Updates in Genitourinary Malignancies: Urothelial Cancers

The 7th Annual LEAD Conference

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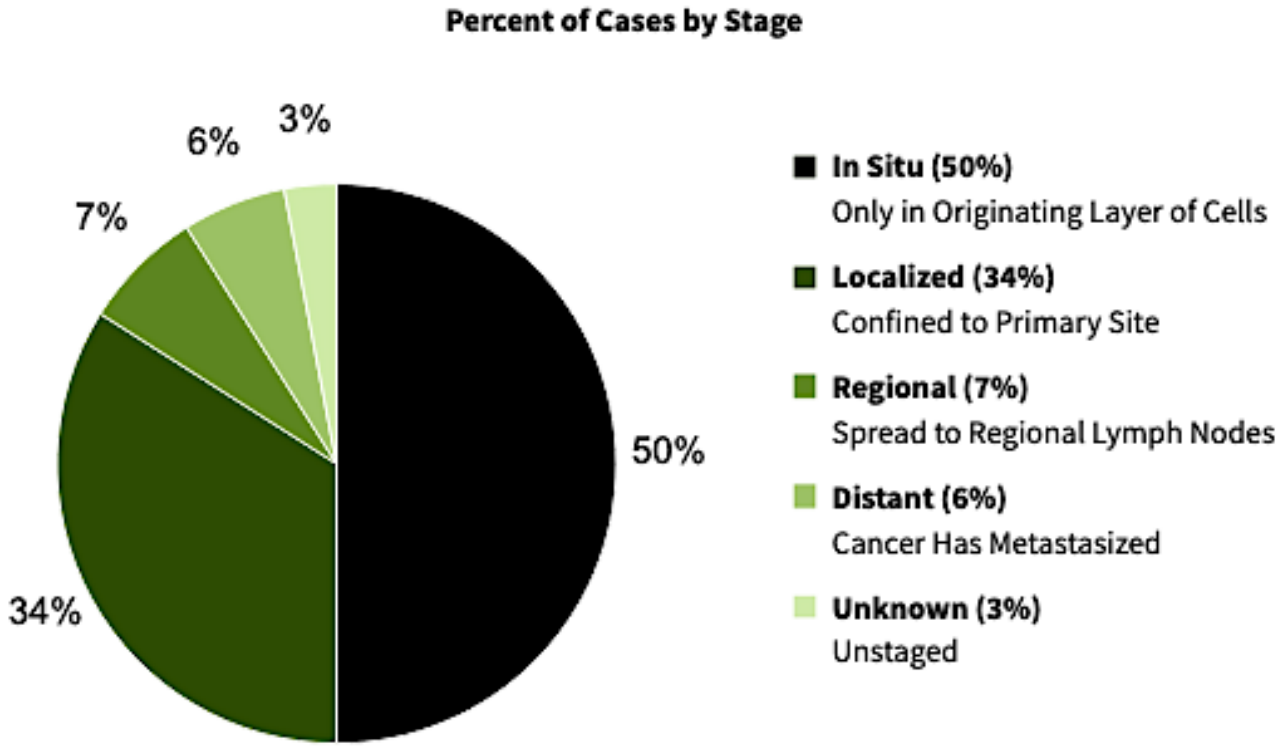
September 27, 2025

OUTLINE

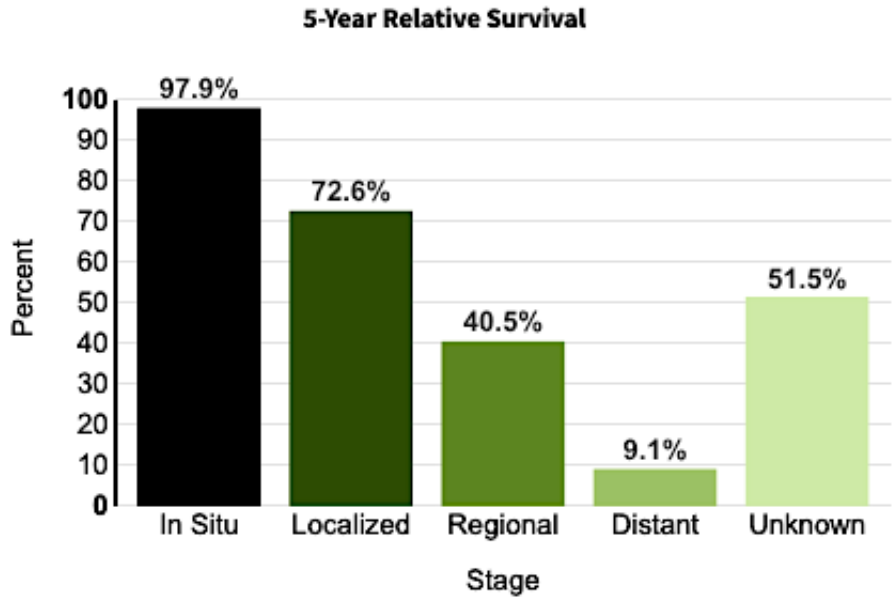
- Epidemiology & state of the field in 2025
- Locally advanced/metastatic urothelial carcinoma (La/mUC)
- Muscle-invasive urothelial carcinoma (MIUC)
- The emerging role of ctDNA & risk-adaptive strategies
- Future directions & summary

EPIDEMIOLOGY OF BLADDER CANCER



Estimated New Cases in 2025	84,870
% of All New Cancer Cases	4.2%

Estimated Deaths in 2025	17,420
% of All Cancer Deaths	2.8%



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SEER 21 2015-2021 Cancer Stat Facts: Bladder Cancer.

STATE OF THE FIELD IN 2025

- **La/mUC:**
  - **1L setting:** 2.5-year follow up data from EV-302 reinforce EV + pembrolizumab as 1L SOC
  - **Maintenance setting:** JAVELIN Bladder Medley investigating intensified maintenance with avelumab ± SG post platinum chemo → how to position in a rapidly evolving landscape?
- **Perioperative MIUC setting:** Current SOC in cisplatin-eligible patients is chemo + IO → early data emerging for ADC + IO regimens in the perioperative setting
- **Emerging role of ctDNA:** ctDNA is redefining perioperative management, enabling risk-stratified precision therapy → upcoming trial readouts including IMvigor011 set to guide clinical integration
- **Key questions & future directions:**
  - Optimal sequencing after EV+P and perioperative IO?
  - Is there a role for consolidative surgery or radiation in La/mUC disease states?
  - Risk-adaptive perioperative trials using clinical and molecular biomarkers to refine patient selection

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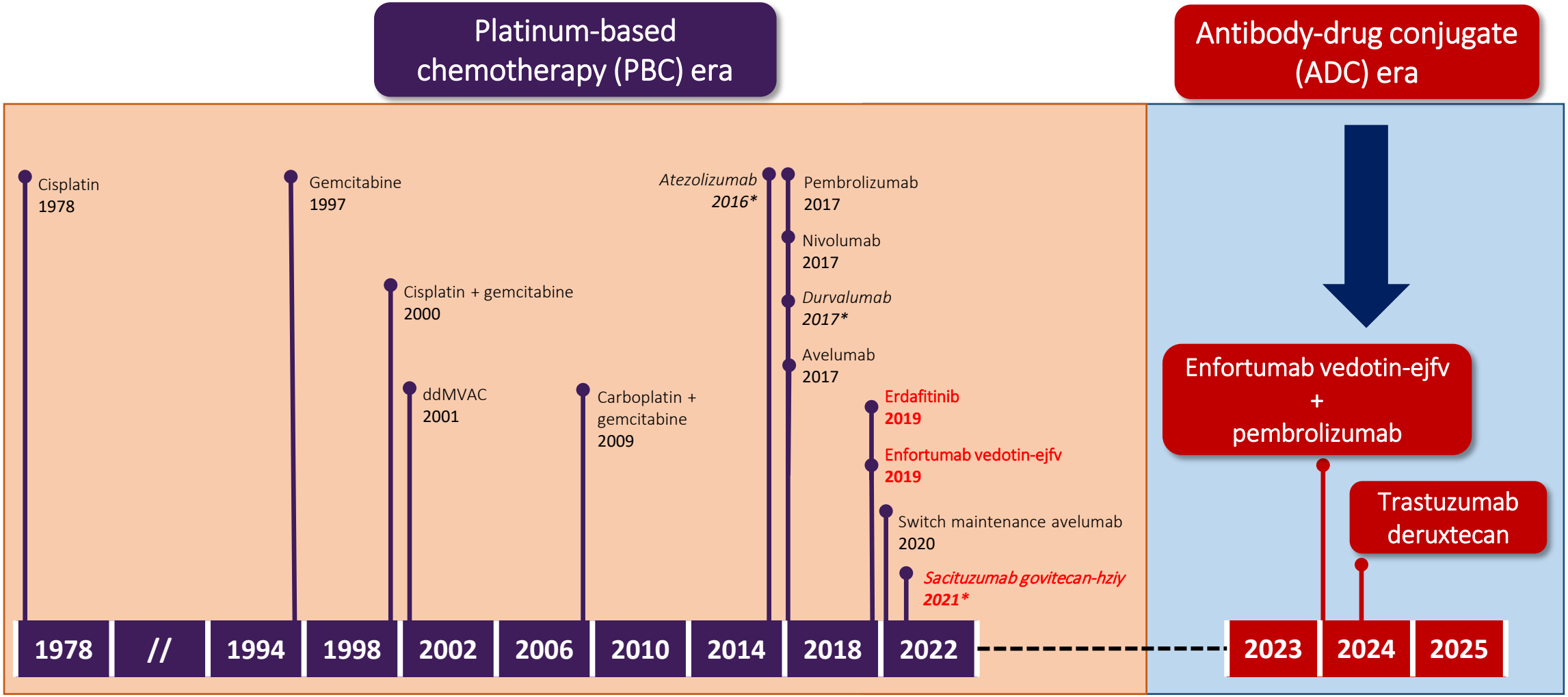
THE ERA OF NOVEL THERAPEUTICS IN La/mUC



*FDA approval voluntarily withdrawn due to confirmatory Phase III trials not meeting primary endpoints

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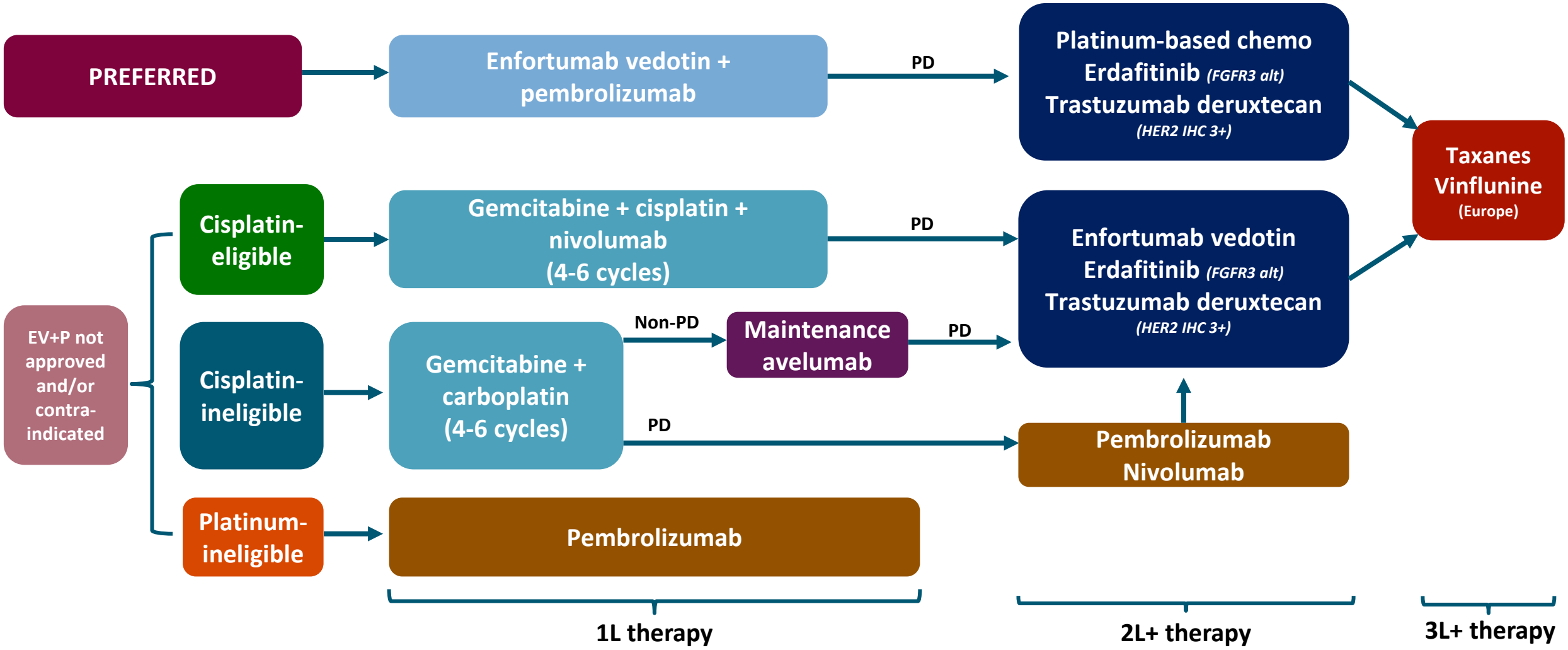
Slide adapted with permission from Parminder Singh, MD.

