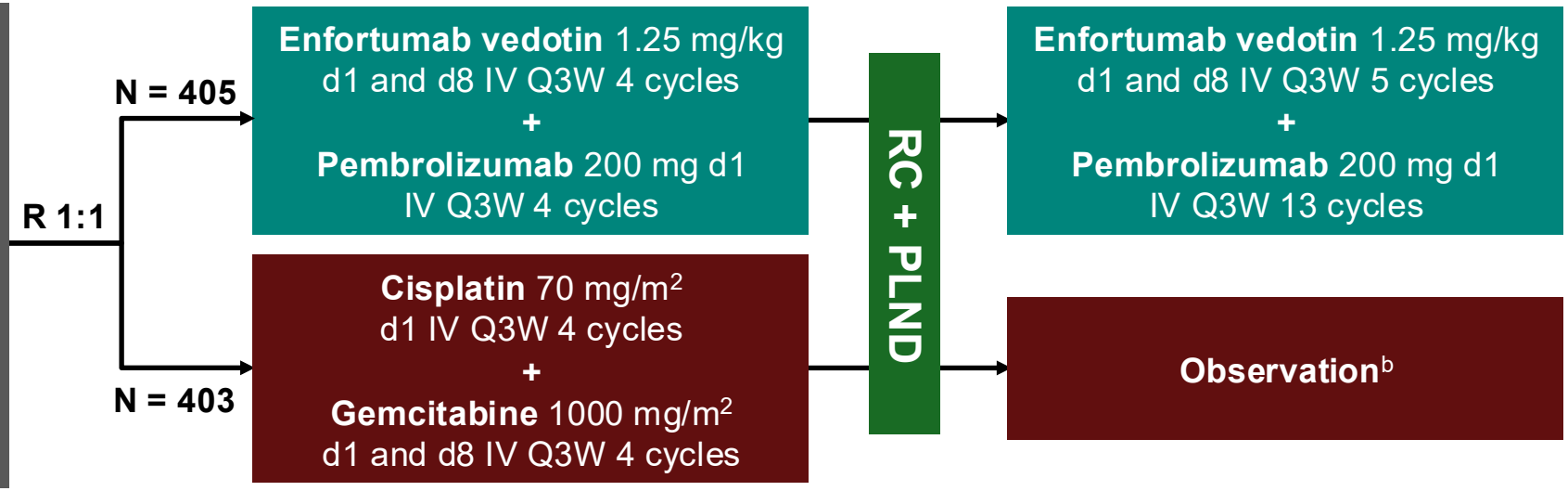
KEYNOTE B15

Key Eligibility Criteria

- Adults with MIBC
- Clinical stage T2-T4aN0M0 or T1-T4aN1M0 by central assessment
- Urothelial histology ≥50%
- Eligible for RC + PLND
- Did not meet any Galsky criteria for cisplatin ineligibility
- ECOG PS 0-1

Stratification Factors

- PD-L1 status (CPS ≥10 vs. <10)[a]
- Clinical stage (T2N0 vs. T3/T4aN0 vs. T1-4aN1)
- Geographic region (US vs. EU vs. Most of World)



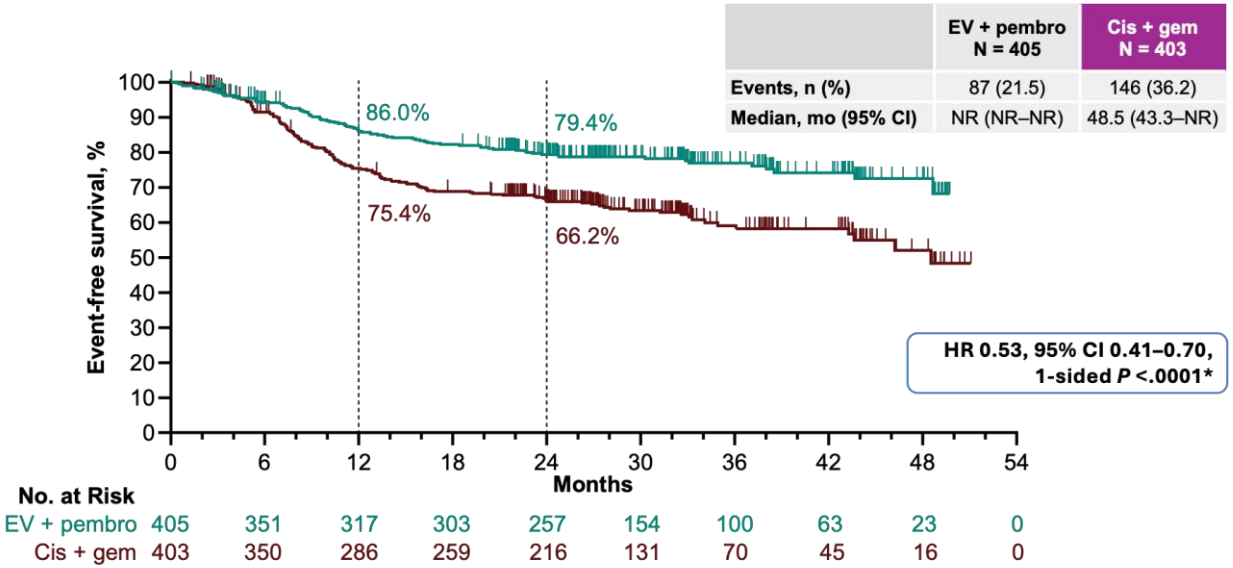
Primary endpoint: Event-free survival (EFS) by BICR

Key secondary endpoints: OS and pathological complete response (pCR; pT0N0, i.e. absence of viable tumor in examined tissue from surgery) by central pathologist review

Other secondary endpoints include: Safety

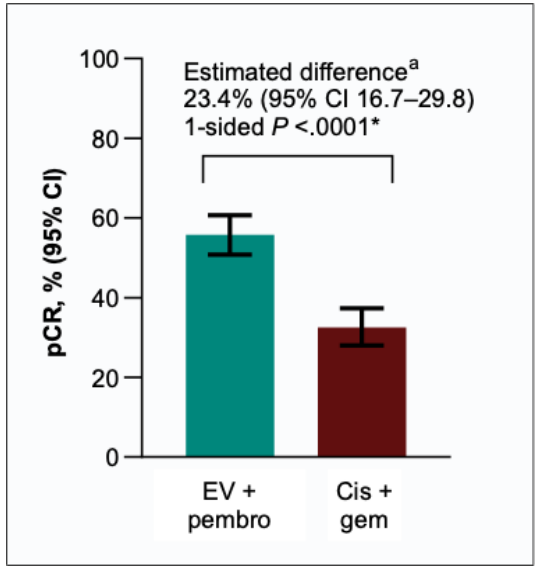
Galsky M. ASCO GU, 2026.

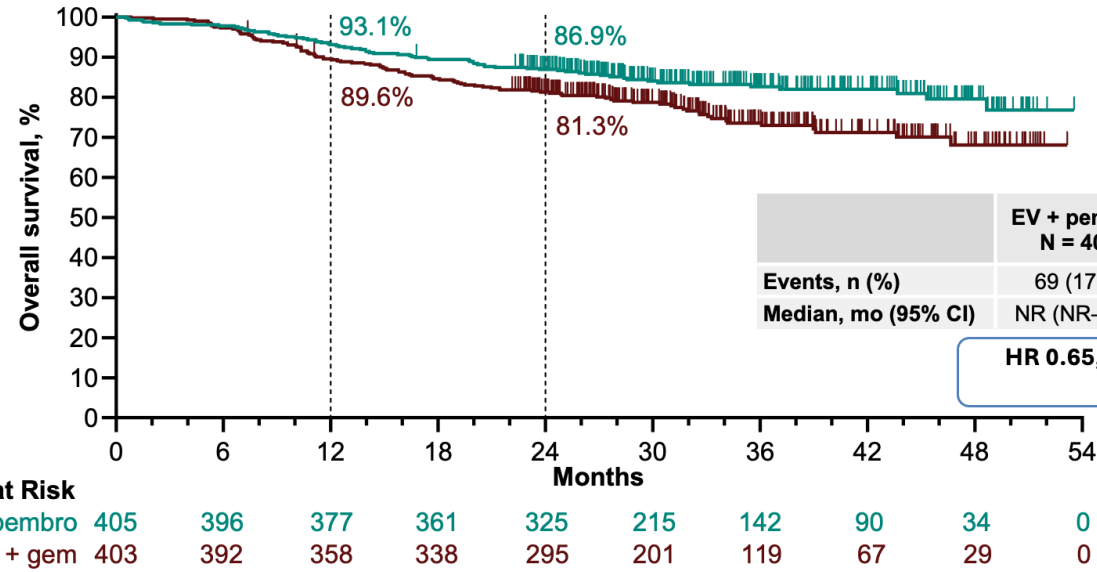
KEYNOTE B15



	EV + pembro N = 405	Cis + gem N = 403
Events, n (%)	87 (21.5)	146 (36.2)
Median, mo (95% CI)	NR (NR–NR)	48.5 (43.3–NR)

HR 0.53, 95% CI 0.41–0.70, 1-sided *P* <.0001*

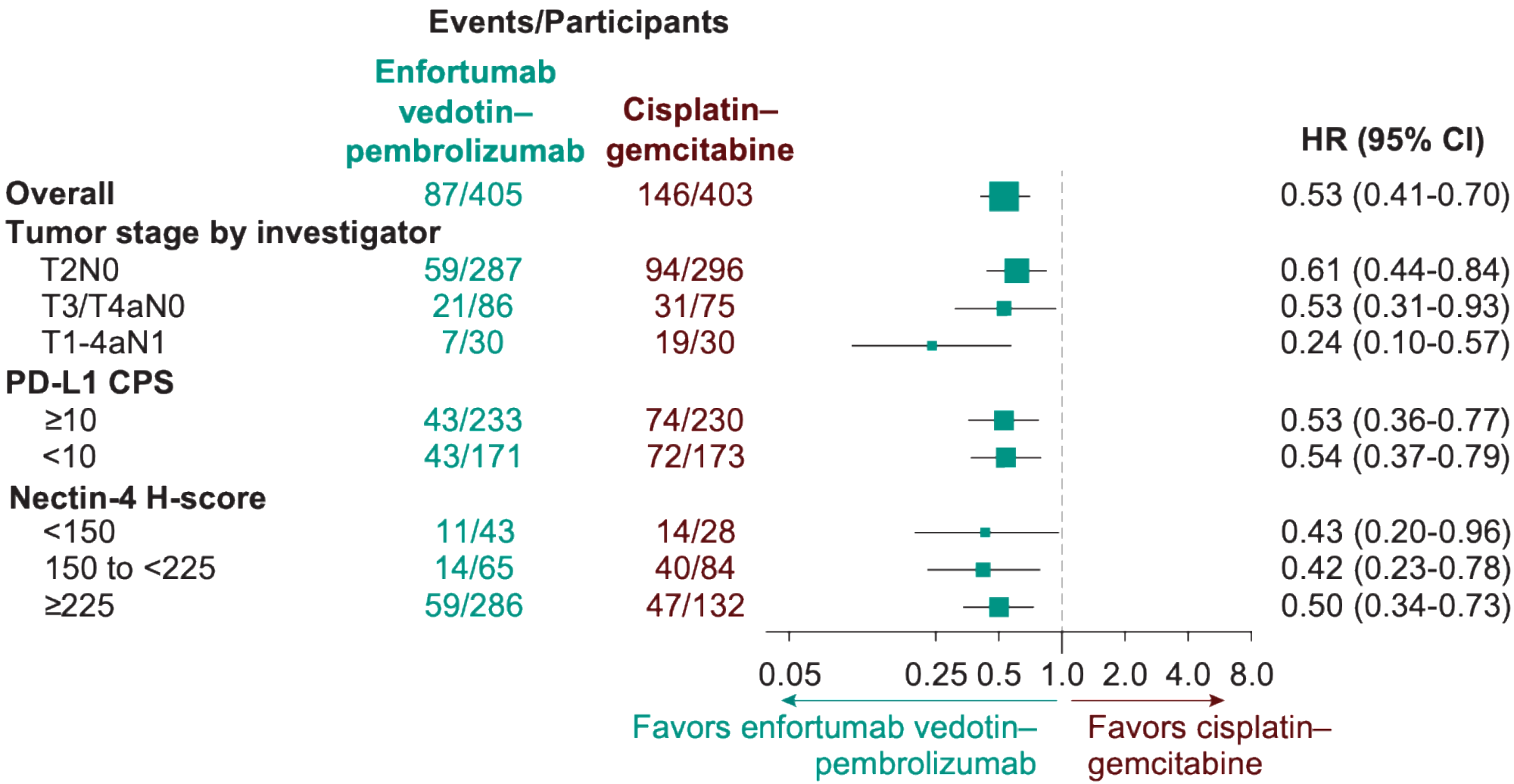




	EV + pembro N = 405	Cis + gem N = 403
Events, n (%)	69 (17.0)	99 (24.6)
Median, mo (95% CI)	NR (NR–NR)	NR (NR–NR)

HR 0.65, 95% CI 0.48–0.89, 1-sided *P* =.0029*

KEYNOTE B15



Participants with Other tumor stage, missing PD-L1 CPS, or missing Nectin-4 H-score at baseline are not included.

Hoimes C. ASCO, 2026.