La/mUC TREATMENT ALGORITHM IN 2025



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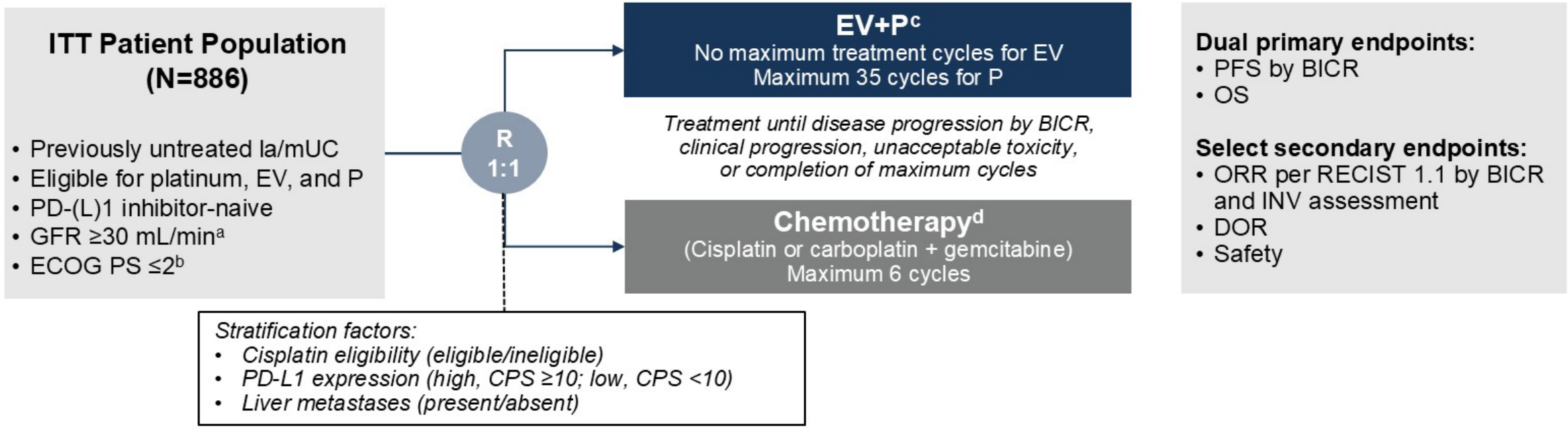
Consideration of clinical trials across the treatment spectrum of La/mUC

ENFORTUMAB VEDOTIN + PEMBROLIZUMAB

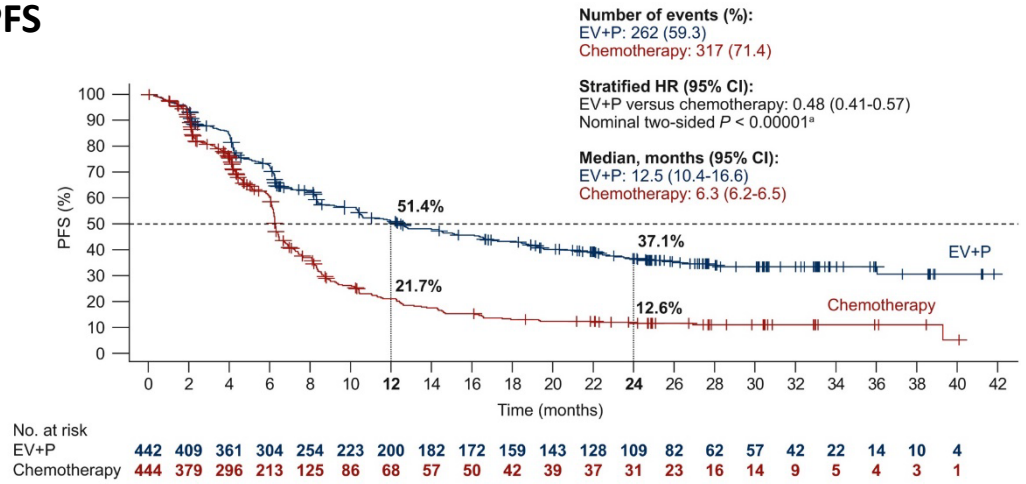
EV-302/KEYNOTE-A39: a phase 3 international, randomized trial (NCT04223856)



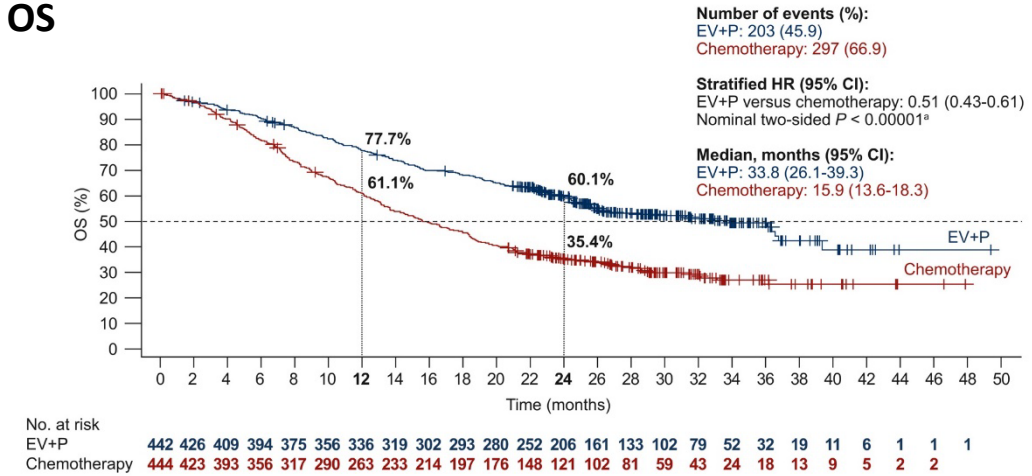
Gupta S. ASCO 2025. Abstract 4502.

EV-302: UPDATED EFFICACY AT 2.5 YEARS

PFS



OS



	EV+P (n=442)	Chemo (n=444)	95% CI	p-value
ORR	67.5%	44.2%	--	<0.00001
Median DoR, mos	23.3	7.0	EV+P: 17.8-NE Chemo: 6.2-9.0	N/A
Median PFS, mos	12.5	6.3	HR 0.48 (0.41-0.57)	<0.00001
Median OS, mos	33.8	15.9	HR 0.51 (0.43-0.61)	<0.00001

- Median follow up: 29 months
- Complete response (cCR): 30.4% vs 14.5%
- Durable separation of PFS and OS curves maintained over time
- **Data reinforce EV+P as SOC for 1L La/mUC**

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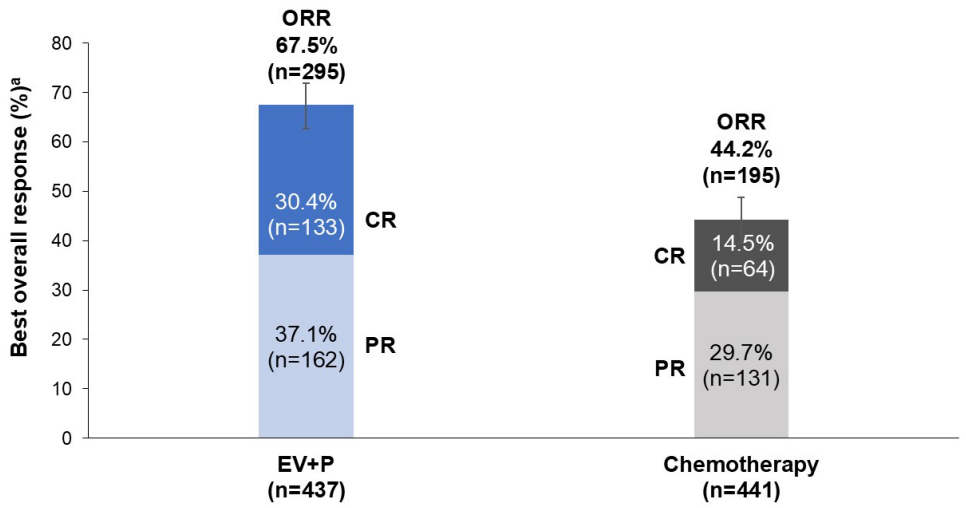
Powles T. Ann Oncol. 2025.

EV-302: EXPLORATORY ANALYSIS OF RESPONDERS



- Baseline features similar between responders (CR+PR) and ITT population
- DoR favors EV+P regardless of cisplatin eligibility (~60% cisplatin eligible in CR+PR groups)
- No validated biomarker predicts EV+P benefit
- **Collectively, data reinforce EV+P as SOC for 1L La/mUC**

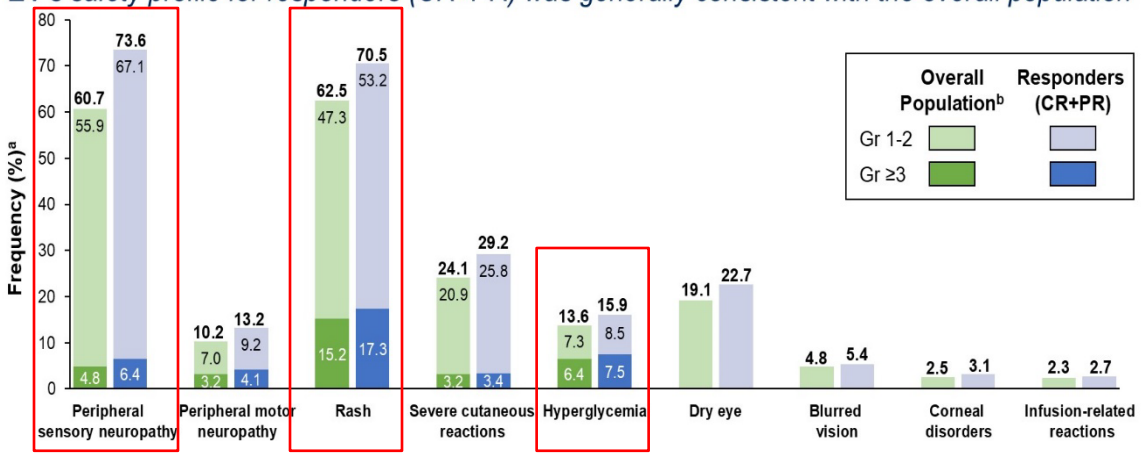
	Responders (CR+PR)			Patients with CR		
	EV+P (n=295)	Chemo (n=195)	95% CI	EV+P (n=133)	Chemo (n=64)	95% CI
Median DoR, mos	**23.3**	7.0	EV+P: 17.8-NE Chemo: 6.2-9.0	**NE**	15.2	EV+P: NE-NE Chemo: 10.3-NE
Probability of maintained response at 24 mos	**49.4%**	24.0%	--	**74.3%**	43.2%	--
Median OS, mos	39.3	32.1	HR 0.59 (0.44-0.79)	NE	NE	HR 0.37 (0.17-0.80)
2-year OS probability	76.3%	59.8%	--	95.4%	85.8%	--

Gupta S. ASCO 2025. Abstract 4502.