EV-302 Design

ITT Patient Population (N=886)

- Untreated la/mUC
- Eligible for EV, P, and platinum
- PD-(L)1 inhibitor-naive
- GFR ≥30 mL/min[a]
- ECOG PS ≤2[b]

R 1:1

EV+P[c]
Treatment until progression[d]

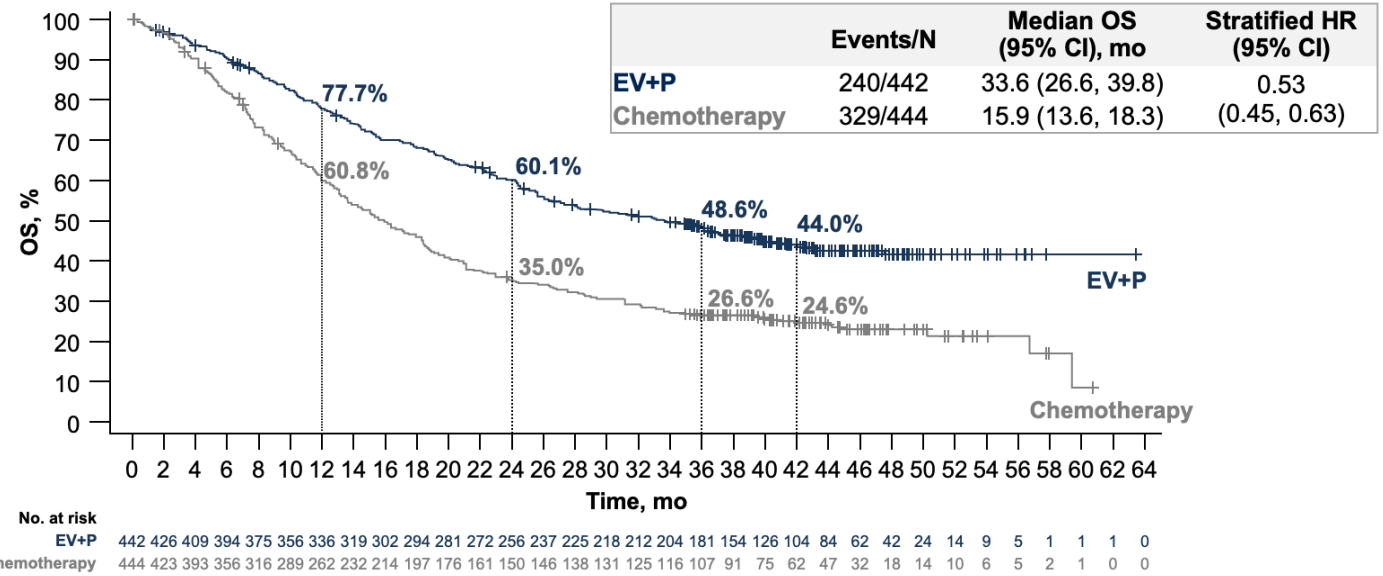
Chemotherapy[e]
(gemcitabine + cisplatin/carboplatin)
Maximum 6 cycles

Stratification factors:
- *Cisplatin eligibility (eligible/ineligible)*
- *PD-L1 expression (high, CPS ≥10; low, CPS <10)*
- *Liver metastases (present/absent)*

Dual primary endpoints:
- PFS by BICR
- OS

Select secondary endpoints:
- ORR per RECIST 1.1 by BICR and INV assessment
- DOR
- Safety

BICR was discontinued at previous data cutoff; therefore, BICR-based endpoints were not updated for this analysis. However, OS follow-up is ongoing

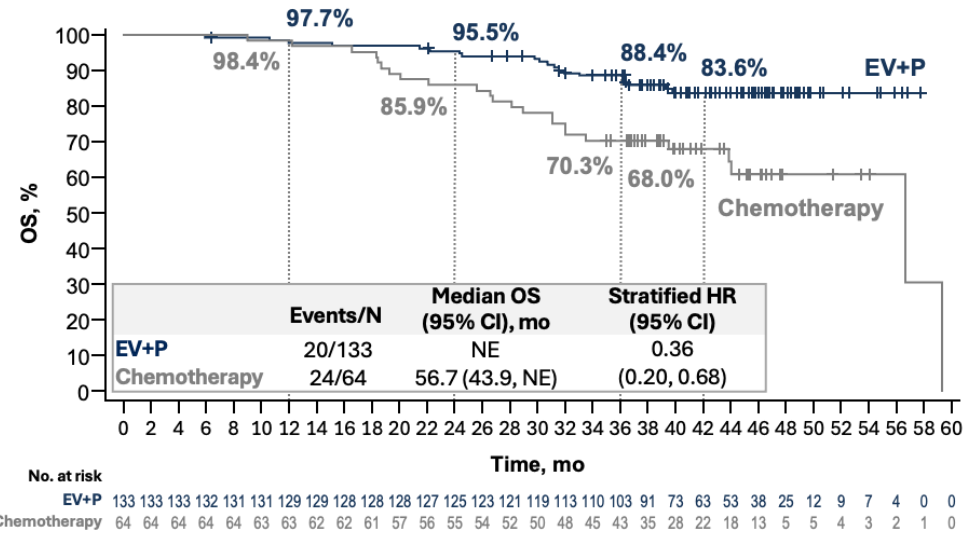


	Events/N	Median OS (95% CI), mo	Stratified HR (95% CI)
EV+P	240/442	33.6 (26.6, 39.8)	0.53 (0.45, 0.63)
Chemotherapy	329/444	15.9 (13.6, 18.3)	

No. at risk

EV+P	442	426	409	394	375	356	336	319	302	294	281	272	256	237	225	218	212	204	181	154	126	104	84	62	42	24	14	9	5	1	1	1	0
Chemotherapy	444	423	393	356	316	289	262	232	214	197	176	161	150	146	138	131	125	116	107	91	75	62	47	32	18	14	10	6	5	2	1	0	0

Patients with a CR



	Events/N	Median OS (95% CI), mo	Stratified HR (95% CI)
EV+P	20/133	NE	0.36 (0.20, 0.68)
Chemotherapy	24/64	56.7 (43.9, NE)	

No. at risk

EV+P	133	133	133	132	131	131	129	129	128	128	128	127	125	123	121	119	113	110	103	91	73	63	53	38	25	12	9	7	4	0	0
Chemotherapy	64	64	64	64	64	63	63	62	62	61	57	56	55	54	52	50	48	45	43	35	28	22	18	13	5	5	4	3	2	1	0

Powles T et al, ASCO 2026;Abstract 4507.

Post-EV+Pembrolizumab Treatment?

Disease progression despite EV+Pembro

Biomarker Assessment: FGFR3 | HER2

FGFR3 Altered

- Erdafitinib

HER2 Positive

- T-DXd

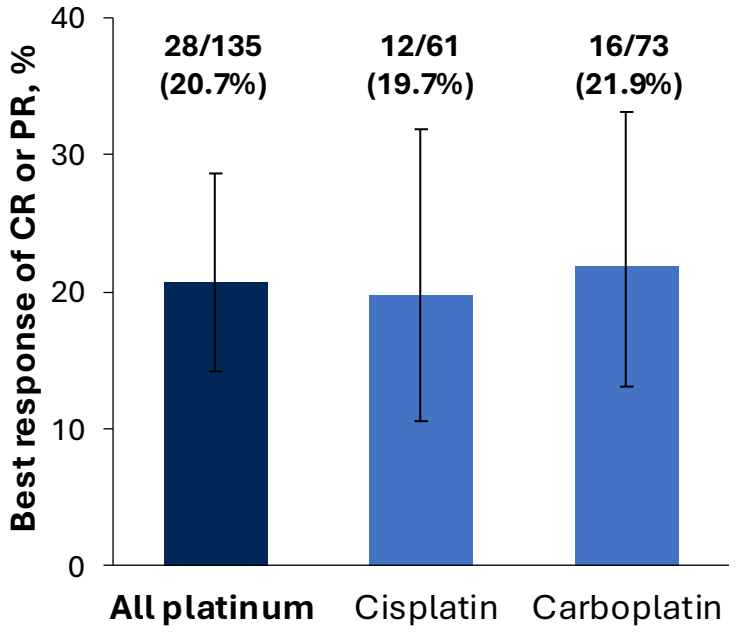
No Actionable Target

- Platinum chemo

Platinum-based Therapy after EV + P

	EV+P (n=442)
Patients who received subsequent anticancer therapies, n (%)	192 (43.4)
Systemic therapy	173 (39.1)
First subsequent systemic therapy, n (%)	
Platinum-containing chemotherapy[a]	135 (30.5)
Carboplatin-based therapy	73 (16.5)
Cisplatin-based therapy	61 (13.8)
PD-(L)1 inhibitor therapy[b]	17 (3.8)
Maintenance	0
EV+P-based therapy	2 (0.5)
Other PD-(L)1 inhibitor therapy	15 (3.4)
Atezolizumab	1 (0.2)
Pembrolizumab	14 (3.2)
Other	21 (4.8)

ORR in evaluable patients receiving subsequent platinum-based chemotherapy[a,c]



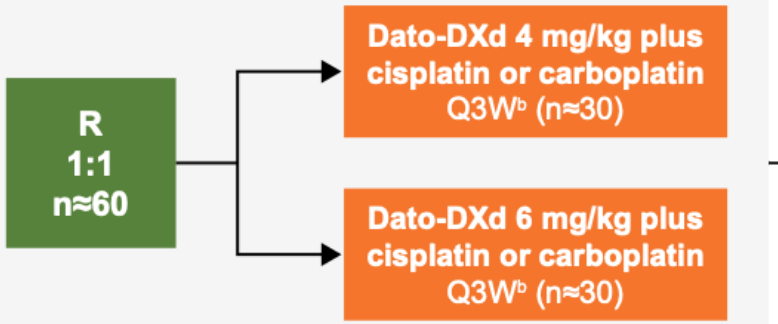
- Median OS from start of platinum-based chemotherapy was 10.9 months (95% CI 8.3, 12.8)

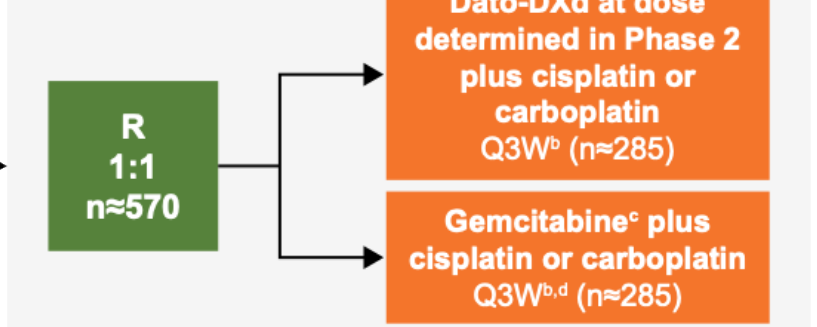
Powles T et al, ASCO 2026;Abstract 4507.

TROPION-Urothelial03: A phase 2/3 study of datopotamab deruxtecan (Dato-DXd) + platinum chemotherapy (CT) vs gemcitabine + platinum CT in participants with locally advanced or metastatic urothelial carcinoma (la/mUC) with progression on or after enfortumab vedotin (EV) + pembrolizumab.

Key inclusion criteria

- Unresectable la/mUC
- Measurable disease on CT/MRI per RECIST 1.1[a]
- ≥18 years of age or minimum legal adult age
- Radiographic progression or relapse during or after 1L EV plus pembrolizumab
- Tumor tissue sample of sufficient quantity from archival or newly obtained tissue
- Eligible to receive cisplatin- or carboplatin-containing chemotherapy
- Eastern Cooperative Oncology Group performance status of 0 or 1





Primary endpoint:
ORR by investigator[e]

Dual primary endpoints:
PFS by BICR[e] and OS

Galsky M et al. ASCO 2026;Abstract TPS4642.

Case 1

- A 68-year-old man with a history of former smoking presented with intermittent gross hematuria.
- Cystoscopy showed a large multifocal papillary tumor burden, and TURBT demonstrated high-grade T1 urothelial carcinoma with concomitant carcinoma in situ.
- Restaging TURBT confirmed persistent high-risk NMIBC without muscle invasion.
- CT urogram and chest imaging showed no evidence of metastatic disease.

Case 2

- A 74-year-old woman developed irritative voiding symptoms and hematuria.
- A TURBT revealed muscle-invasive urothelial carcinoma, cT3N0M0.
- Baseline staging CT chest/abdomen/pelvis showed a solitary bladder mass without nodal or visceral metastases.
- Baseline labs notable for a creatinine of 1.8.

Case 3

- A 71-year-old man underwent TURBT for gross hematuria and was found to have high-grade muscle-invasive urothelial carcinoma.
- He declined neoadjuvant chemotherapy because of frailty concerns and a desire to proceed directly to surgery.
- He underwent radical cystoprostatectomy with pelvic lymph node dissection, and final pathology showed pT3N0 urothelial carcinoma with extravesical extension and negative surgical margins.
- Postoperatively, he recovered without major complications.
- Signatera testing post-cystectomy revealed detectable ctDNA.
- Cross-sectional imaging remained negative for overt recurrence at that time.

Agenda

Introduction: Welcome GU Oncology Fellows!

Module 1: Prostate Cancer — Dr Aggarwal

Module 2: Urothelial Bladder Cancer — Dr Galsky

Module 3: Renal Cell Carcinoma — Dr Zhang

Updates in renal cell carcinoma Research To Practice

Tian Zhang, MD, MHS, FASCO

Associate Professor

Associate Director of Clinical Research

Simmons Comprehensive Cancer Center

UT Southwestern Medical Center

Dallas, TX 75230

Outline

- Adjuvant RCC
  - ctDNA from Keynote 564 (ASCO 2026)
  - LITESPARK 022 – approval of pembrolizumab/belzutifan
  - RAMPART – durvalumab vs surveillance (ASCO 2026)
  - Trial in progress: STRIKE

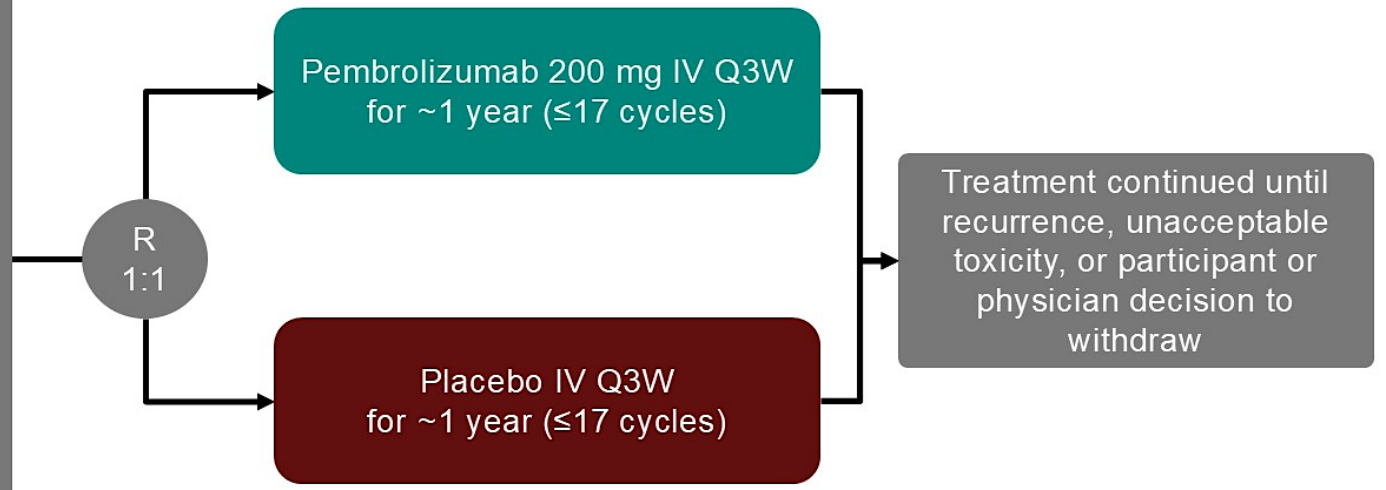
- Metastatic RCC
  - Checkmate 9ER trial bone & liver metastases subgroups (ASCO 2026)
  - CLEAR: patterns of progression (ASCO 2026)
  - LITESPARK011: Lenvatinib + belzutifan vs cabozantinib (GU ASCO 2026)
  - TiNivo-2: tivozanib+nivolumab vs tivozanib (ASCO 2026)
  - Trial in progress: LITESPARK033

- Non-clear cell RCC
  - Cabozantinib-nivolumab (ASCO 2026)

KEYNOTE-564 Study Design (NCT03142334)

Key Eligibility Criteria
- Age ≥18 years
- Histologically confirmed clear cell RCC
- No prior systemic therapy for advanced disease
- Surgery ≤12 weeks prior to randomization
- Postnephrectomy intermediate-high risk of recurrence (M0):
  - pT2, grade 4 or sarcomatoid, N0
  - pT3, any grade, N0
- Postnephrectomy high risk of recurrence (M0):
  - pT4, any grade, N0
  - Any pT, any grade, N+
- Postnephrectomy and complete resection of metastasis (M1 NED)
- ECOG PS score of 0 or 1

Stratification Factors
- M stage (M0 vs M1 NED)
- M0 group further stratified:
  - ECOG PS score of 0 vs 1
  - US vs rest of the world



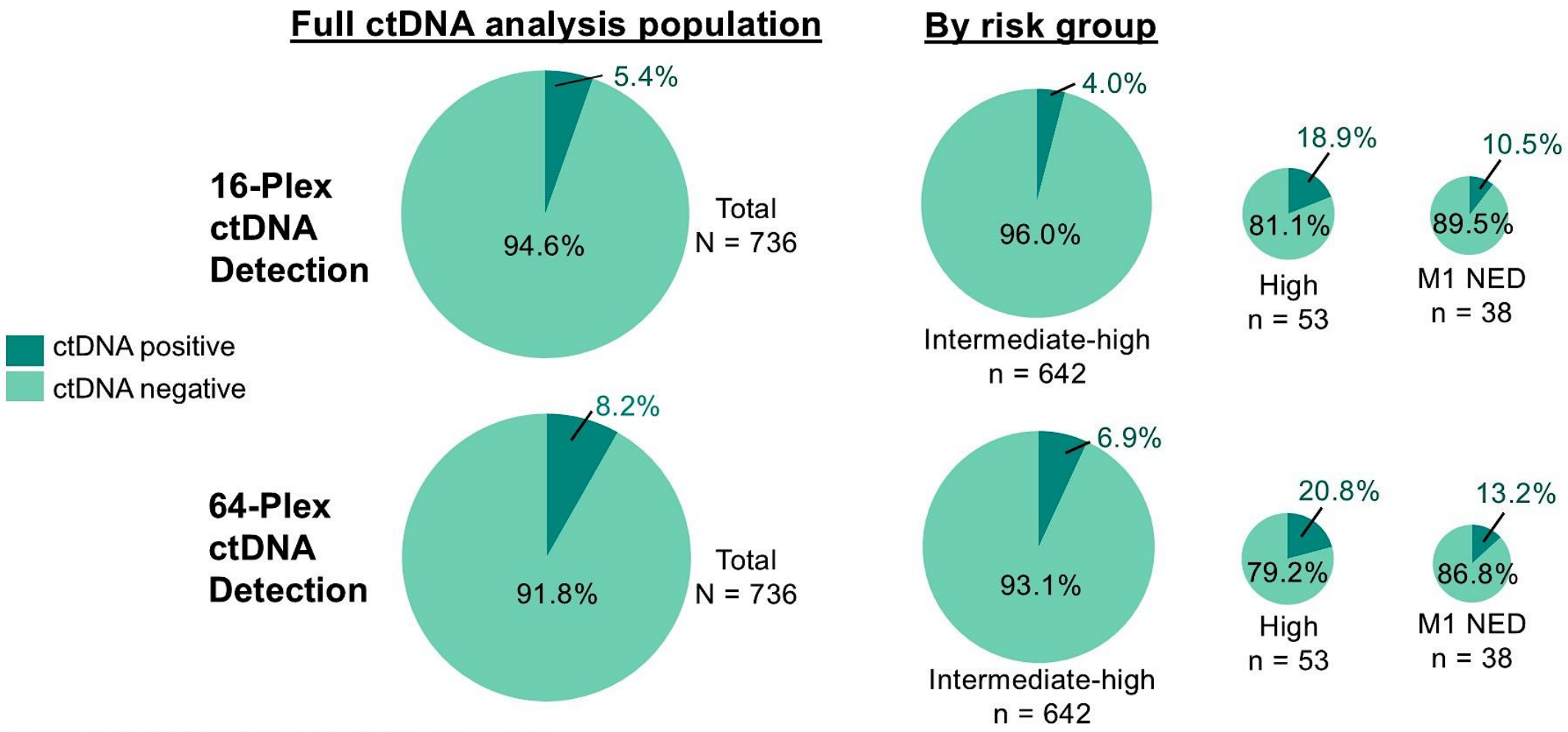
Primary end point: DFS by investigator
Key secondary end point: OS
Other secondary end point: Safety

Exploratory end points: Association of baseline ctDNA metrics and ctDNA change from baseline to cycle 5 day 1 (C5D1) with DFS[a] for pembrolizumab and placebo separately, and ctDNA clearance rate at C5D1

[a]Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of baseline ctDNA to predict disease recurrence were also evaluated.

Choueiri et al, ASCO 2026

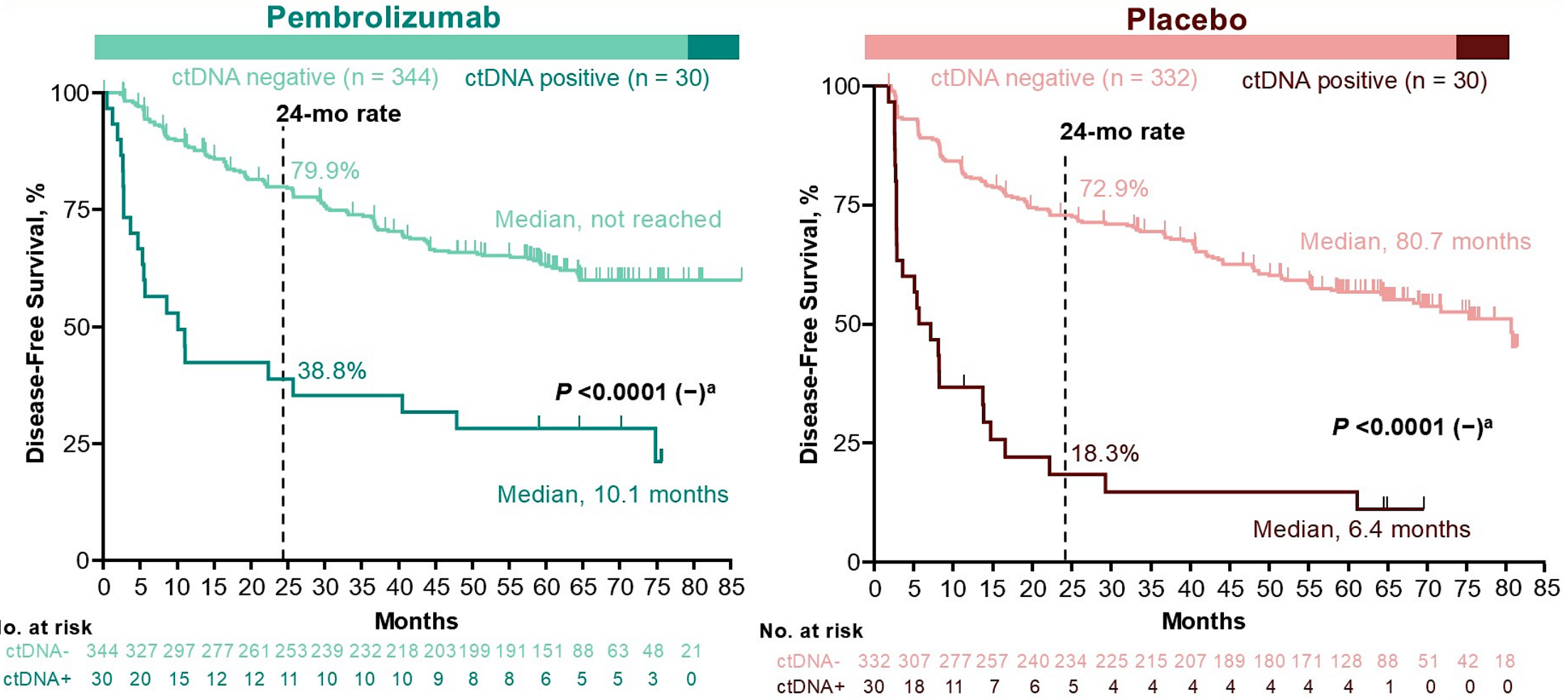
Exome-based ctDNA Status at Baseline Postsurgery[a]



[a]Analysis includes both treatment arms. Clinical data cutoff: September 25, 2024.

Choueiri et al, ASCO 2026

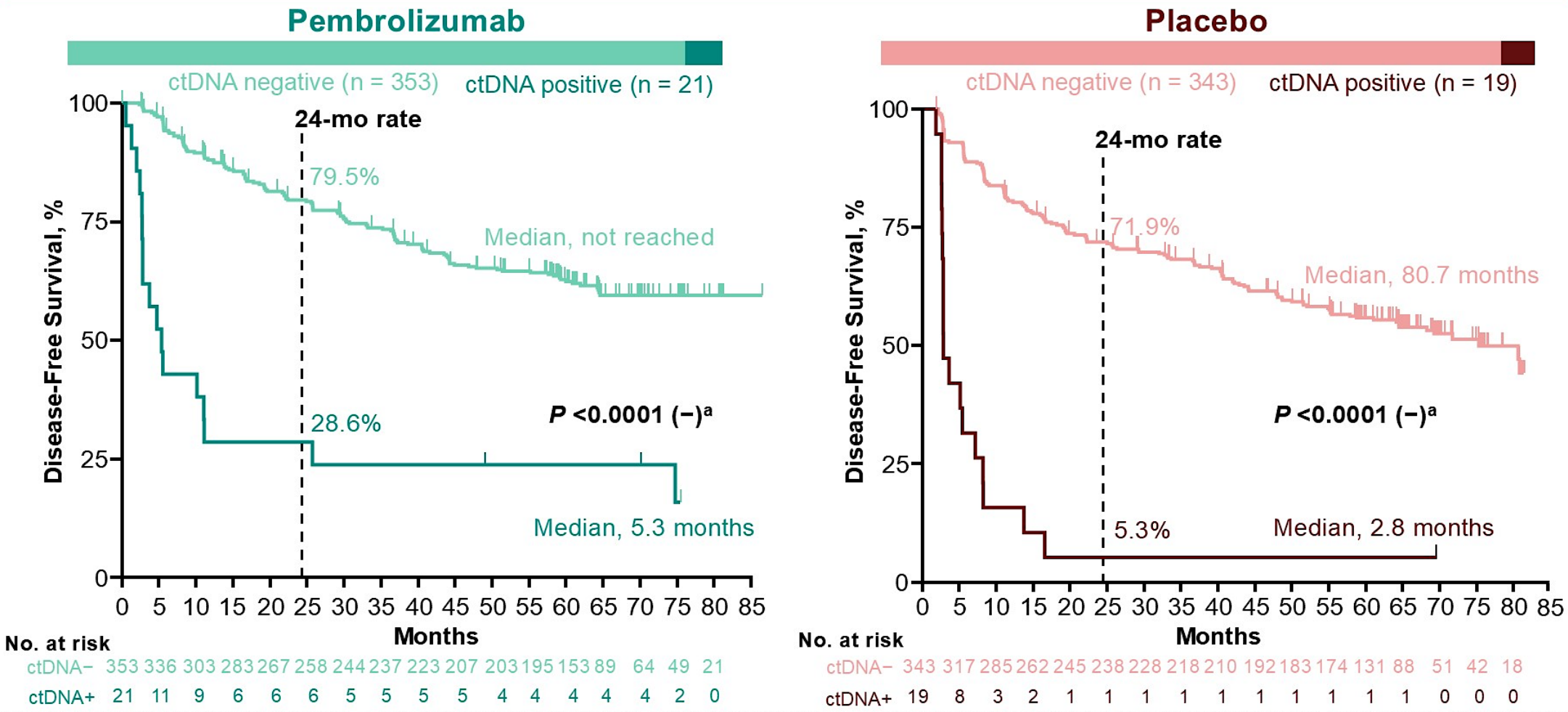
Kaplan-Meier Estimates of DFS by Baseline ctDNA Status Within Each Treatment Arm: Exome-Based 64-Plex Assay



a"–" indicates that the observed association is negative. The association between baseline ctDNA metrics and DFS remained significant after adjusting for risk groups and other stratification factors. Statistical significance prespecified at multiplicity-adjusted α = 0.05. Clinical data cutoff: September 25, 2024.

Choueiri et al, ASCO 2026

Kaplan-Meier Estimates of DFS by Baseline ctDNA Status Within Each Treatment Arm: Exome-Based 16-Plex Assay



a"−" indicates that the observed association is negative. The association between baseline ctDNA metrics and DFS remained significant after adjusting for risk groups and other stratification factors. Statistical significance prespecified at multiplicity-adjusted α = 0.05. Clinical data cutoff: September 25, 2024.

Choueiri et al, ASCO 2026

Study Design: LITESPARK-022 (NCT05239728)

Key Eligibility Criteria

- Histologically confirmed ccRCC with no prior systemic therapy
- Surgery ≤12 weeks prior to randomization
- ECOG PS 0 or 1
- One of the following:
  - Intermediate-high risk of recurrence (M0):
    - pT2, grade 4 or sarcomatoid, N0
    - pT3, any grade, N0
  - High risk of recurrence (M0):
    - pT4, any grade, N0
    - Any pT, any grade, N+
  - M1 NED

Median follow-up (data cutoff, Aug 23, 2025):
28.4 months (range, 15.0–40.1)

Stratification Factors

- Intermediate-high vs high vs M1 NED
- Tumor grade 1-2 vs 3-4

Primary endpoint: DFS by investigator
Key secondary endpoint: OS
Other secondary endpoints include: safety

LITESPARK022: Baseline characteristics

Characteristic, n (%)	Pembrolizumab + belzutifan (N = 921)	Pembrolizumab + placebo (N = 920)
Age, median (range), yrs	59.0 (20–91)	60.0 (24–86)
Sex		
Male	673 (73.1)	642 (69.8)
Female	248 (26.9)	278 (30.2)
US Region		
US	140 (15.2)	115 (12.5)
Non-US	781 (84.8)	805 (87.5)
Race		
White	576 (62.5)	581 (63.2)
All others	303 (32.9)	315 (34.2)
Missing	42 (4.6)	24 (2.6)
ECOG PS		
0	788 (85.6)	777 (84.5)
1	133 (14.4)	143 (15.5)

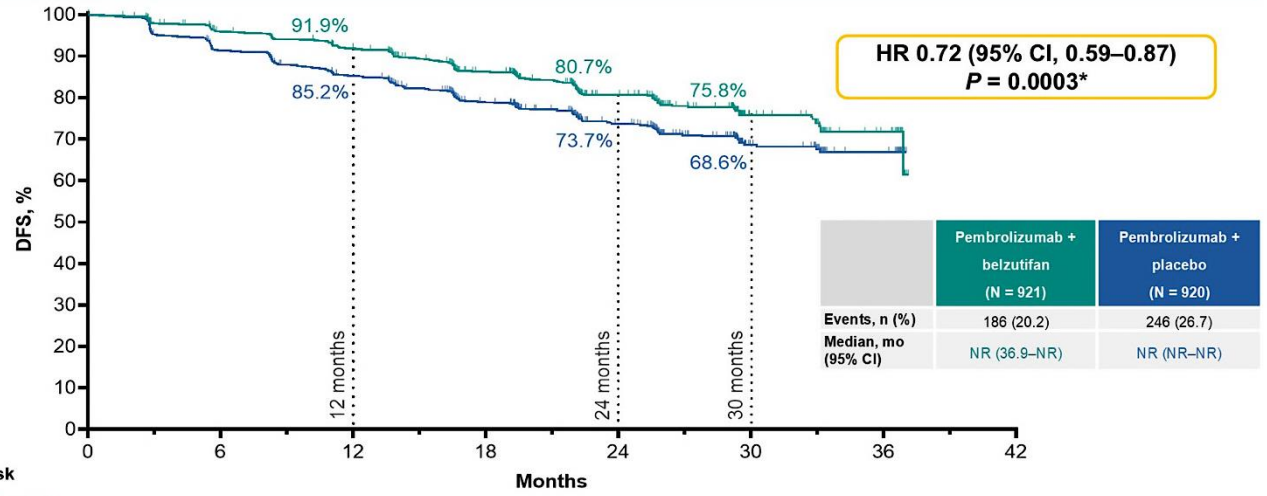
Characteristic, n (%)	Pembrolizumab + belzutifan (N = 921)	Pembrolizumab + placebo (N = 920)
Risk Category[a]		
Intermediate-to-High	779 (84.6)	782 (85.0)
High	58 (6.3)	53 (5.8)
M1 NED	84 (9.1)	84 (9.1)
Sarcomatoid features		
Present	104 (11.3)	84 (9.1)
Absent	730 (79.3)	724 (78.7)
Unknown	87 (9.4)	112 (12.2)
Tumor grade		
1-2	322 (35.0)	328 (35.7)
3-4	599 (65.0)	592 (64.3)
PD-L1 status[b]		
CPS <1	222 (24.1)	217 (23.6)
CPS ≥1	547 (59.4)	502 (54.6)
Not available[c]	152 (16.5)	201 (21.8)

Majority non-US
Intermediate-high risk
~9% M1 NED

[a]One participant had stage 2 (T2, N0, M0), grade 2 disease and was thus ineligible for these categories. [b]Programmed death ligand 1 (PD-L1) combined positive score (CPS) was determined via the number of PD-L1–staining cells (tumor cells, lymphocytes, and macrophages) divided by the total number of viable tumor cells, multiplied by 100. [c]Includes participants with missing or non-evaluable assessment of PD-L1 status.
Data cutoff: August 23, 2025.