EV-302: TREATMENT-RELATED AEs & MANAGEMENT

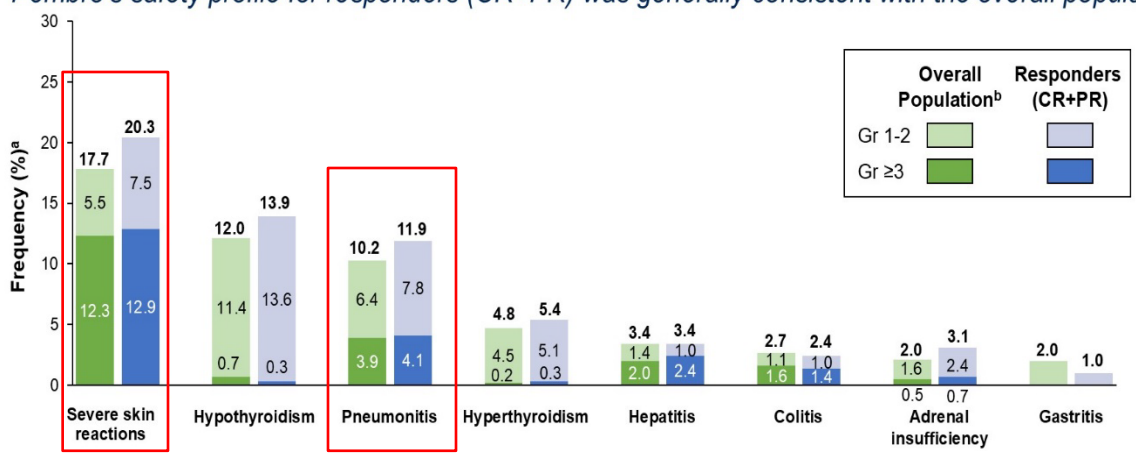
Treatment-related AEs of special interest for EV (EV+P arm)

EV's safety profile for responders (CR+PR) was generally consistent with the overall population



Treatment-emergent AEs of special interest for pembro (EV+P arm)

Pembro's safety profile for responders (CR+PR) was generally consistent with the overall population



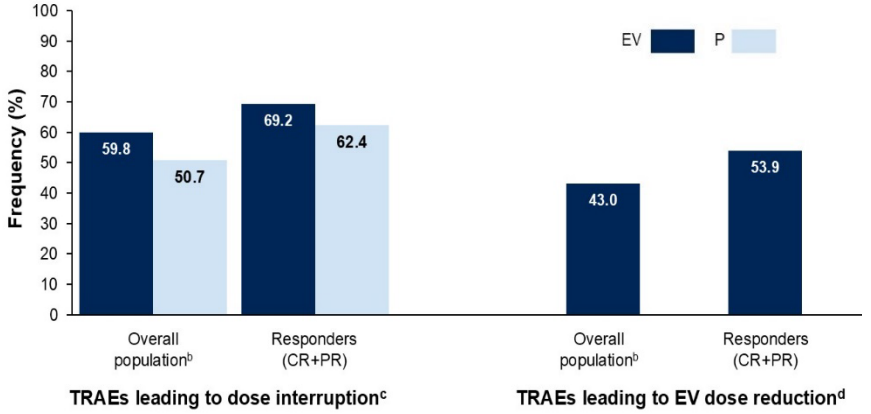
Overall population:

- Median EV+P duration: 12 cycles (range, 1-54)
- Median EV duration: 7.1 months (9 cycles)
- Median pembrolizumab duration: 8.5 months (11 cycles)

Responders (CR+PR):

- Median EV+P duration: 19 cycles (range, 1-54)
- Median EV duration: 9.7 months (12 cycles)
- Median pembrolizumab duration: 13.2 months (17 cycles)

Dose modifications were common among responders with longer treatment duration



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EV TOXICITY

	SKIN REACTIONS (including SJS/TEN)	NEUROPATHY (sensory and motor)	HYPERGLYCEMIA	PNEUMONITIS/ ILD
Median time to onset, months (range)[1]	**1.7** (0.1 – 17.2)	**6.0** (0.3 – 25.0)	**0.5** (0.3 – 3.5)	**4.0** (0.3 – 26.2)
Incidence[1]	**All-grade: 70%** **≥ G3: 17%**	**All-grade: 63%** **≥ G3: 7%**	**All-grade: 13%** **≥ G3: 9%**	**All-grade: 10%** **≥ G3: 4%**
Grading per CTCAE v5.0[2*]	**G1:** <10% BSA w/ or w/o symptoms **G2:** 10-30% BSA w/ or w/o symptoms **G3:** >30% BSA with moderate or severe symptoms limiting ADLs **G4:** life-threatening with any % BSA **SJS:** Skin sloughing w/ epidermal or mucous membrane detachment (G3: <10% BSA; G4: 10-30% BSA; **TEN (G4): >30% BSA**)	**G1:** mild symptoms **G2:** moderate symptoms limiting instrumental ADLs **G3:** severe symptoms limiting self-care ADLs; assistance required **G4:** life-threatening requiring urgent intervention	**G1:** elevated glucose; no medical intervention **G2:** change in baseline mgmt for DM; oral antiglycemic initiated **G3:** insulin initiated; hospitalization indicated **G4:** life-threatening requiring urgent intervention	**G1:** Asymptomatic; clinical or diagnostic observations **G2:** symptomatic requiring medical intervention **G3:** severe symptoms requiring oxygen **G4:** life-threatening with respiratory compromise requiring airway intervention
Management[3]	**G1-G2:** • Topical steroids and/or antihistamines • Hold EV if needed → resume same dose **G2 with fever or G3:** • Hold EV until ≤ G1 • Refer to Derm • Resume EV at same dose or reduce by one level **Suspected SJS/TEN or bullous lesions:** • Hold EV and immediately refer to Derm **Recurrent G3, G4, or confirmed SJS/TEN:** • Discontinue EV permanently	**G2:** • Hold EV until ≤ G1 • 1st occurrence: resume EV at same dose level • Recurrence: resume EV, but reduce by one level **≥ G3:** • Discontinue EV permanently	**Check baseline HgbA1c** **Blood glucose > 250 mg/dL:** • Hold EV • Treat with insulin/oral agents as indicated • Resume EV at same dose level once BG ≤ 250 mg/dL **Poor glucose control:** • Refer to Endocrinology for optimization of antiglycemic regimen **G4 (e.g., DKA):** • Discontinue EV permanently	**G2:** • Hold EV until ≤ G1 • Resume EV at same dose or reduce by one level • Refer to Pulm **≥ G3 or recurrent G2:** • Discontinue EV permanently • Refer to Pulm

EV Dose Reduction Schedule

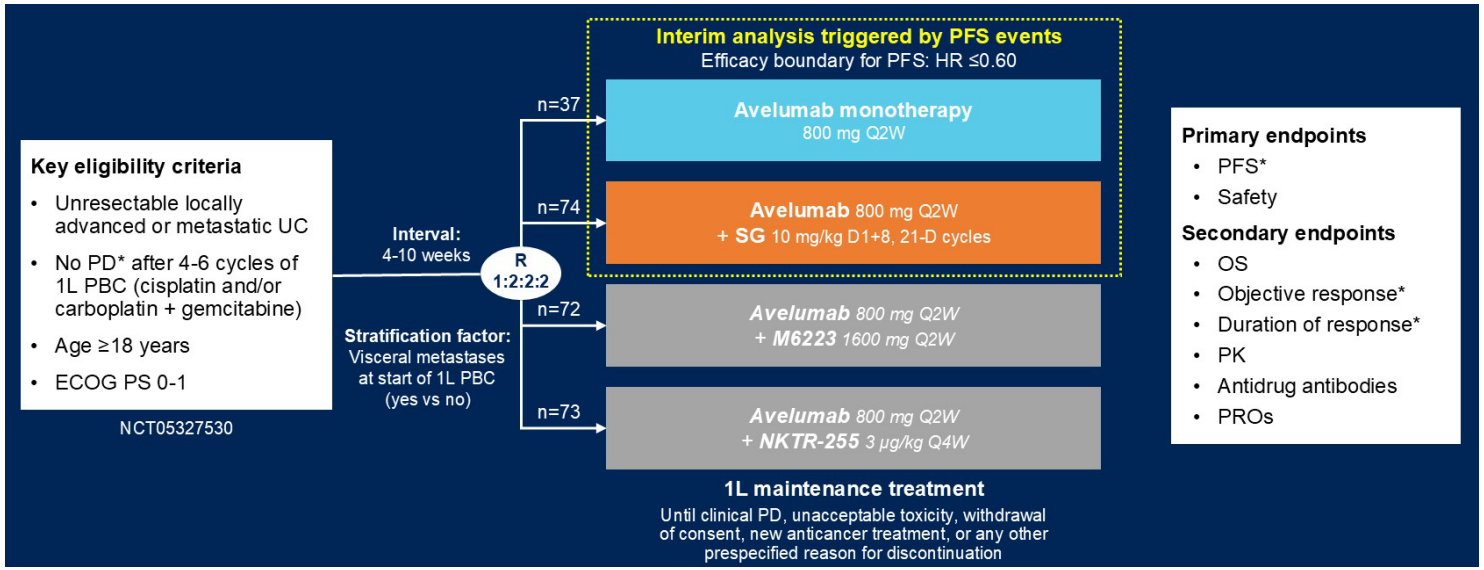
- Starting Dose: 1.25 mg/kg (up to 125 mg)
- 1st Dose Reduction: 1.00 mg/kg (up to 100 mg)
- 2nd Dose Reduction: 0.75 mg/kg (up to 75 mg)
- 3rd Dose Reduction: 0.50 mg/kg (up to 50 mg)

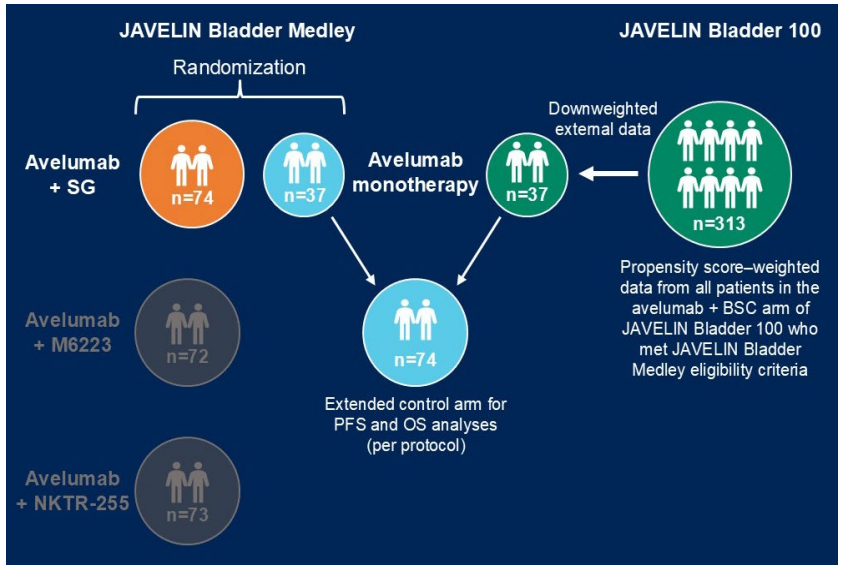
*AEs in EV-302 were graded using CTCAE v4.03.

1. Powles T. N Engl J Med. 2024. 2. U.S. Department of HHS. CTCAE Version 5.0. 2017. 3. U.S. FDA. PADCEV® (enfortumab vedotin-ejfv) for injection, for intravenous use. 2025.