Choueiri et al, GU ASCO 2026

DFS by Investigator, ITT Population

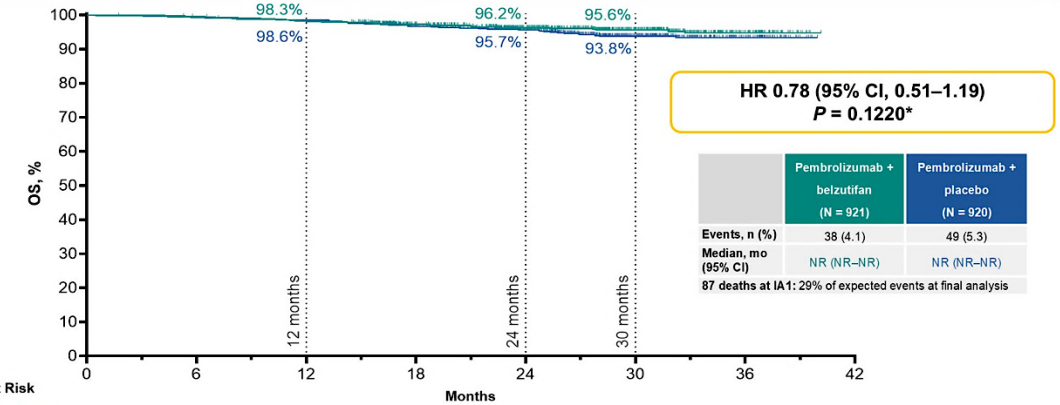


No. at Risk								
Pembrolizumab + belzutifan	921	850	805	669	451	153	35	0
Pembrolizumab + placebo	920	823	759	619	417	140	38	0

*Denotes statistical significance by stratified log-rank test (p-value boundary, 0.01632).
NR, not reached. ITT population comprised all randomized participants. HRs and 95% CI estimated via stratified Cox proportional hazard model.
Median follow-up: 28.4 months (range, 15.0–40.1). Data cutoff: August 23, 2025.

FDA approval 6/12/2026 Pembrolizumab + belzutifan for adjuvant RCC

Interim OS Results, ITT Population

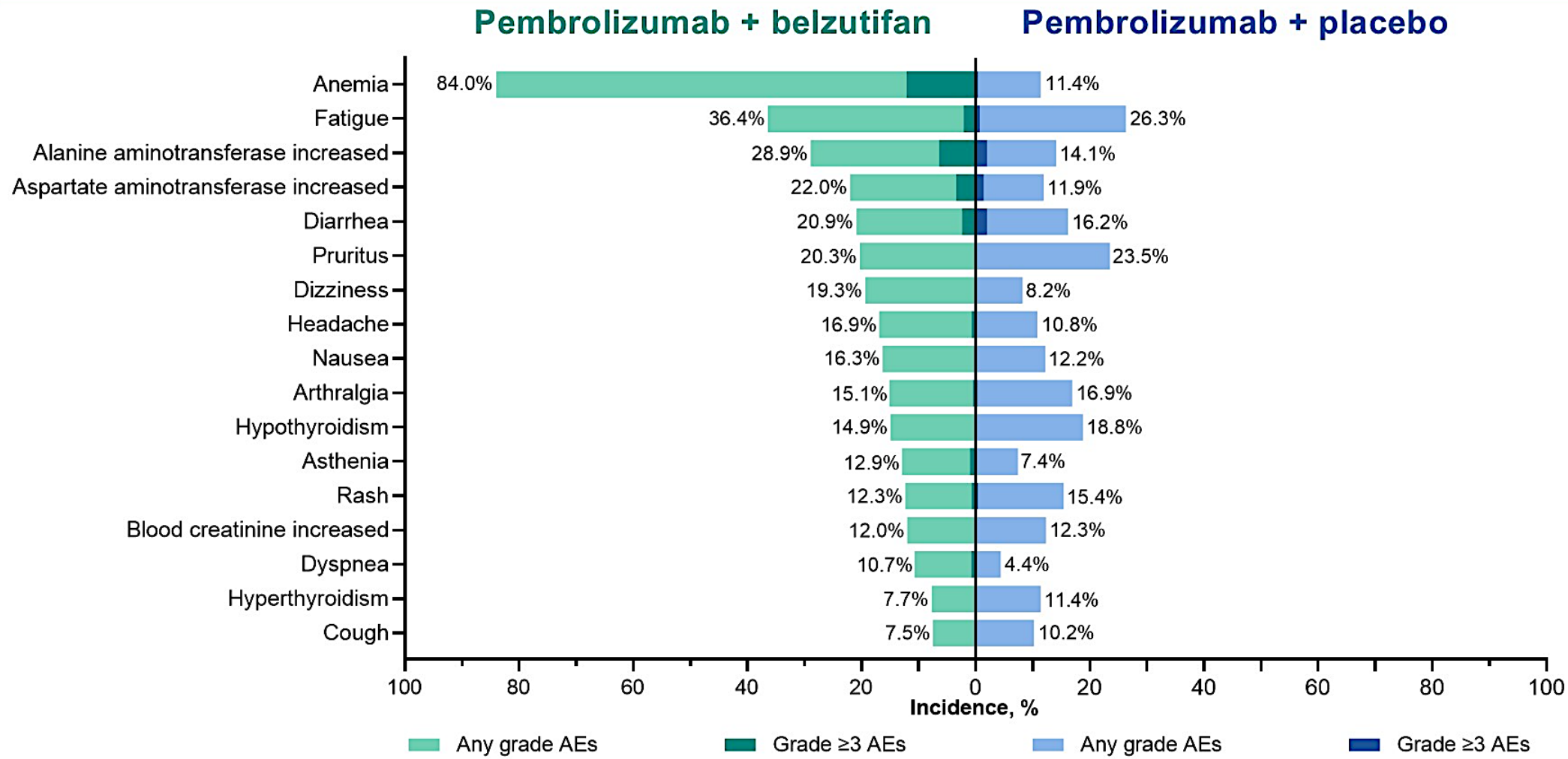


No. at Risk								
Pembrolizumab + belzutifan	921	914	900	805	631	319	70	0
Pembrolizumab + placebo	920	914	907	807	638	319	69	0

*Did not reach statistical significance by stratified log-rank test (p-value boundary, 0.00003).
Final analysis for OS to occur after approximately 300 OS events. HRs and 95% CI estimated via stratified Cox proportional hazard model.
Median follow-up: 28.4 months (range, 15.0–40.1). Data cutoff: August 23, 2025.

Choueiri et al, GU ASCO 2026

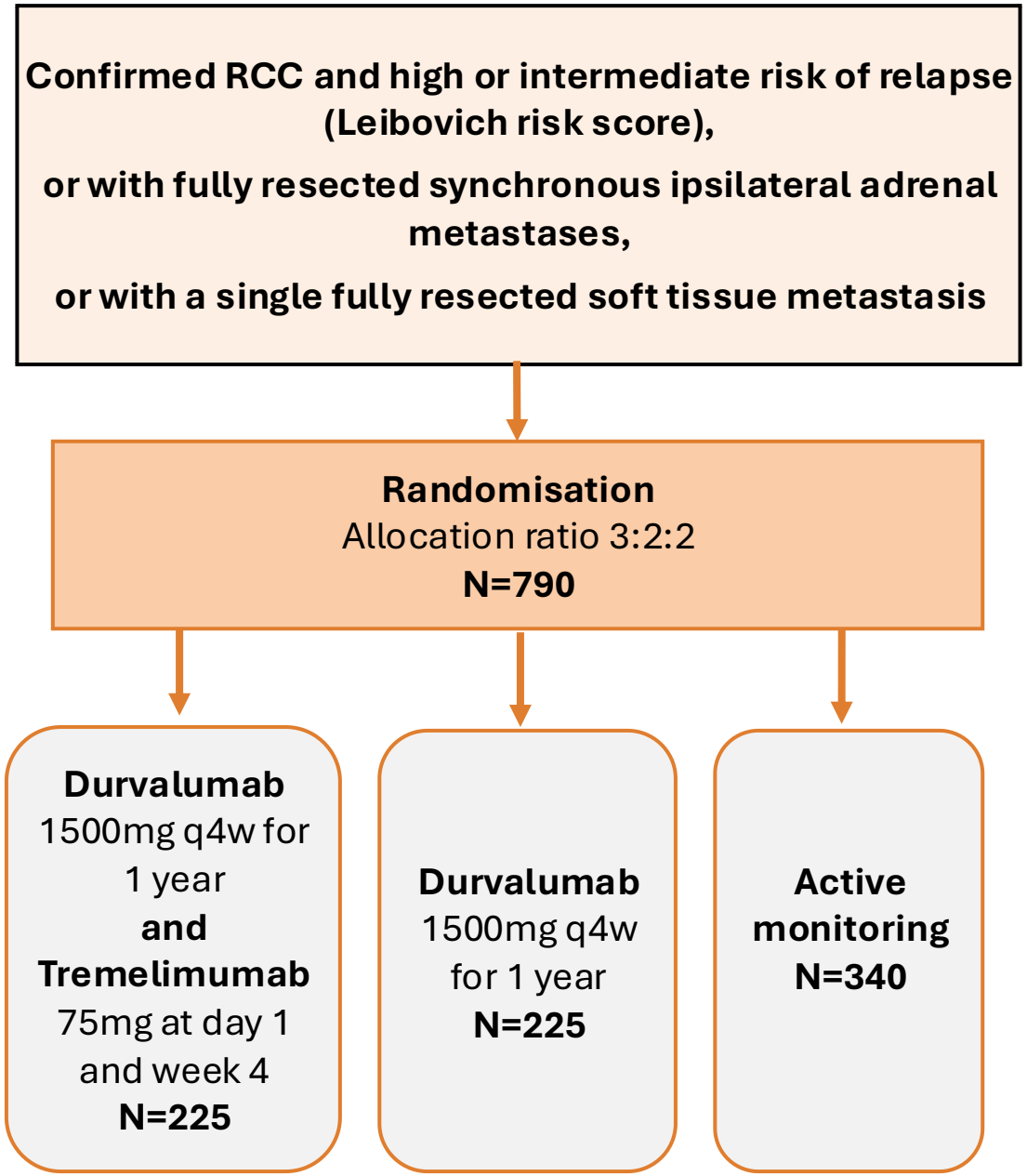
Treatment-Emergent AEs with Incidence ≥10%, As-Treated Population



Choueiri et al, GU ASCO 2026

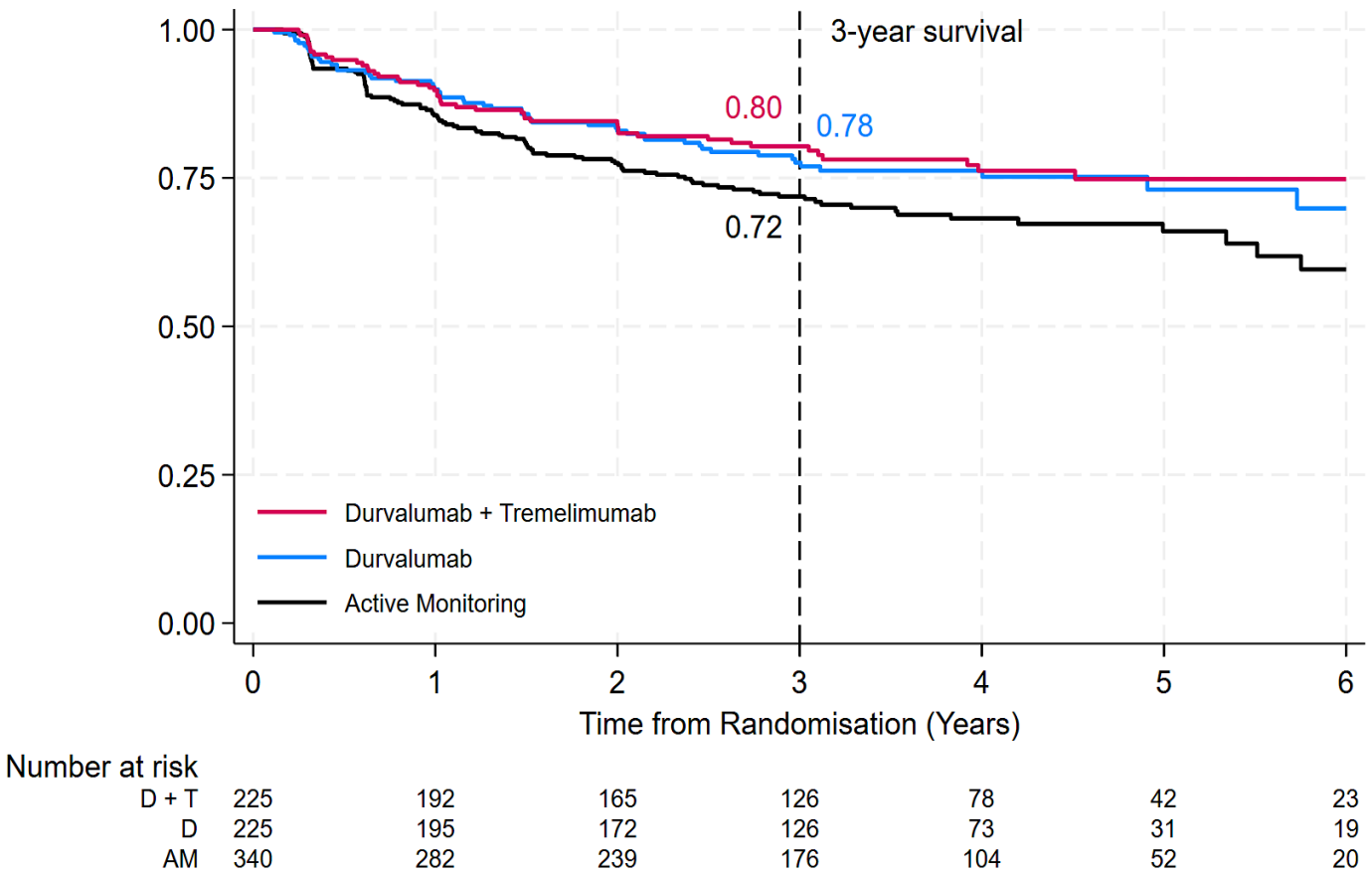
RAMPART Trial Design

- Original sample size: 1750
- Impacted by COVID-19 and KEYNOTE-564 results
- Modified design blinded to accumulating outcome data
- Primary outcome: Disease Free Survival (DFS)
- Pre-specified and pre-powered analysis: DFS by risk of relapse at baseline



Larkin et al, ASCO 2026

RAMPART Disease Free Survival (DFS) – ITT Population

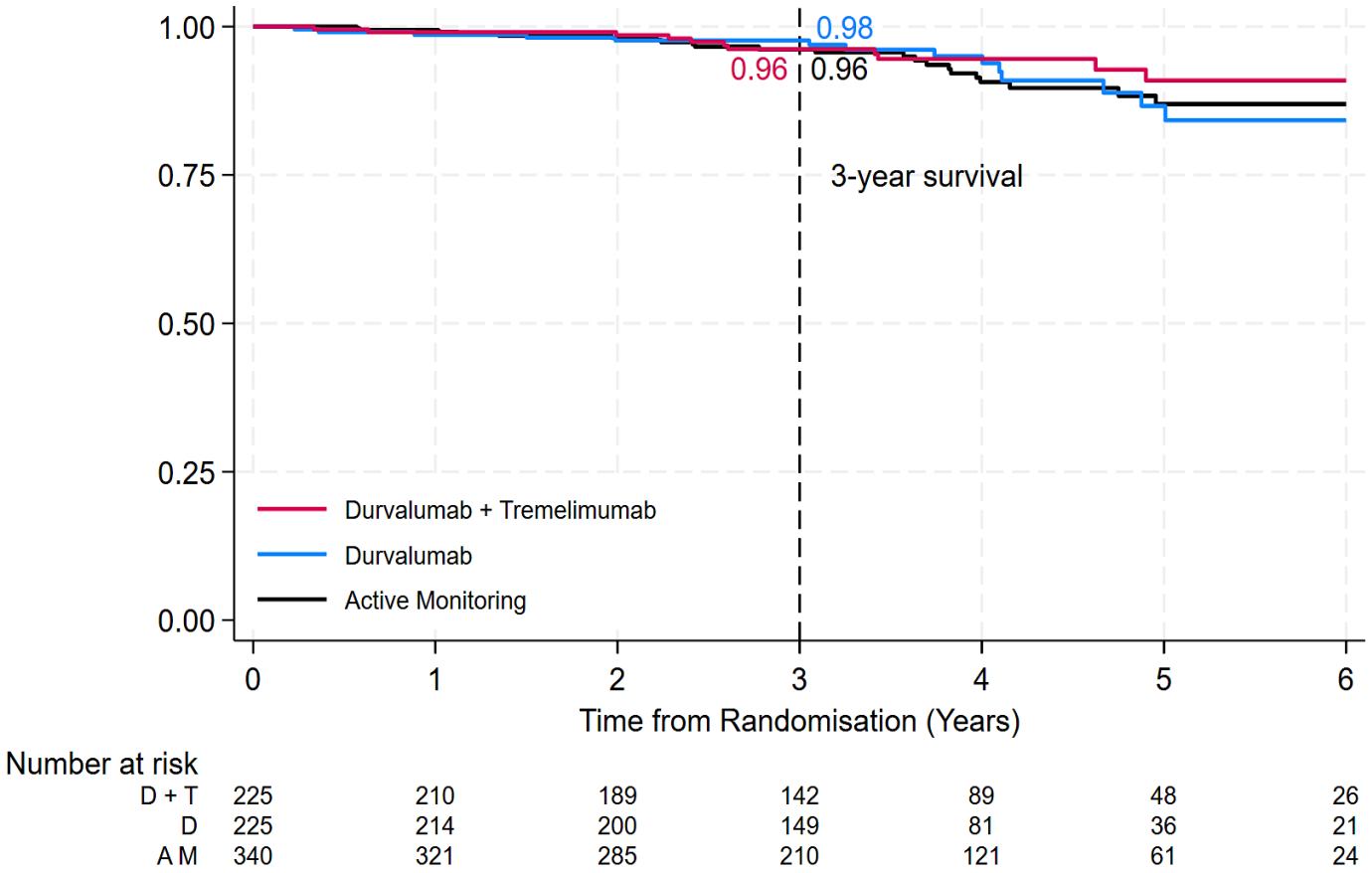


3-year DFS		
Durvalumab + Tremelimumab (N= 225)	**Durvalumab (N= 225)**	**Active Monitoring (N= 340)**
80%	78%	72%
Median Follow Up: 3.5 years		

Proportional Hazards (PH) Multivariable Model Results		
	HR (95% C.I.)	**One-sided p-value**
Durvalumab vs Active Monitoring	0.74 (0.53, 1.04)	0.041
Durvalumab + Tremelimumab vs Active Monitoring	0.65 (0.45, 0.93)	0.0094

Larkin et al, ASCO 2026

RAMPART Overall Survival (OS) – ITT Population

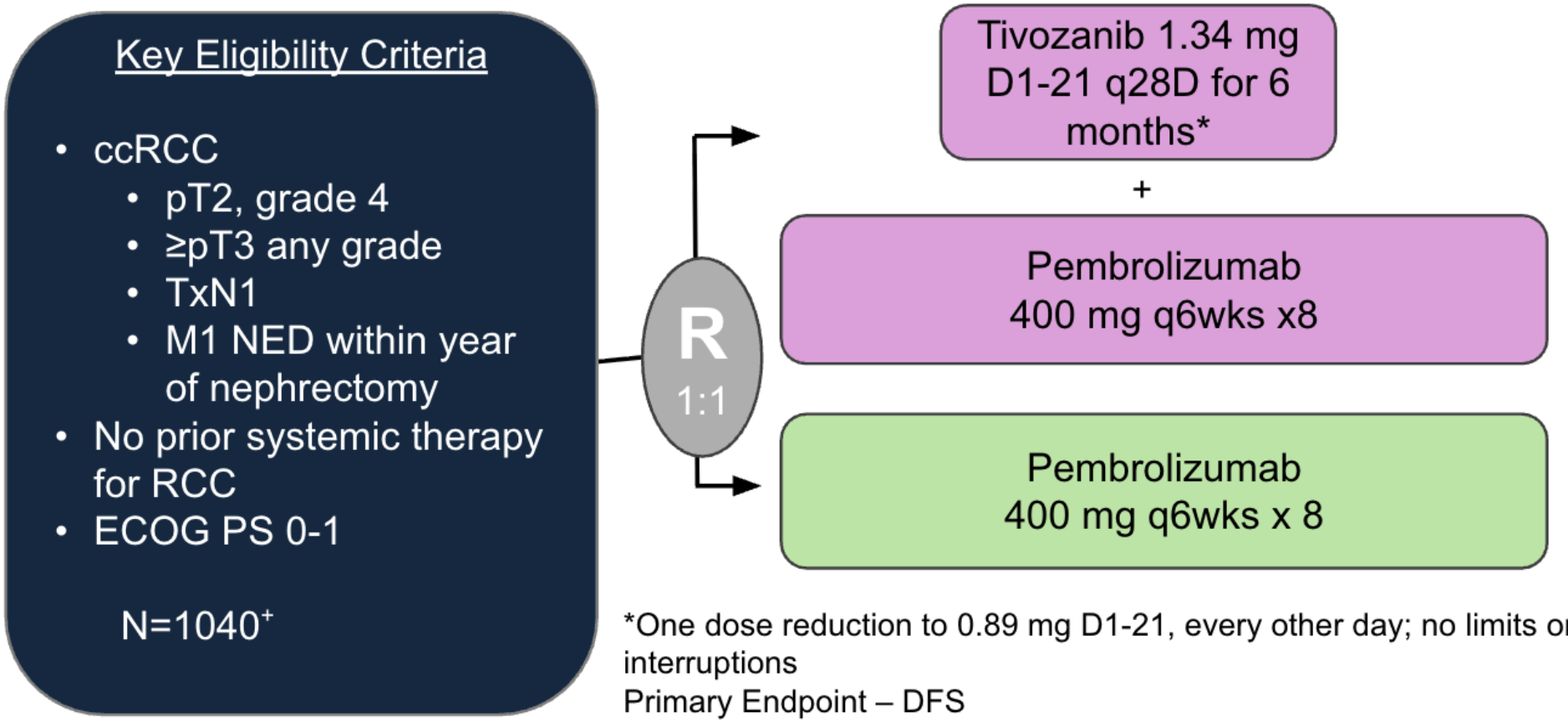


3-year OS		
Durvalumab + Tremelimumab (N= 225)	**Durvalumab (N= 225)**	**Active Monitoring (N= 340)**
96%	98%	96%

Proportional Hazards (PH) Multivariable Model Results		
	HR (95% C.I.)	**One-sided p-value**
Durvalumab vs Active Monitoring	0.99 (0.52, 1.92)	0.492
Durvalumab + Tremelimumab vs Active Monitoring	0.71 (0.34, 1.46)	0.176

Larkin et al, ASCO 2026

A032201/STRIKE – actively enrolling!



*One dose reduction to 0.89 mg D1-21, every other day; no limits on dose interruptions
Primary Endpoint – DFS
Key Secondary Endpoint - OS
Secondary Endpoints – QOL, Toxicities, Biomarkers

+ Stratify by T2/T3, T4/N1 or M1NED

Courtesy McGregor B, Alliance meeting 2026

Outline

- Adjuvant RCC
  - ctDNA from Keynote 564 (ASCO 2026)
  - LITESPARK 022 – approval of pembrolizumab/belzutifan
  - RAMPART – durvalumab vs surveillance (ASCO 2026)
  - Trial in progress: STRIKE

- Metastatic RCC
  - Checkmate 9ER trial bone & liver metastases subgroups (ASCO 2026)
  - CLEAR: patterns of progression (ASCO 2026)
  - LITESPARK011: Lenvatinib + belzutifan vs cabozantinib (GU ASCO 2026)
  - TiNivo-2: tivozanib+nivolumab vs tivozanib (ASCO 2026)
  - Trial in progress: LITESPARK033

- Non-clear cell RCC
  - Cabozantinib-nivolumab (ASCO 2026)

First-line metastatic renal cell carcinoma phase 3 trial designs

- Clear cell renal cell carcinoma
- Measurable metastatic disease, (RECIST criteria)
- No prior systemic treatments
- Good performance status
- Archival tissue available

Stratification factors:
IMDC criteria
(favorable, intermediate, poor)
Region (US vs outside US)
Performance status

RANDOMIZATION

Common control cohort in all trials → Sunitinib 50mg PO daily 4weeks on, 2 weeks off

Checkmate 214, phase 3
n= 1096 → Ipilimumab 1mg/kg IV + Nivolumab 3mg/kg IV q3wk x4 cycles Then nivolumab 3mg/kg IV q2wk

Javelin Renal 101, phase 3
n= 886 → Axitinib 5mg PO BID Avelumab 10mg/kg IV q2wk

Keynote 426, phase 3
n= 861 → Axitinib 5mg PO BID Pembrolizumab 200mg IV q3wk

IMMotion 151, phase 3
n= 915 → Bevacizumab 15mg/kg IV q3wk Atezolizumab 1200mg IV q3wk

Checkmate 9ER
n= 638 → Cabozantinib 40mg PO daily Nivolumab 240mg IV q2wk

CLEAR
n= 1069 → Lenvatinib 20mg PO daily Pembrolizumab 200mg IV q3wk

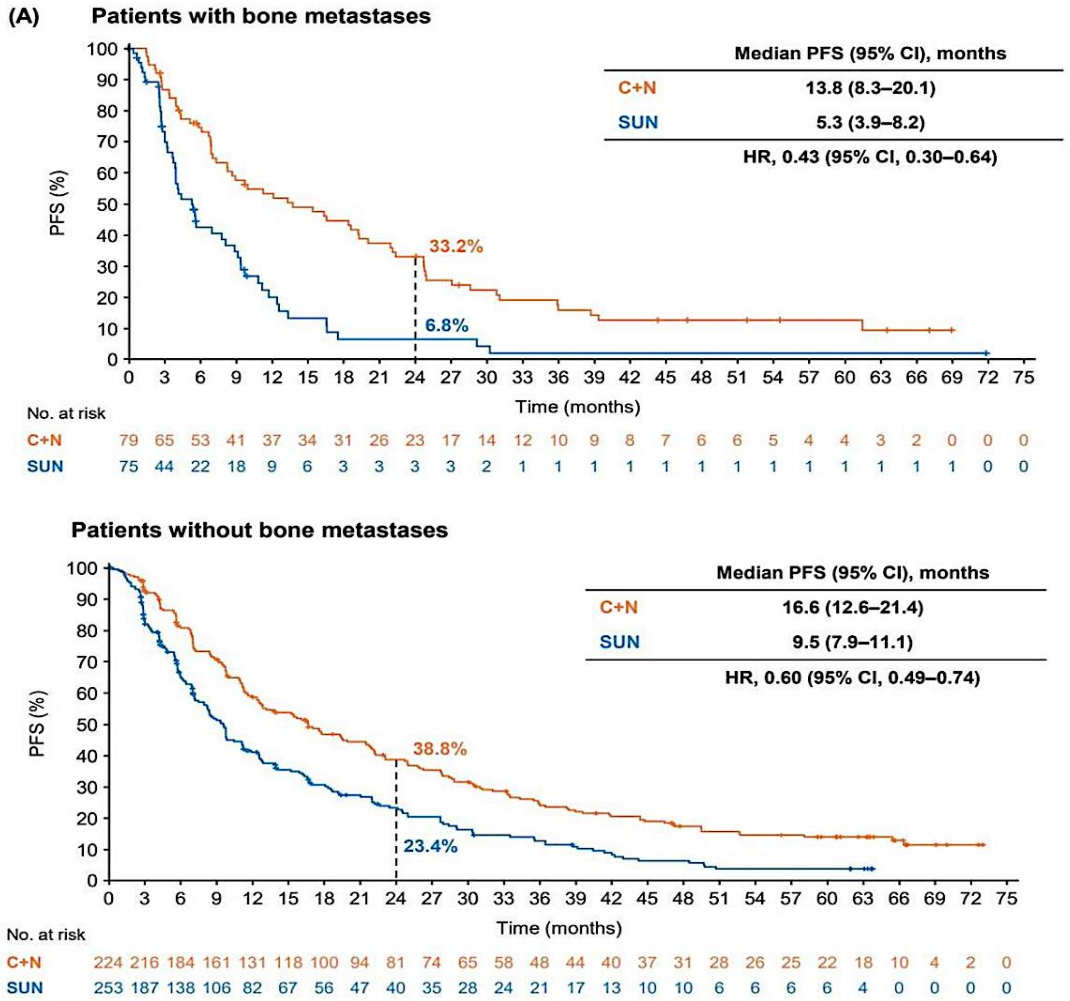
Treat until disease progression or unacceptable toxicity