MAINTENANCE INTENSIFICATION IN La/mUC

JAVELIN Bladder Medley: a phase 2 international, randomized trial (NCT05327530)



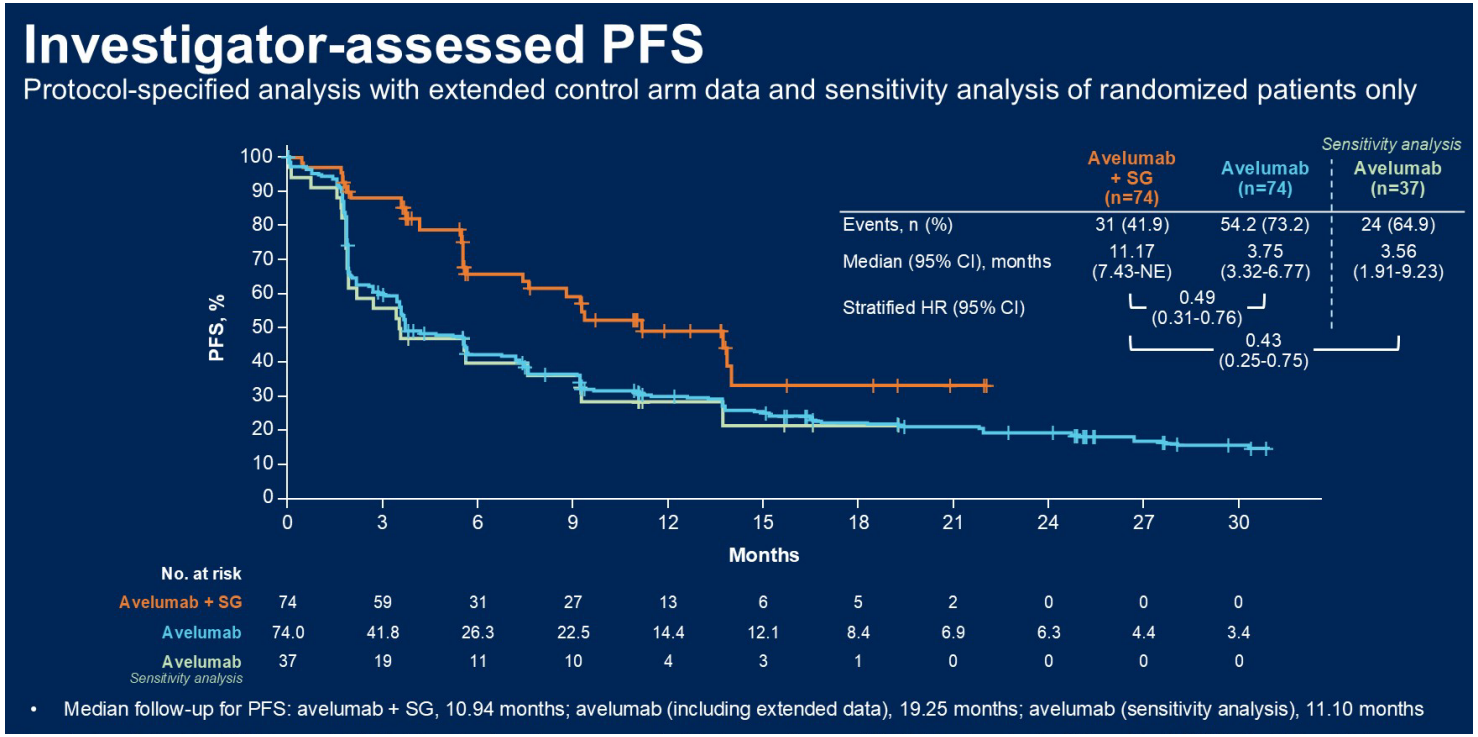


Design:

- 1L platinum-based chemo x4-6 cycles without PD → maintenance avelumab ± SG until PD or unacceptable toxicity
- Per protocol, PFS and OS data in the control arm were extended using external data from the JAVELIN Bladder 100 phase 3 trial; external patients were propensity-score weighted based on predefined prognostic factors

Hoffman-Censits J. ASCO 2025. Abstract 4501.

MAINTENANCE INTENSIFICATION IN La/mUC



	Avelumab + SG (n=74)	Avelumab (n=37 for ORR; n=74 for PFS/OS)	95% CI
ORR	24.3%	2.7%	Avelumab + SG: 15.1-35.7 Avelumab: 0.1-14.2
Median PFS, mos	11.2	3.8	HR 0.49 (0.3-0.8)
Median OS, mos	Immature at time of data cutoff		

- **Interim analysis: higher ORR and PFS trend with combination**
- cCR: 6.8% vs 2.7%
- OS immature at data cutoff
- Safety population: Avelumab + SG (n=73) vs avelumab (n=36)
- **G3 TRAEs: 70% vs 0%**
  - Neutropenia (40%)
  - Decreased ANC (23%)
  - Diarrhea (12%)
  - Febrile neutropenia (11%)
- **1 SG-related death: acute SAH in setting of sepsis and pancytopenia**

Hoffman-Censits J. ASCO 2025. Abstract 4501.

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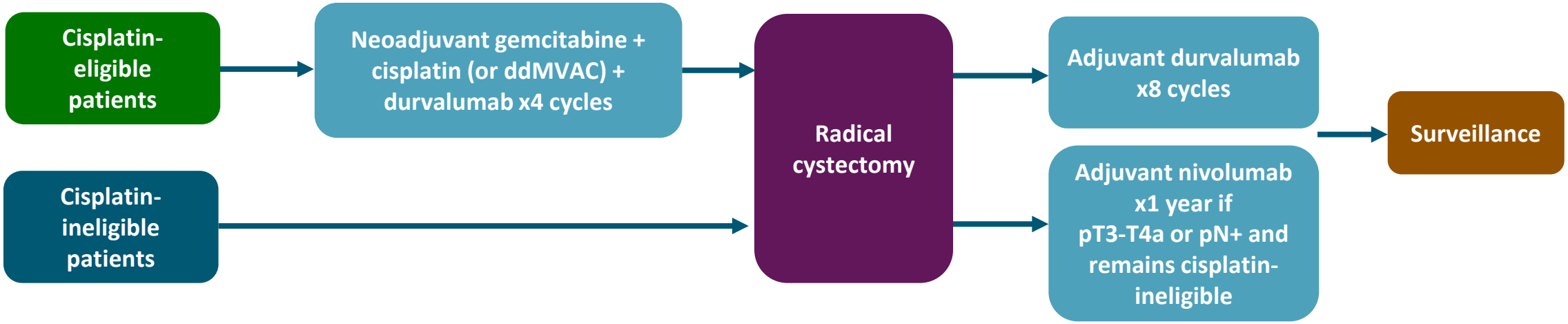
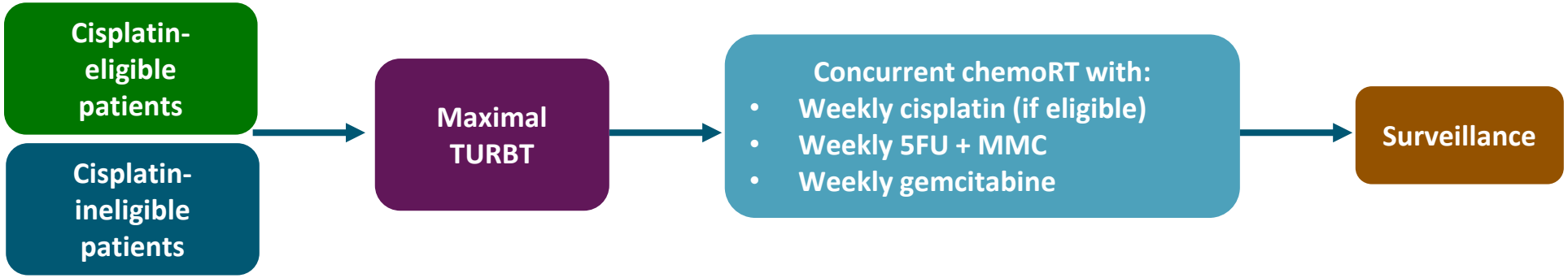
MIUC TREATMENT ALGORITHM IN 2025

RADICAL CYSTECTOMY



BLADDER-SPARING ChemoRT (select patients)



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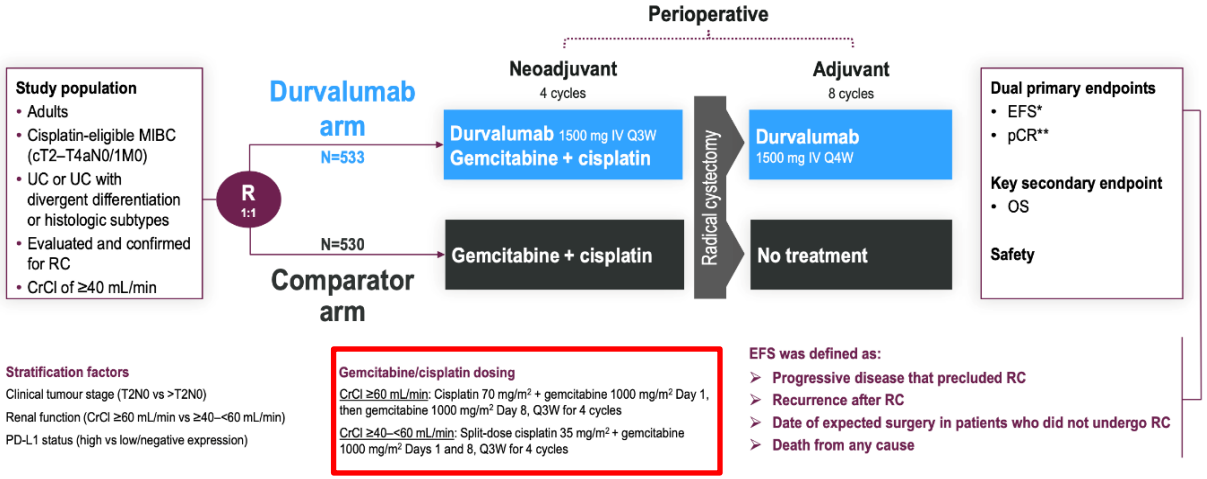
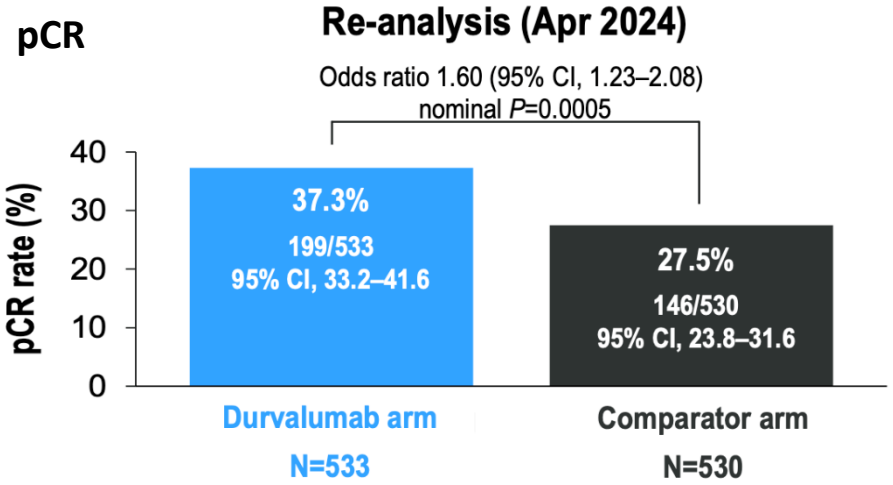
Always consider clinical trials, particularly in cisplatin-ineligible patients