Primary endpoints:
Overall survival
Progression free survival

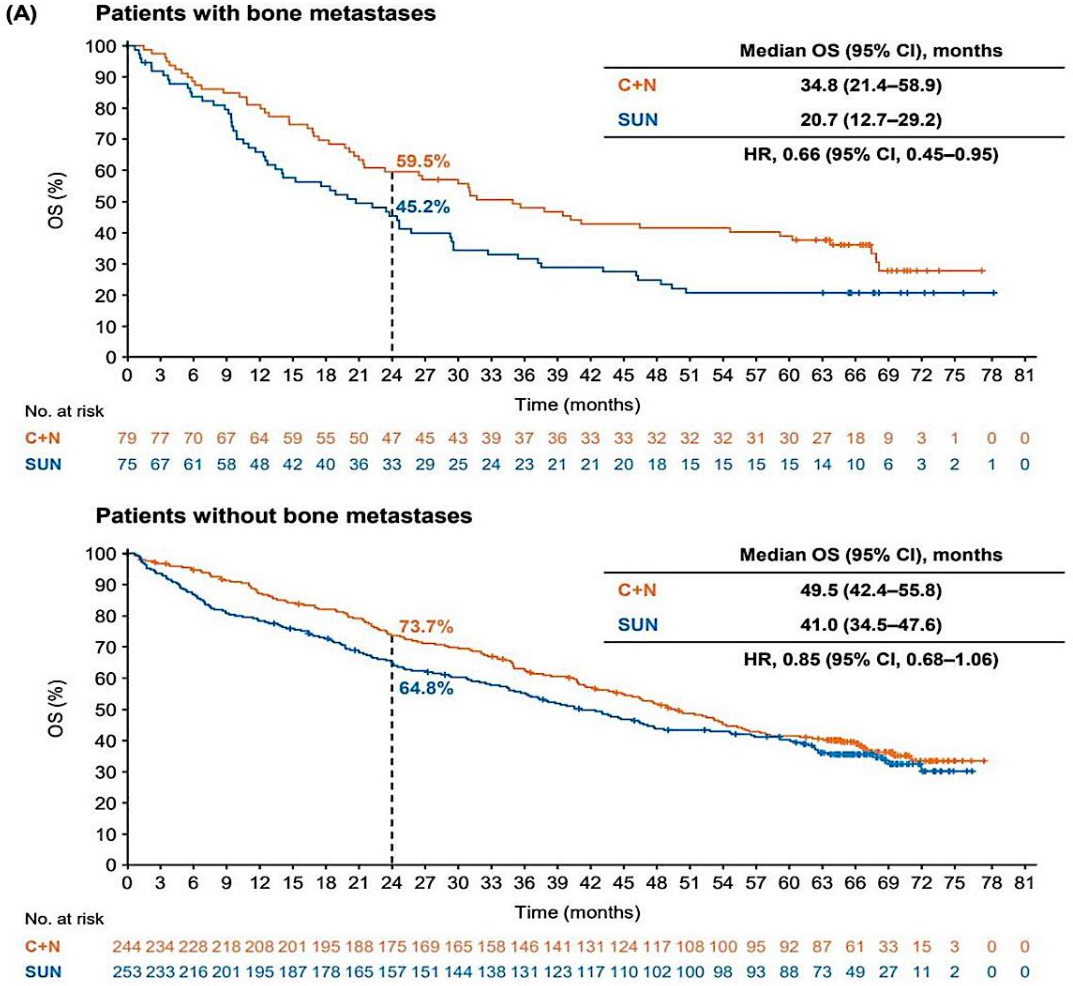
Secondary endpoints:
Objective response rates
Duration of responses
Patient-reported quality of life
Safety of combinations

Checkmate 9ER: subgroup analyses – patients with bone mets

Progression Free Survival



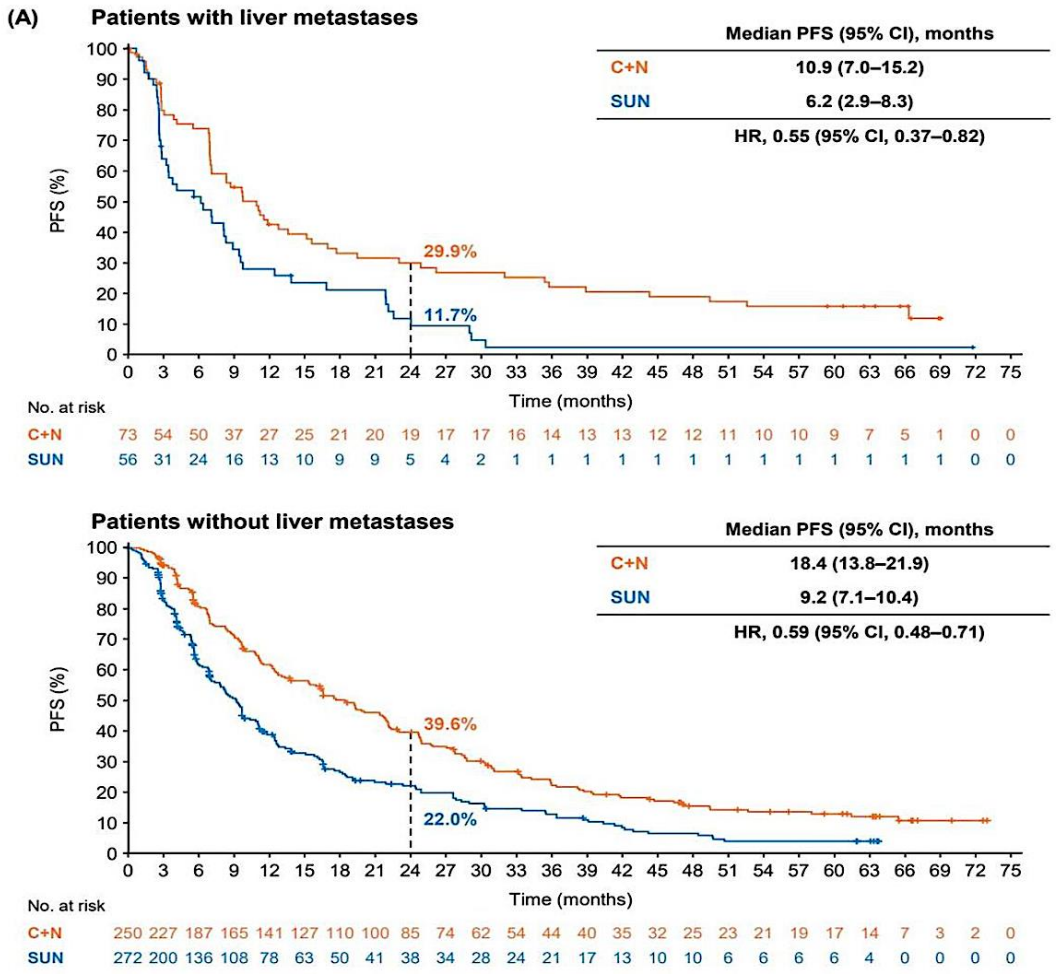
Overall Survival



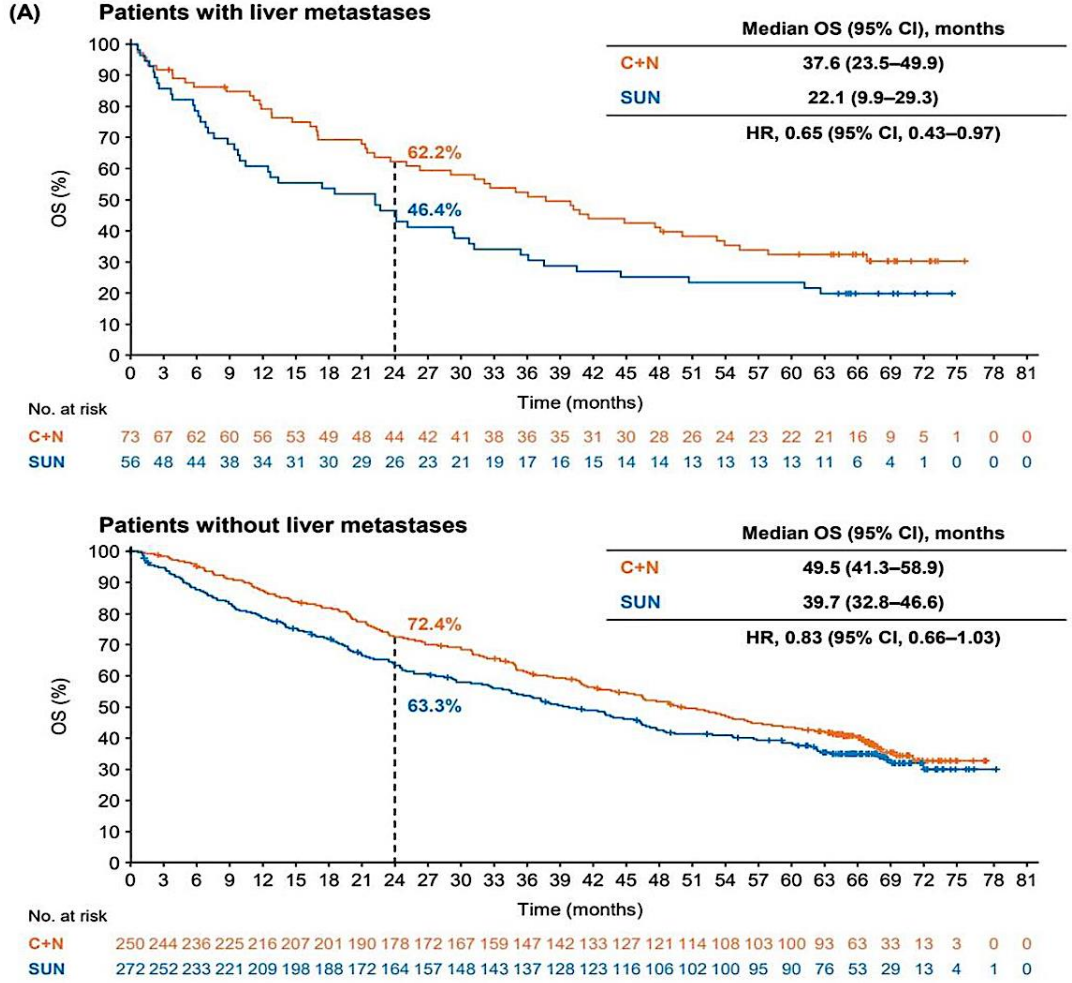
Apolo AB et al, ASCO 2026

Checkmate 9ER: subgroup analyses – patients with hepatic mets

Progression Free Survival



Overall Survival

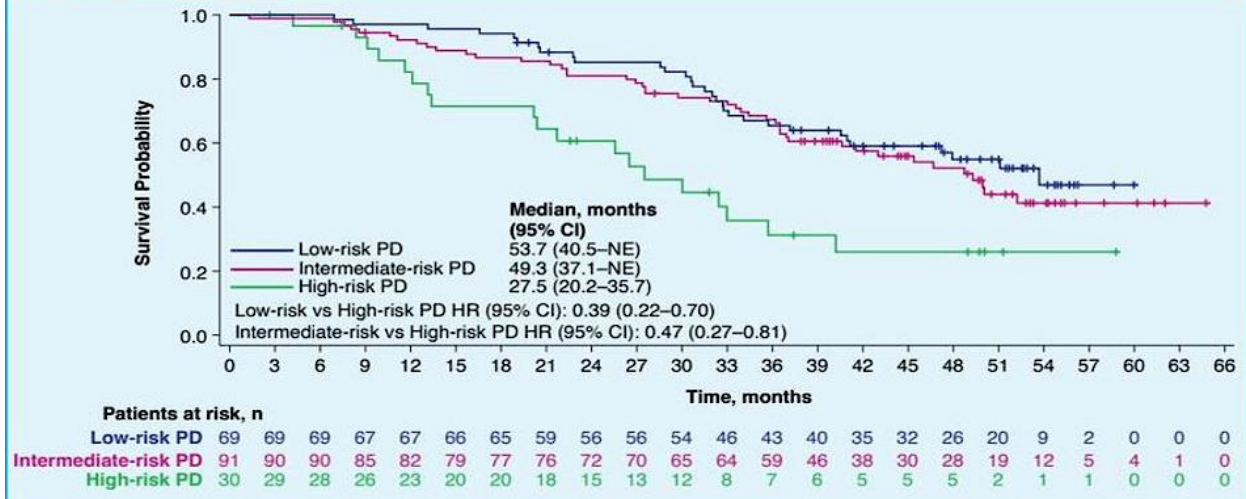


Shah et al, ASCO 2026

CLEAR: outcomes based on patterns of progression

- Low risk & intermed risk PD had favorable OS
- Low-risk PD had more time on next-line tx

Figure 3. Kaplan–Meier Plot of OS by PD-Risk Groups in the Lenvatinib-Plus-Pembrolizumab Arm

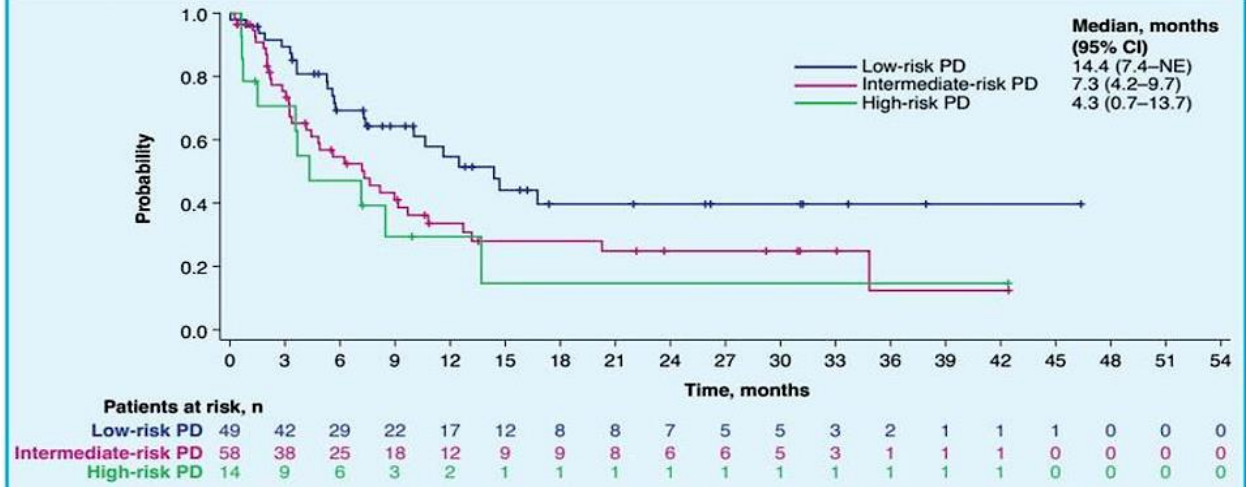


Low-risk PD (progression of existing lesions); intermediate-risk PD (new lesions without progression of existing lesions); high-risk PD (progression of existing lesions plus new lesions).[5]

CI, confidence interval; HR, hazard ratio; NE, not estimable; OS, overall survival; PD, progressive disease.