NIAGARA: PERIOPERATIVE SOC IN CIS-ELIGIBLE MIUC

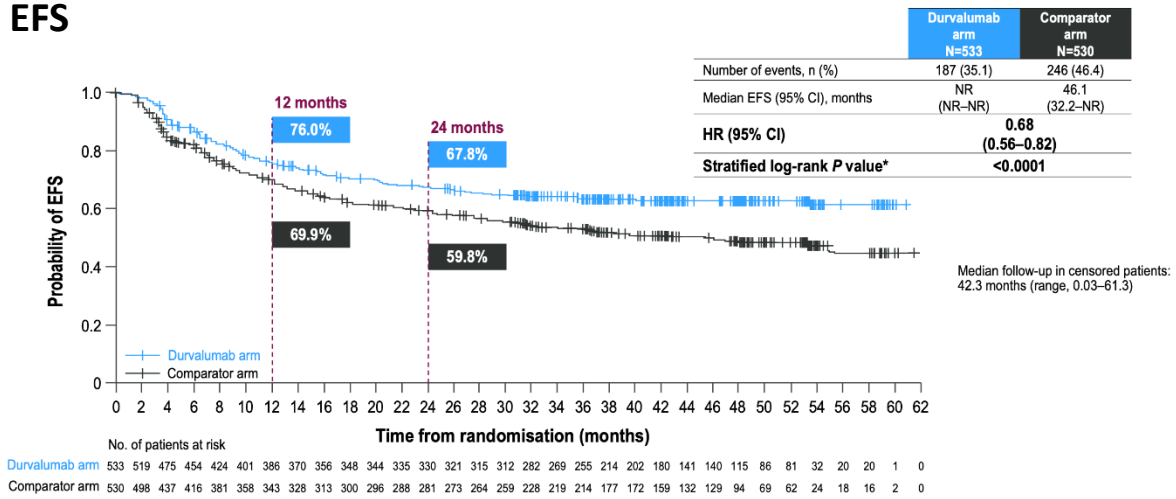
NIAGARA: a phase 3 international, randomized trial (NCT03732677)[1,2]



pCR



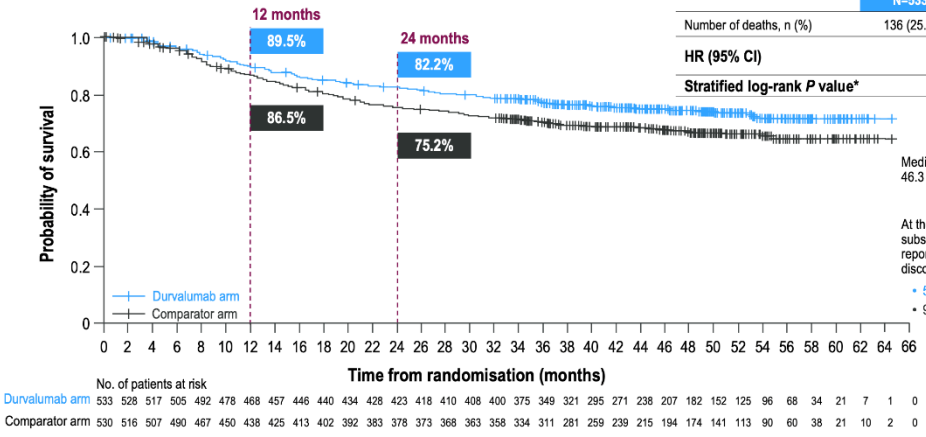
EFS



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

Median follow-up in censored patients: 42.3 months (range, 0.03–61.3)

OS



	Durvalumab arm N=533	Comparator arm 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	

Median follow-up in censored patients: 46.3 months (range, 0.03–64.7)

At the time of this analysis, at least 1 subsequent anti-cancer therapy was reported after treatment discontinuation for:
- 53 patients in the durvalumab arm
- 93 patients in the comparator arm

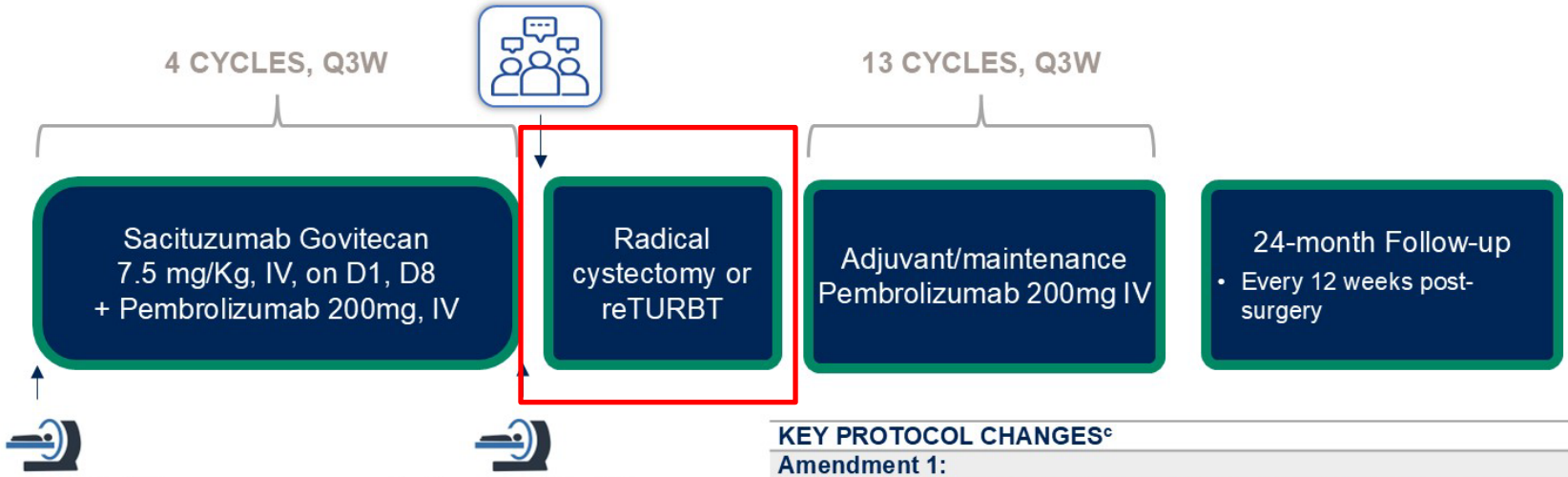
1. Powles T. ESMO 2024. Abstract LBA5. 2. Powles T. N Engl J Med 2024.

SURE-02: SG + PEMBRO IN CIS-INELIGIBLE/DECLINED MIUC

SURE-02: a phase 2, single-arm trial (NCT05535218)

NCT05535218

Population:
- Aged ≥18 years
- Histologically confirmed cT2-T3b N0M0 MIBC (absence of nodal or metastatic disease at screening)
- Predominant UC histology
- ECOG PS of 0-1
- Ineligible or refusing NAC
- Ineligible or refusing chemoRT
- Scheduled for RC



Primary endpoint:
- Clinical CR rate (imaging CR + ypT0Nx)

Secondary endpoints:
- Efficacy: any downstaging rate, EFS[a], MFS, BI-EFS[b], OS, after neoadjuvant treatment
- Safety (CTCAE v.5.0)

Exploratory endpoints
- Biomarkers of response
- Changes in biomarker expression
- Microbiome data in urine and feces

KEY PROTOCOL CHANGES[c]

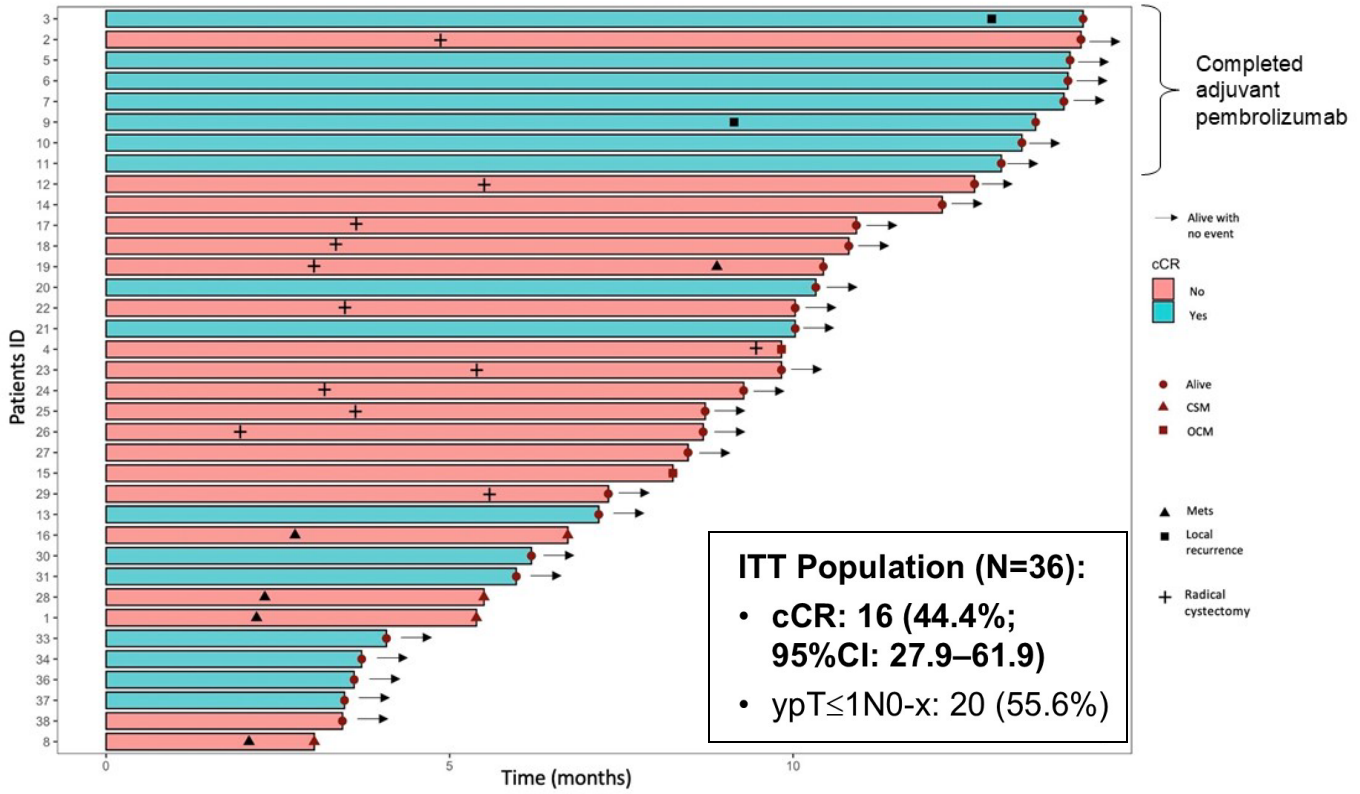
Amendment 1:
- Dose reduction of sacituzumab govitecan from 10 mg/Kg to 7.5 mg/Kg from C1D1.
- Introduction of G-CSF use (Peg-GCSF) as primary prophylaxis since C1D9.
- Exclusion of patients who had ≥3 risk factors for febrile neutropenia as indicated by the ASCO guidelines.[d]

Amendment 2:
- Change in primary endpoint from ypT0N0 rate to cCR rate (no change in sample size and statistical plan)
- Addition of a further inclusion criterion:
  - ChemoRT refusing/unsuited patients
- Restriction to cT2-T3bN0M0 patients.

Necchi A. ASCO 2025. Abstract 4518.

SURE-02: SG + PEMBRO IN CIS-INELIGIBLE/DECLINED MIUC

Median Follow-up: 10 months (IQR: 7.3 – 13)

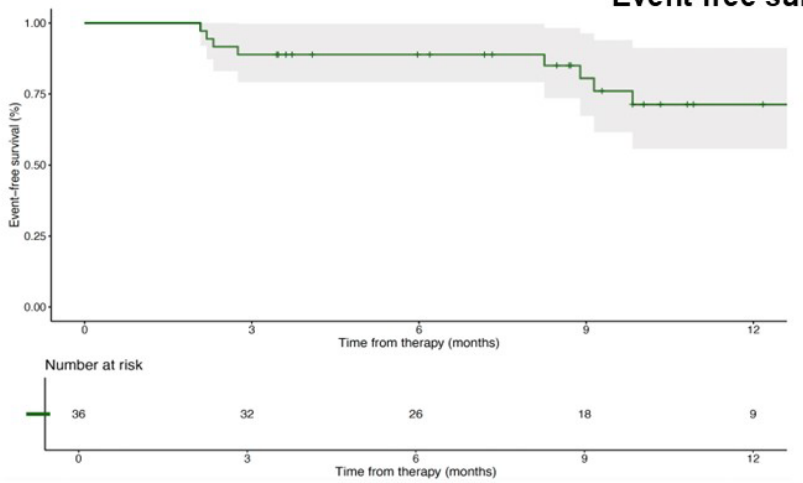


ITT Population (N=36):

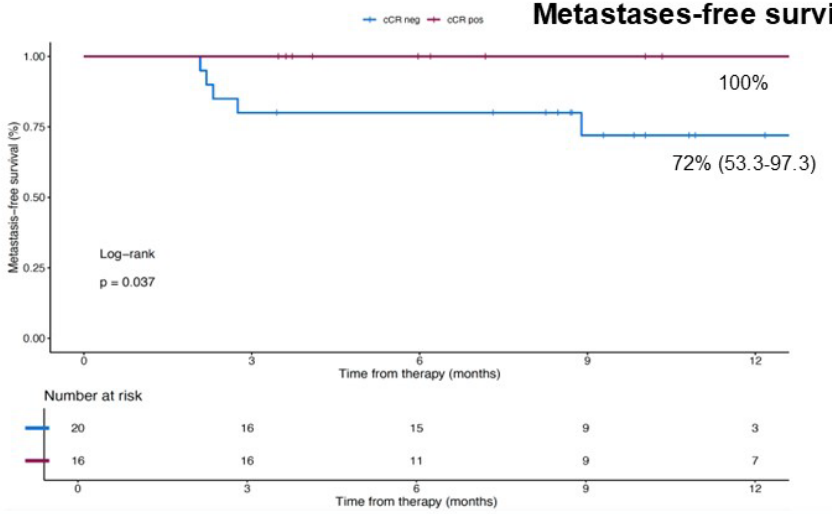
- **cCR: 16 (44.4%; 95%CI: 27.9–61.9)**
- ypT≤1N0-x: 20 (55.6%)

- 12m EFS:[a] 71.3% (95%CI: 55.7-91.2)
- 12m MFS: 84.2% (95%CI: 72-98.5)
- 12m Bladder-intact-EFS[b] in cCR patients (N=16): 100%
- 12m Bladder-intact-EFS in reTURBT patients (N=23): 74% (95%CI 54.8-99)

Event-free survival



Metastases-free survival



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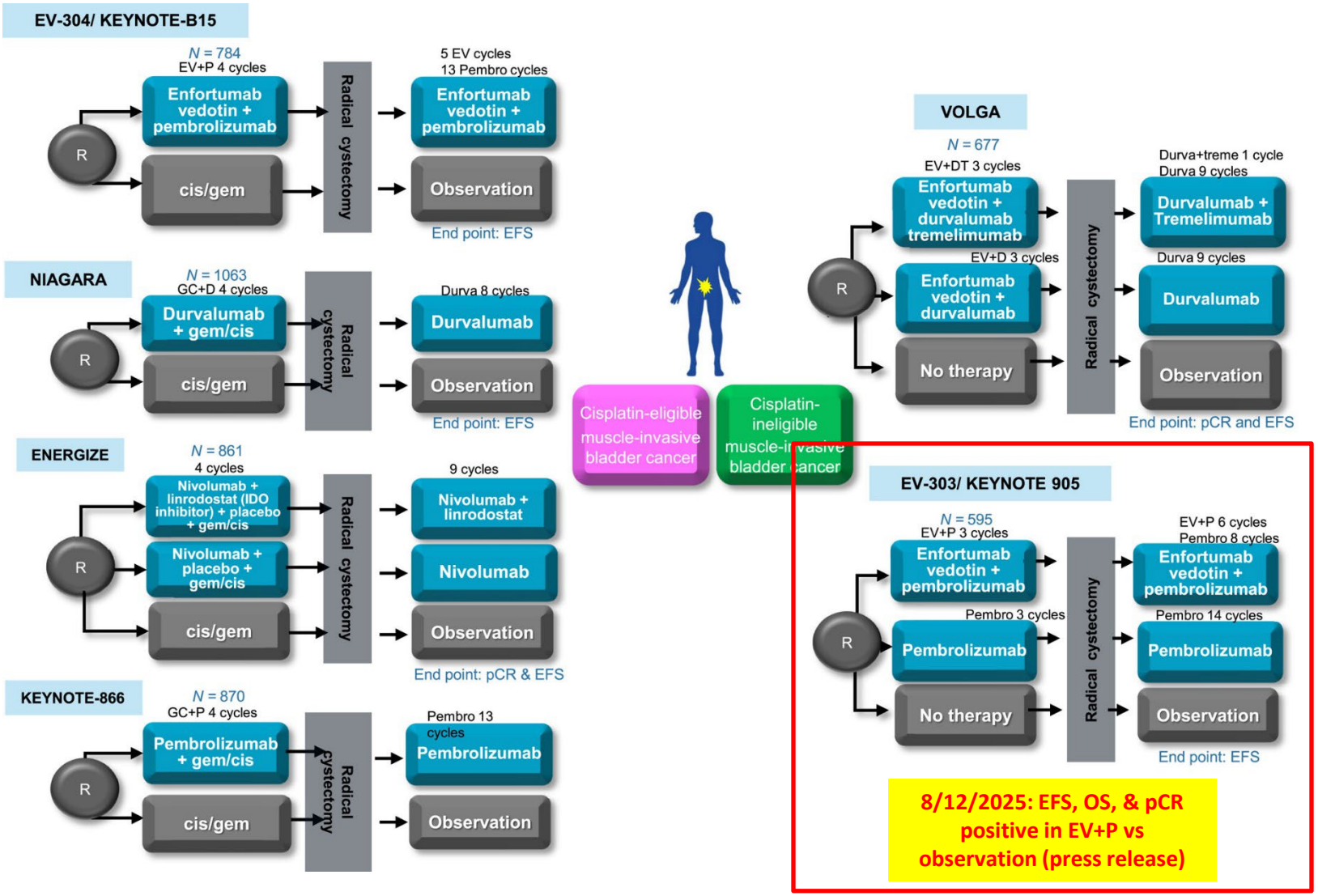
Necchi A. ASCO 2025. Abstract 4518.

ONGOING PERIOPERATIVE TRIALS IN MIUC



Apolo AB. Cancer. 2025.

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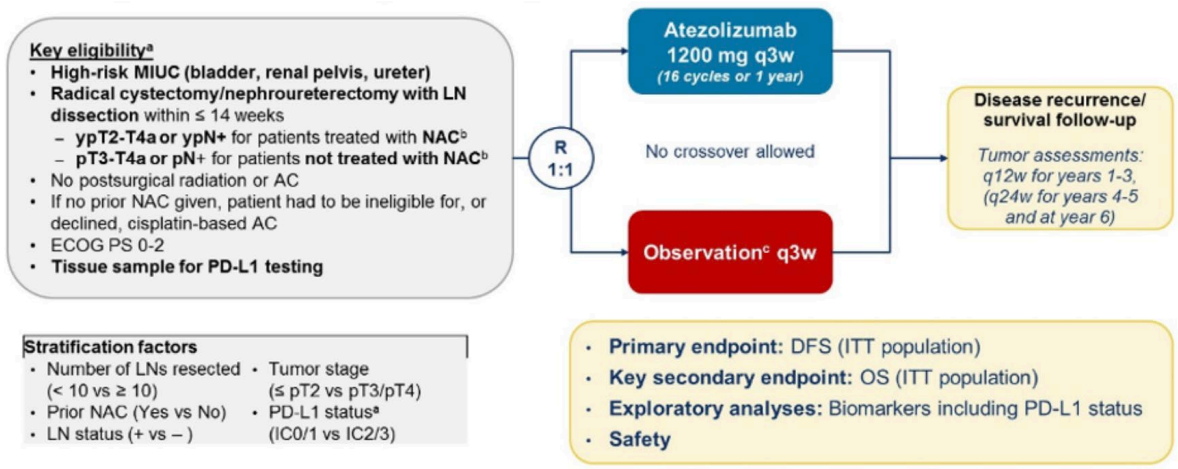
THE EMERGING ROLE OF ctDNA IN MIUC

- Tumor-informed ctDNA detects molecular residual disease (MRD) and refines relapse risk after perioperative therapy and cystectomy
- ctDNA positivity is strongly prognostic for inferior outcomes; early clearance correlates with benefit
- Trials are investigating ctDNA both as a prognostic and predictive biomarker to guide adjuvant immunotherapy and surveillance

Gao X. Cancer Cell Int. 2025.

IMvigor010

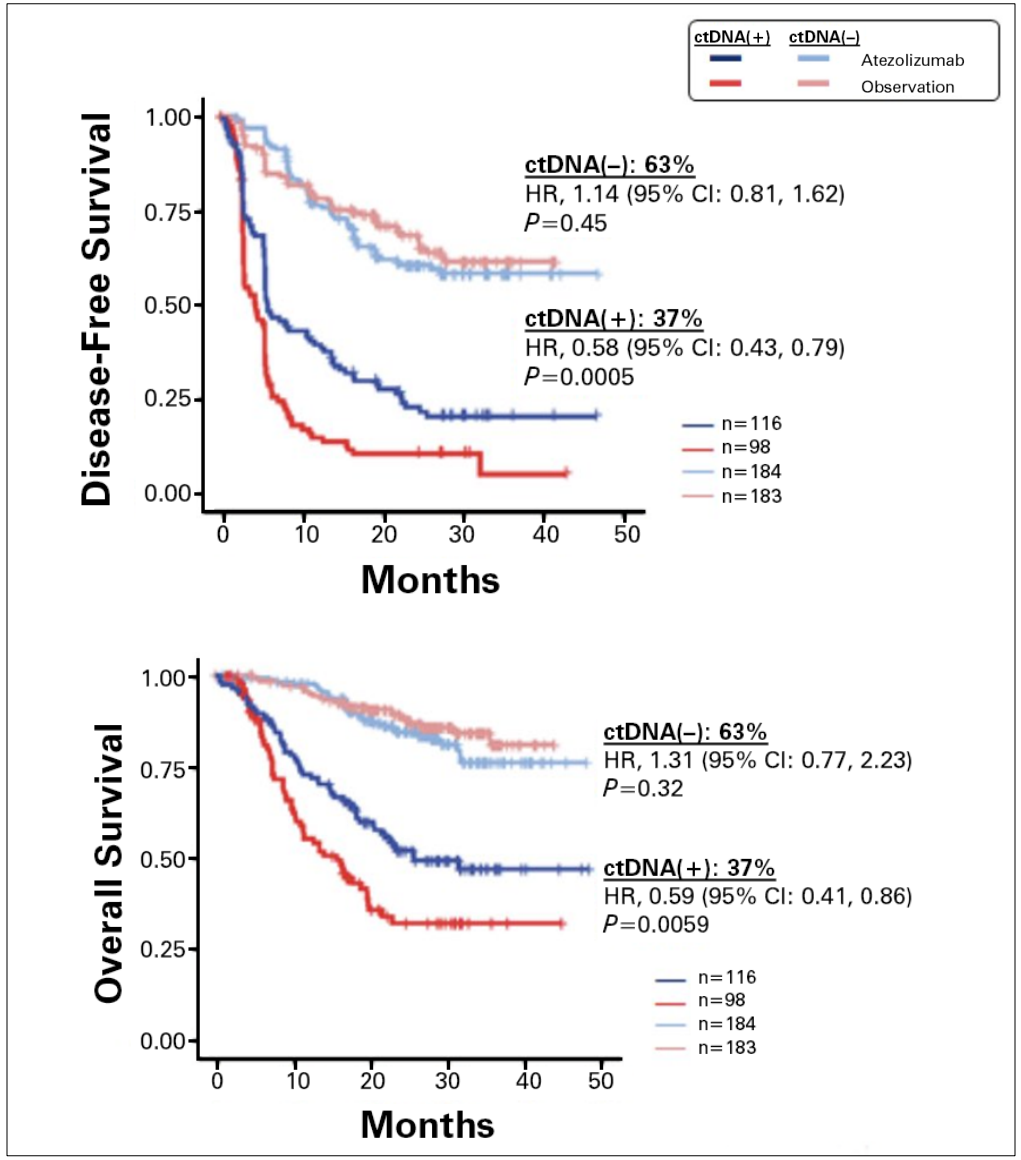
IMvigor010: A phase 3, international, randomized trial (NCT02450331)



Did not meet primary DFS endpoint, but...