Low risk: growth of existing lesions
Intermed risk: new lesions
High risk: new lesions and growth of existing lesions

Figure 4. Kaplan–Meier Plot of Time-to-Treatment Discontinuation of First Anticancer Medication During Survival Follow-Up (months) by PD-Risk Groups in the Lenvatinib-Plus-Pembrolizumab Arm

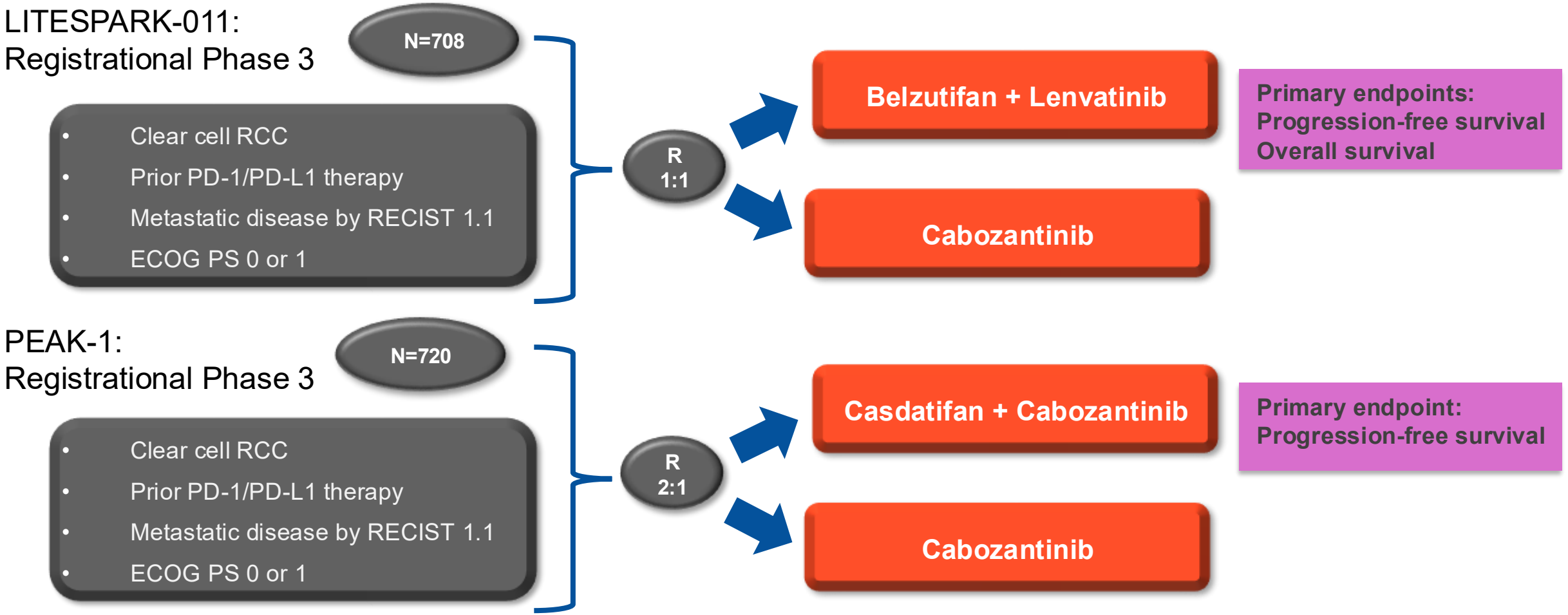


Low-risk PD (progression of existing lesions); intermediate-risk PD (new lesions without progression of existing lesions); high-risk PD (progression of existing lesions plus new lesions).[5]

CI, confidence interval; NE, not estimable; PD, progressive disease.

Grunwald et al, ASCO 2026

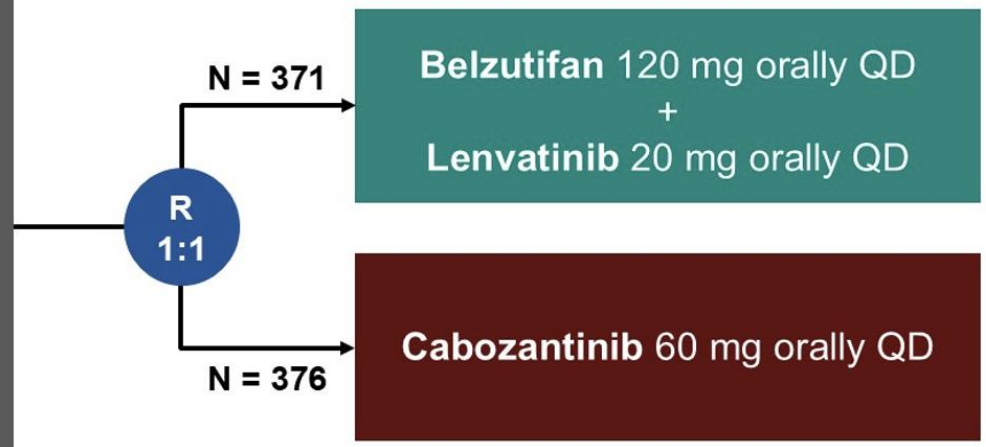
Combination HIF2a inhibitor/VEGF TKI registrational trials ongoing



LITESPARK011 – trial schema

Key Eligibility Criteria

- Unresectable, locally advanced or metastatic clear cell RCC
- Karnofsky Performance Status score ≥70%
- ≤2 prior systemic regimens
- Progression on/after anti−PD-(L)1 mAb as 1L or 2L therapy or progression ≤6 months of the last dose of adjuvant anti−PD-(L)1 mAb
- Prior VEGFR-TKI was permitted



Stratification Factors

- IMDC prognostic score:[a] 0 vs. 1-2 vs. 3-6
- Line of treatment for prior anti−PD-(L)1: 1L, adjuvant, neoadjuvant-adjuvant vs. 2L
- Geographic region: North America vs. western Europe vs. rest of world

Dual Primary Endpoints:

- PFS per RECIST 1.1 by BICR
- OS

Key Secondary Endpoint:

- ORR per RECIST 1.1 by BICR

Other Secondary Endpoints Include:

- DOR per RECIST 1.1 by BICR
- Safety

Exploratory Endpoints Include:

- Time to deterioration in patient-reported outcomes

Choueiri et al, GU ASCO 2026

Baseline Characteristics

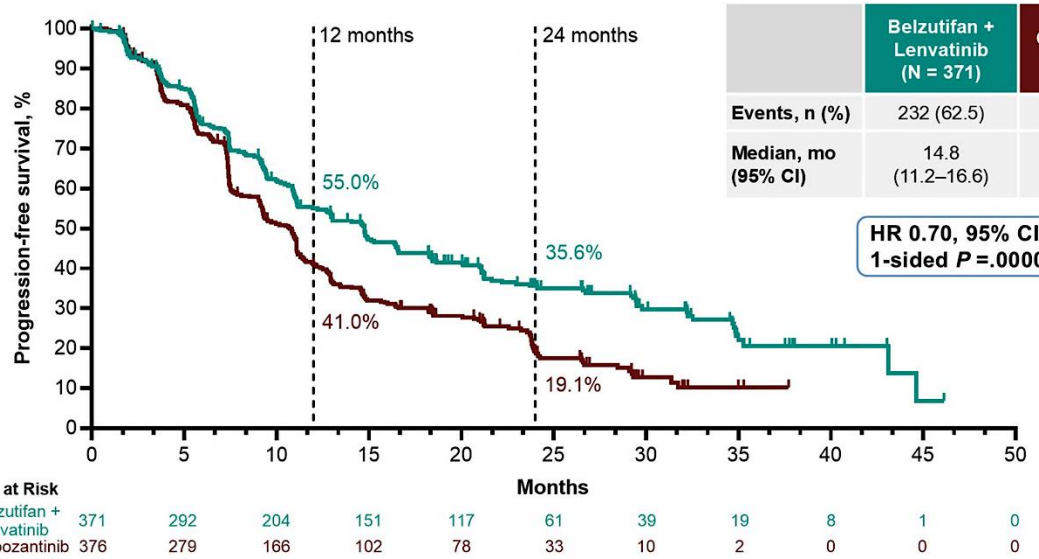
Characteristic, n (%)	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
Median age (range), years	63.0 (30–85)	62.5 (30–86)
Sex		
Male	273 (73.6)	292 (77.7)
Female	98 (26.4)	84 (22.3)
KPS score		
90 or 100	276 (74.4)	277 (73.7)
70 or 80	95 (25.6)	99 (26.3)
Geographic region		
North America	64 (17.3)	63 (16.8)
Western Europe	221 (59.6)	216 (57.4)
Rest of world	86 (23.2)	97 (25.8)
IMDC prognostic risk categories		
Favorable (score 0)	84 (22.6)	95 (25.3)
Intermediate (score 1-2)	226 (60.9)	215 (57.2)
Poor (score 3-6)	61 (16.4)	66 (17.6)
Prior lines of therapy		
Adjuvant only	15 (4.0)	18 (4.8)
1	252 (67.9)	251 (66.8)
2	100 (27.0)	107 (28.5)
3	4 (1.1)	0
Number of prior VEGFR-TKIs		
0	158 (42.6)	165 (43.9)
1	203 (54.7)	205 (54.5)
2	10 (2.7)	6 (1.6)

Data cutoff date, IA2: 9 April 2025

Choueiri et al, GU ASCO 2026

LITESPARK011 – primary endpoints

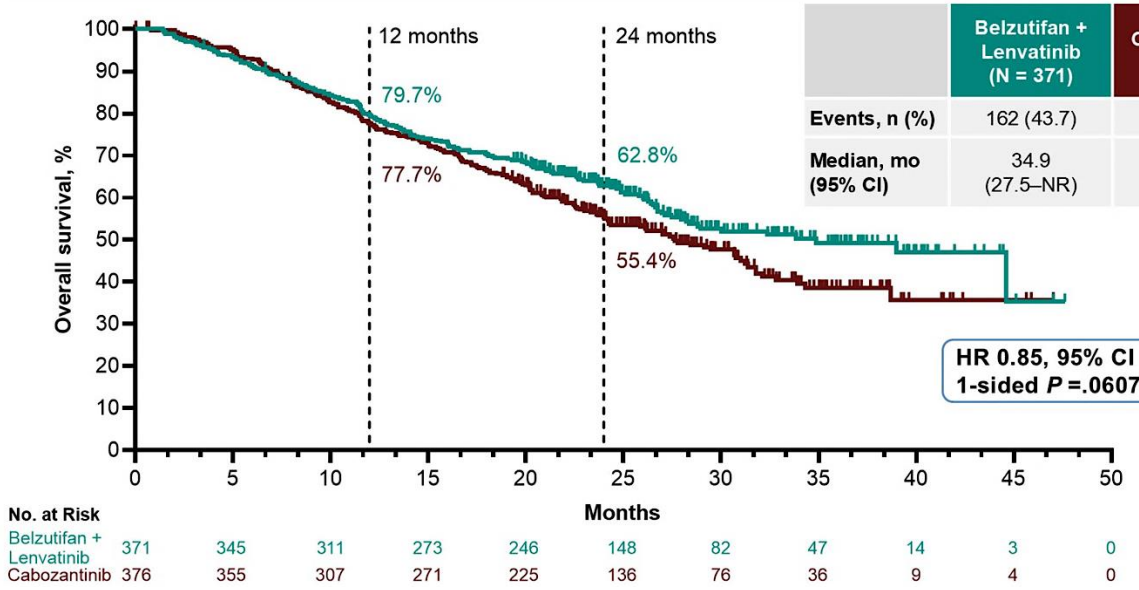
Progression Free Survival



	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
Events, n (%)	232 (62.5)	273 (72.6)
Median, mo (95% CI)	14.8 (11.2–16.6)	10.7 (9.2–11.1)

HR 0.70, 95% CI 0.59–0.84, 1-sided *P* =.00007*

Overall Survival



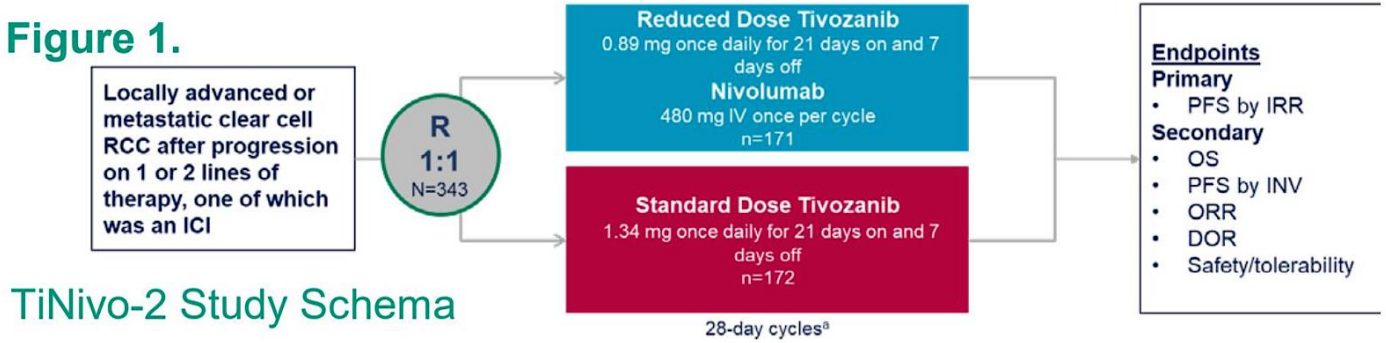
	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
Events, n (%)	162 (43.7)	192 (51.1)
Median, mo (95% CI)	34.9 (27.5–NR)	27.6 (24.0–31.4)

HR 0.85, 95% CI 0.68–1.05, 1-sided *P* =.06075

Choueiri et al, GU ASCO 2026

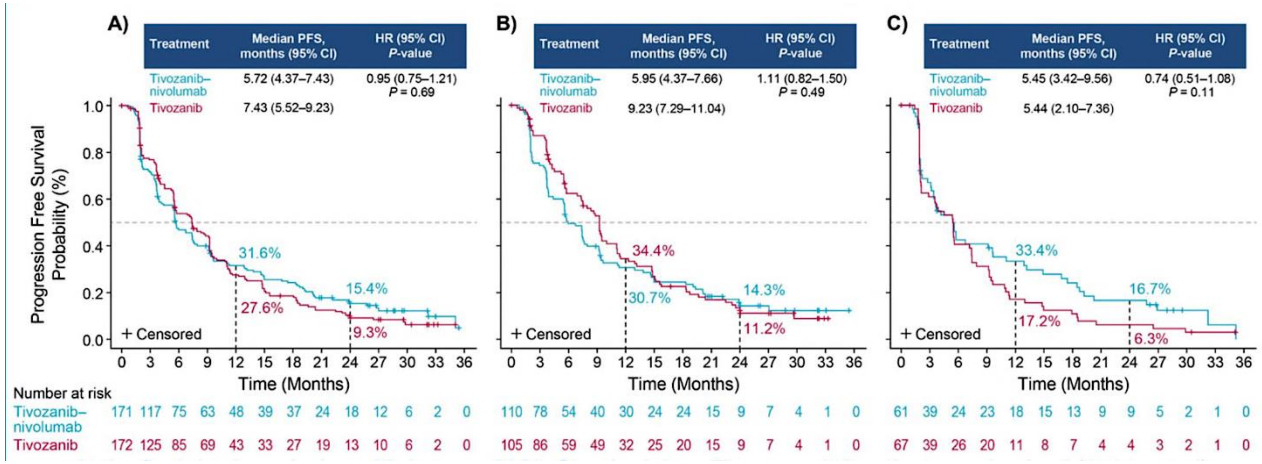
TiNivo2: Follow up outcomes

Figure 1.