...benefit with atezolizumab observed in ctDNA+ pts

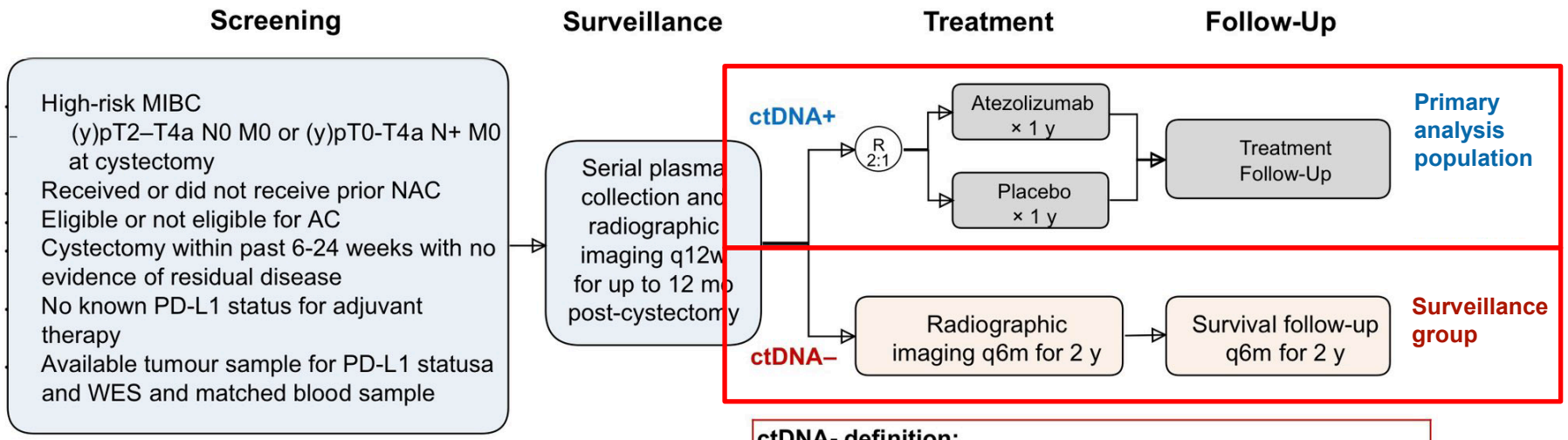
IMvigor011 (NCT04660344)



1. Powles T. Nature. 2021. 2. Powles T. Eur Urol. 2024.

IMvigor011

IMvigor011: A phase 3, international, randomized trial (NCT04660344)



Primary endpoint:
- Investigator-assessed DFS

Key secondary endpoint:
- OS

ctDNA- definition:
- Disease-free status at baseline
- ≥1 ctDNA− result and no ctDNA+ result
- ≥1 post-baseline diseases assessment
- Completed ≥12 mo of surveillance post-cystectomy or discontinued surveillance <12 mo with no ctDNA+ result

ClinicalTrials.gov ID, NCT04660344. Stratification factors were nodal status (positive vs negative), tumour stage after cystectomy (≤(y)pT2 vs (y)pT3/(y)pT4), PD-L1 IHC status (IHC score of IC0/1 vs IC2/3 by VENTANA SP142 IHC assay) and time from cystectomy to first ctDNA+ sample (≤20 weeks vs >20 weeks). AC, adjuvant chemotherapy; IHC, immunohistochemistry; NAC, neoadjuvant chemotherapy; OS, overall survival; q6m, every 6 months; q12w, every 12 weeks; WES, whole-exome sequencing. aPD-L1 status was determined by the VENTANA SP142 IHC assay.

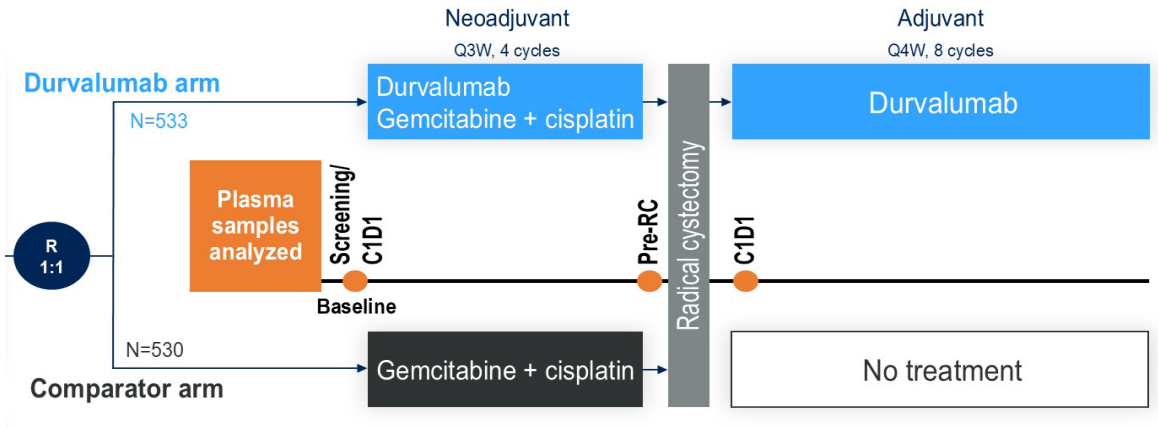
8/18/2025: DFS and OS positive in ctDNA+ pts treated with atezolizumab vs placebo (press release)

EAU 2024: analysis of ctDNA- pts on surveillance

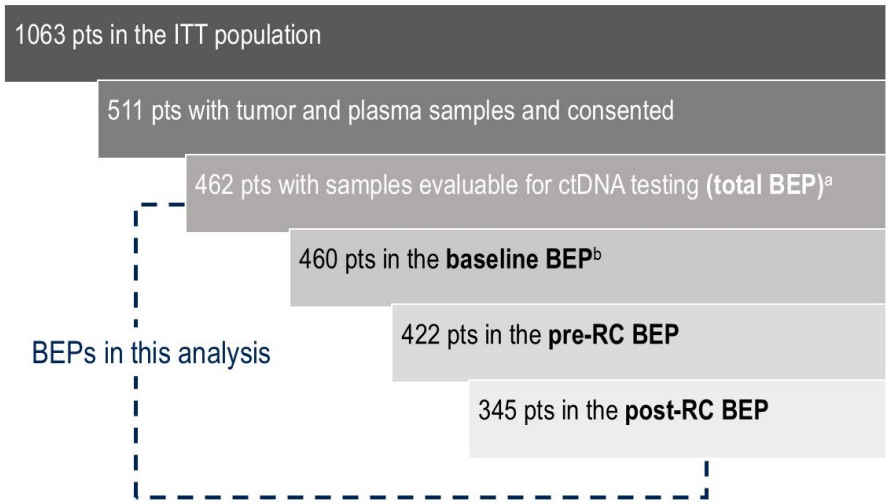
- Median f/u: 16.3 mos
- DFS at 12 mos: 92%
- DFS at 18 mos: 88%
- OS at 12 mos: 100%
- OS at 18 mos: 98%

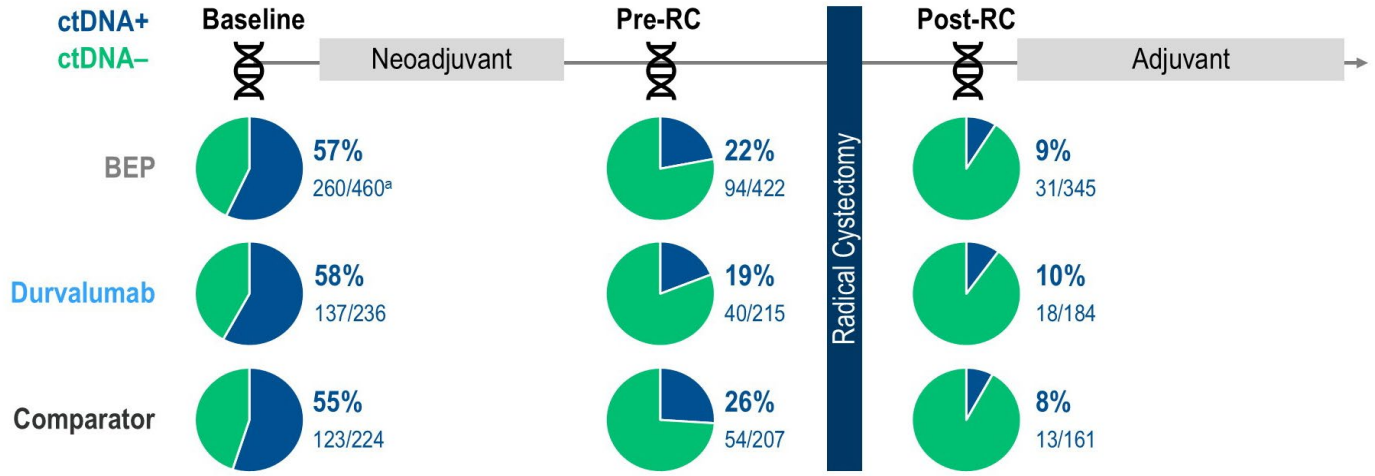
Powles T. EAU 2024.

ctDNA IN NIAGARA



- Planned exploratory analysis of longitudinal Signatera tumor-informed ctDNA
- Baseline ctDNA+ in biomarker evaluable population (BEP): 57%
- ctDNA+ rates decreased after neoadjuvant treatment and radical cystectomy
- ctDNA status was strongly prognostic for outcomes



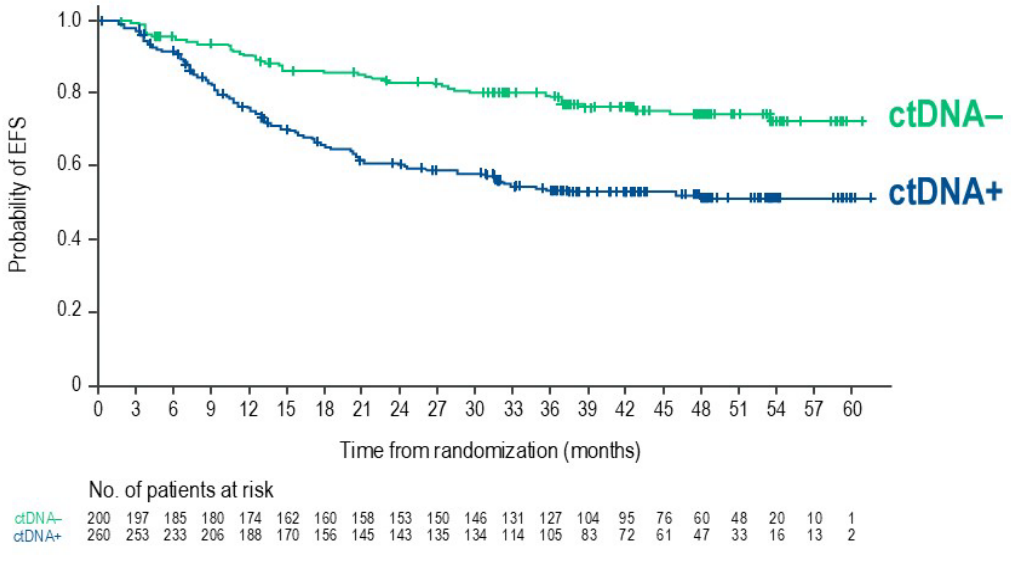


Powles T. ASCO 2025. Abstract 4503.

ctDNA IN NIAGARA

Baseline ctDNA was prognostic for EFS

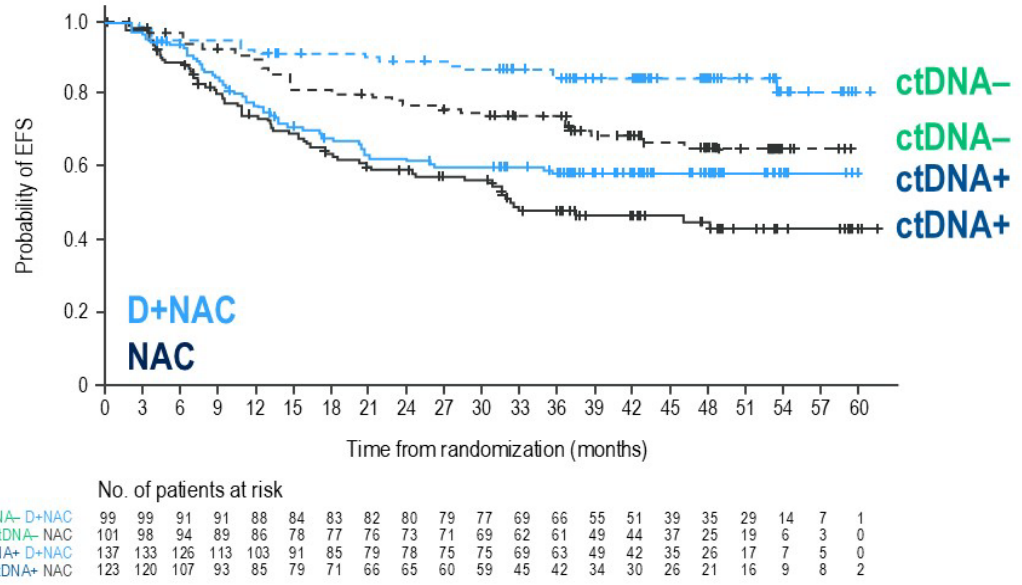
EFS (combined arms)



ctDNA– vs ctDNA+	**HR, 0.42** (95% CI, 0.30–0.60)