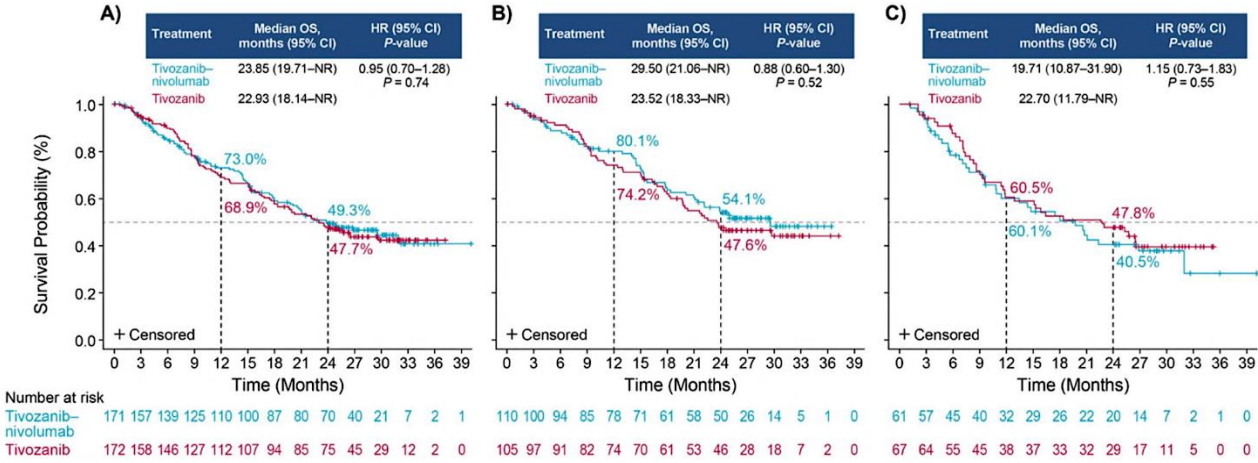


TiNivo-2 Study Schema

Progression Free Survival



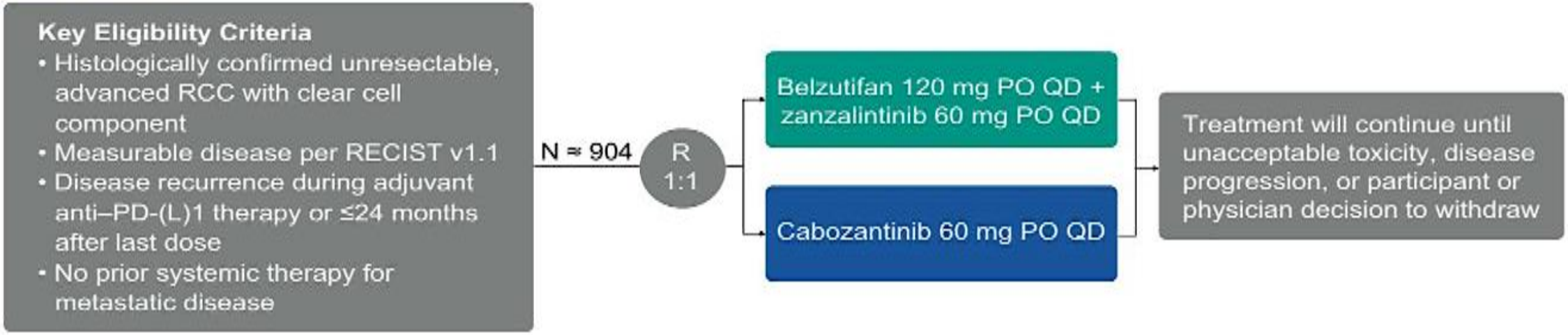
Overall Survival



Motzer et al, ASCO 2026

LITESPARK 033:
Combining belzutifan with zanzalintinib

Study design



Stratification factors
- Recurrence following adjuvant anti–PD-(L)1 therapy (≤6 months vs >6 months after last dose)
- IMDC risk (favorable vs intermediate vs poor)
- Sarcomatoid features (yes vs no)

Primary end points:
- PFS per RECIST v1.1 by BICR and OS

Key secondary end point:
- OR per RECIST v1.1 by BICR

Secondary end points:
- DOR per RECIST v1.1 by BICR, safety and PROs

IMDC, International Metastatic RCC Database Consortium; PO, by mouth; QD, once daily; R, randomization.

Suarez C et al, ASCO 2026

Outline

- Adjuvant RCC
  - ctDNA from Keynote 564 (ASCO 2026)
  - LITESPARK 022 – approval of pembrolizumab/belzutifan
  - RAMPART – durvalumab vs surveillance (ASCO 2026)
  - Trial in progress: STRIKE

- Metastatic RCC
  - Checkmate 9ER trial bone & liver metastases subgroups (ASCO 2026)
  - CLEAR: patterns of progression (ASCO 2026)
  - LITESPARK011: Lenvatinib + belzutifan vs cabozantinib (GU ASCO 2026)
  - TiNivo-2: tivozanib+nivolumab vs tivozanib (ASCO 2026)
  - Trial in progress: LITESPARK033

- Non-clear cell RCC
  - Cabozantinib-nivolumab (ASCO 2026)

Phase 2 Trial of CaboNivo in nccRCC Efficacy Outcomes

Outcome	All pts (n=53)	1st line (n=39)	2nd line (n=14)	Papillary (n=16)	UCPF (n=16)	FH-def** (n=8)	Unclass. (n=8)	Transloc. (n=5)
PR/CR, n (%)	23 (43)*	18 (46)*	5 (36)	5 (31)*	13 (38)	7 (88)	4 (50)	1 (20)
SD, n (%)	27 (51)	19 (49)	8 (57)	10 (63)	10 (62)	1 (12)	2 (25)	4 (80)
PD, n (%)	3 (6)	2 (5)	1 (7)	1 (6)	0	0	2 (25)	0
mPFS, mo. (95% CI)	11 (8-14)	11 (8-16)	14 (5-23)	11 (7-25)	10 (5-13)	16 (5-37)	8 (1-34)	14 (5-41)

*1 patient with papillary RCC treated in 1st-line achieved a CR; all other responses were PRs
**FH-deficient RCC previously included primarily in papillary cohort in prior presentations/manuscripts[1,2]

Abbreviations: FH-def, Fumarate Hydratase deficient; mPFS, median PFS; Transloc., translocation-associated RCC; Unclass., unclassified; UCPF, unclassified with papillary features

[1]Lee JCO 2022
[2]Fitzgerald Eur Urol 2024

Phase 2 Trial of CaboNivo in nccRCC Safety Outcomes

Treatment Administered

Drug Exposure	N (%)
Median treatment duration, months (95% CI)	11.5 (6.4, 24.8)
Treatment-emergent AE	
Any grade	53 (100%)
Grade 3 or 4	36 (68%)
Treatment discontinuation due to AE	
Cabozantinib	23 (43%)
Nivolumab	22 (42%)
Both study drugs	18 (34%)

Symptomatic AEs in ≥35% patients

Adverse Event	All Grades	Grade 3-4
Fatigue	37 (70)	0
Hand-Foot Skin Reaction	35 (66)	2 (4)
Diarrhea	33 (62)	4 (8)
Constipation	23 (43)	0
Pain	22 (42)	1 (2)
Dry mouth	21 (40)	0
Hypertension	21 (40)	6 (11)
Nausea	21 (40)	1 (2)
Oral mucositis	20 (38)	0
Back pain	19 (36)	0
Cough	19 (36)	0
Headache	19 (36)	0

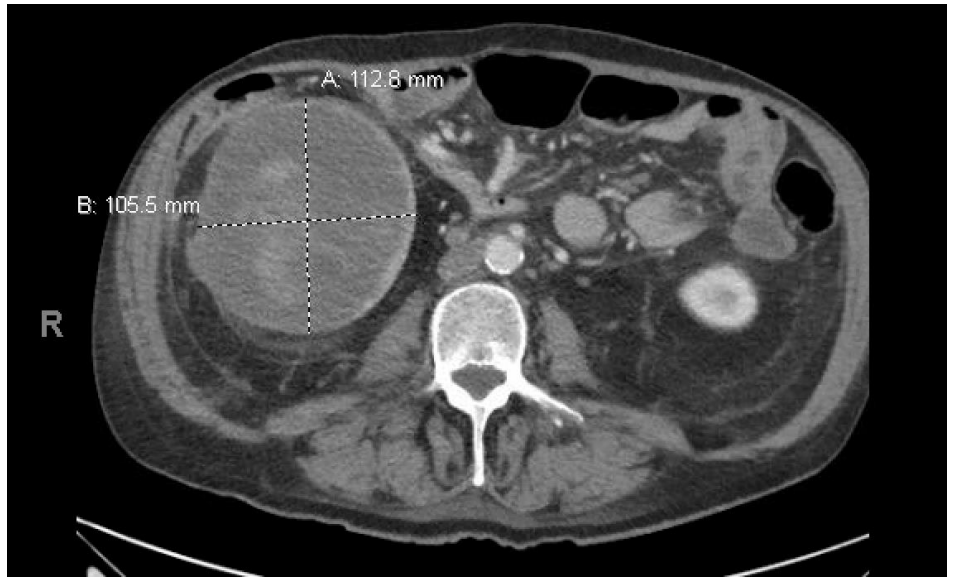
Select laboratory AEs*

Adverse Event	All Grades	Grade 3-4
AST increase	48 (91)	10 (19)
ALT increase	40 (75)	11 (21)
Platelet decrease	38 (72)	0
Amylase increase*	28 (53)	10 (19)
Lipase increase*	25 (47)	8 (15)

* Predominantly asymptomatic; only 1 pt discontinued study drugs for pancreatitis

Case 1

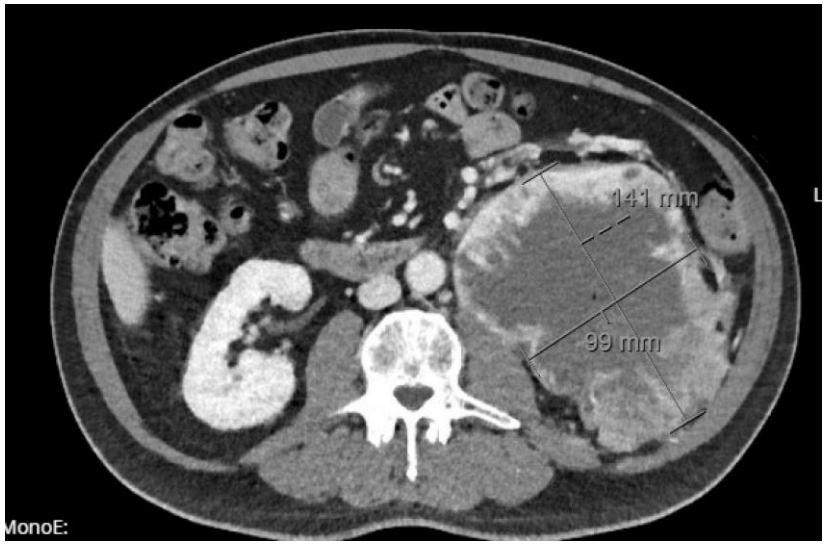
- 58yo man with 11cm R renal mass, no neoadjuvant treatment
- Underwent R radical nephrectomy
- Pathology: clear cell RCC, Fuhrman's grade 3
- Post-op labs 1 month after surgery:
  - Hgb 14 g/dL, Platelets 171, WBC 5.72, Cr 1.2 mg/dL, normal hepatic function
- Restaging imaging negative for recurrence



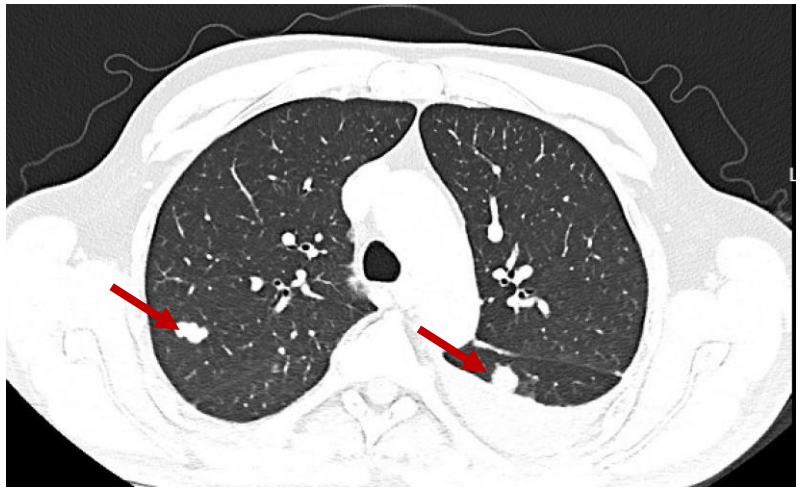
Axial CT A/P w/ IV contrast

Case 2

- 68yo man presented with weight loss and fatigue, shortness of breath, found to have 14cm L renal mass, metastatic to lungs
- Biopsy L kidney mass: RCC, clear cell type, IHC positive PAX8 & CA9
- Post-op labs 1 month after surgery:
  - Hgb 12.5 g/dL, Platelets 560, WBC 4.5,
  - Cr 1.8 mg/dL, Ca 10.8 mg/dL
- Started cabozantinib/nivolumab
- Stable L renal mass, resolved lung nodules at 9 months



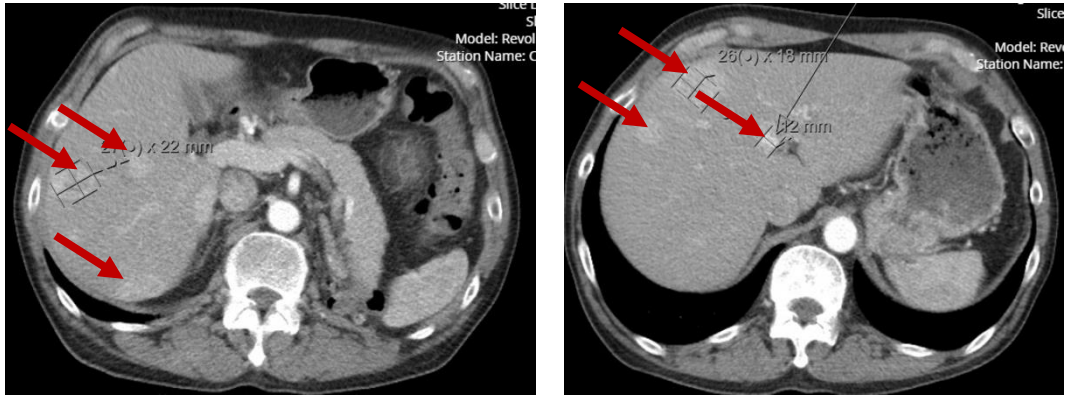
Axial CT A/P w/ IV contrast


Axial CT chest w/ IV contrast

Case 3 – refractory RCC

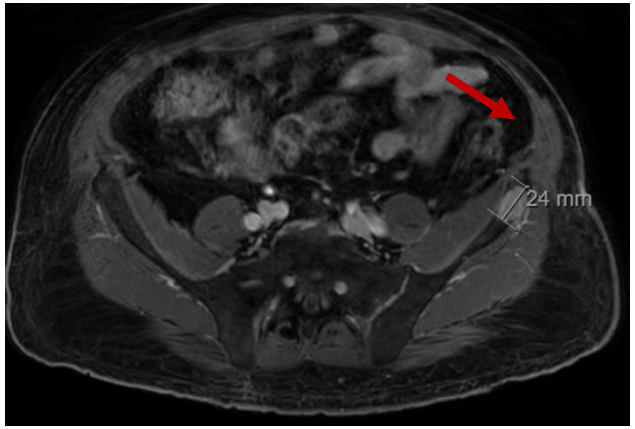
- 62yo man s/p nephrectomy 3 years prior, develops new lung metastases
- Nephrectomy pathology:
  - Renal cell carcinoma, clear cell type, Fuhrman's grade 2, IHC positive CA9, BAP1 intact
- Initial labs with anemia - IMDC intermediate risk
- Started ipilimumab/nivolumab
- 6 months later on nivolumab – develops new liver metastases, started on cabozantinib
- 1 year on cabozantinib with response in liver – develops new painful bone met in pelvis

Progression after ipi/nivo:



CT abdomen with contrast

Progression after cabozantinib:



MRI pelvis post gadolinium

Patterns of Care: Exploring How Community Oncologists Manage Metastatic Triple-Negative Breast Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, July 21, 2026

5:00 PM – 6:00 PM ET

Faculty

Professor Peter Schmid, FRCP, MD, PhD

Melinda Telli, MD, FASCO

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

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