Perioperative D+NAC provided EFS benefit regardless of baseline ctDNA status

EFS (per arm)



ctDNA–: D+NAC vs NAC	**HR, 0.45** (95% CI, 0.24–0.84)
ctDNA+: D+NAC vs NAC	**HR, 0.73** (95% CI, 0.51–1.05)

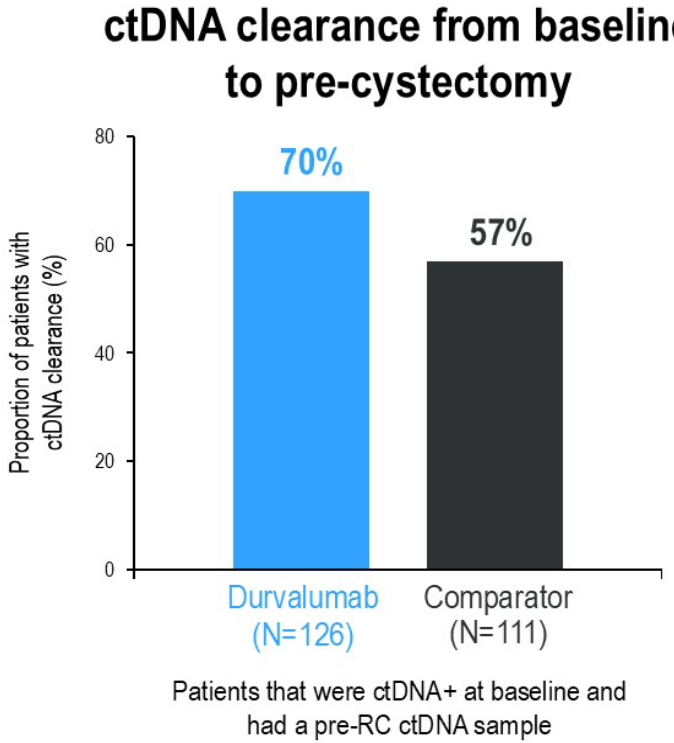
Durvalumab arm = D+NAC; Comparator arm = NAC

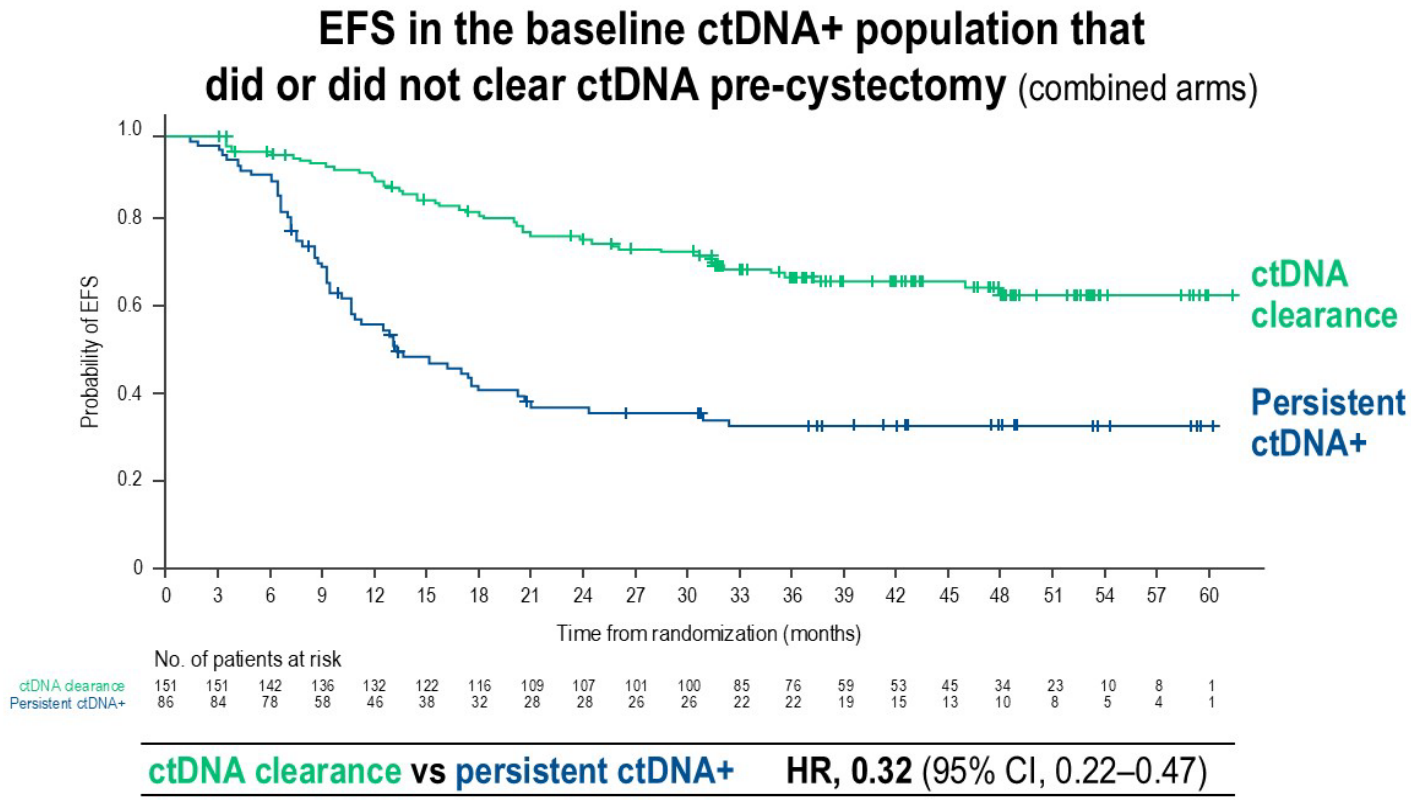
- **BEP baseline ctDNA+ = 57%**

Powles T. ASCO 2025. Abstract 4503.

ctDNA IN NIAGARA

ctDNA clearance after neoadjuvant therapy and before cystectomy was higher in the Durvalumab arm and was associated with improved EFS

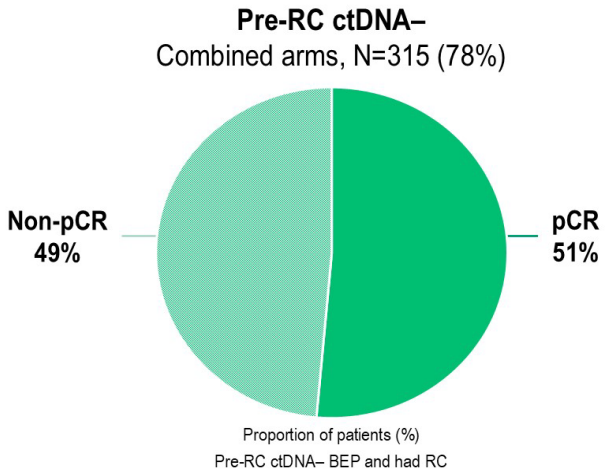




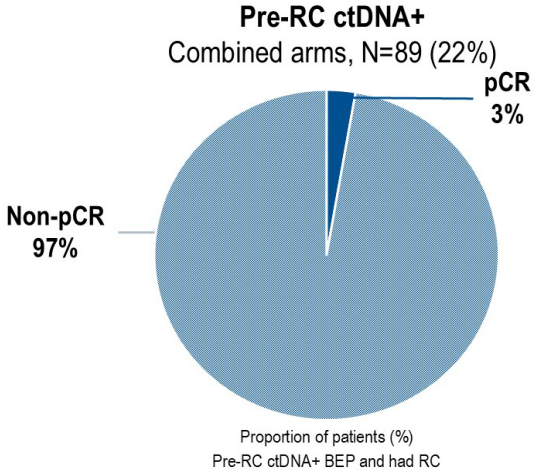
- **BEP with baseline ctDNA+ and evaluable sample pre-RC = 237 patients**

Powles T. ASCO 2025. Abstract 4503.

ctDNA IN NIAGARA

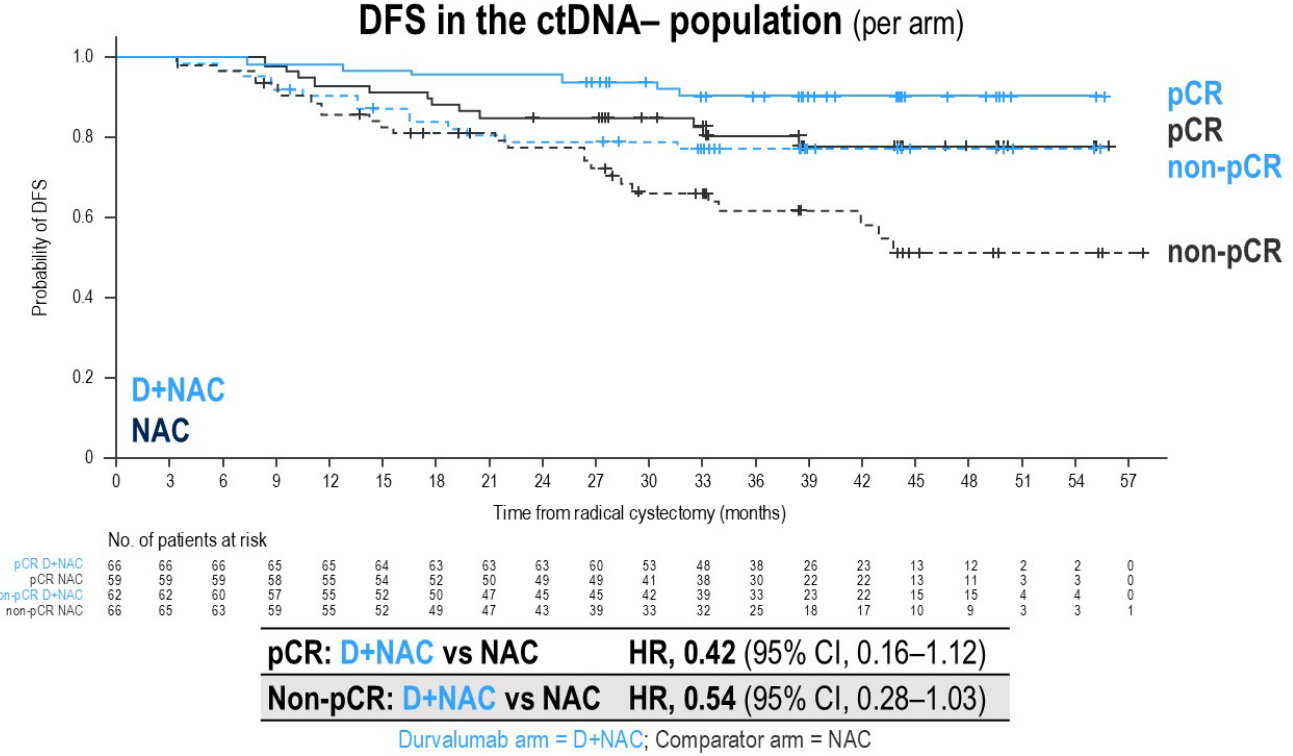


ctDNA– status was not associated with pCR



ctDNA+ status was highly correlated with non-pCR

Patients with **ctDNA- post-cystectomy** derived DFS benefit from D+NAC irrespective of pathologic response status



pCR: D+NAC vs NAC	**HR, 0.42** (95% CI, 0.16–1.12)
Non-pCR: D+NAC vs NAC	**HR, 0.54** (95% CI, 0.28–1.03)

Durvalumab arm = D+NAC; Comparator arm = NAC

Powles T. ASCO 2025. Abstract 4503.

THE EMERGING ROLE OF ctDNA IN MIUC

Domain	Emerging themes	Practice implications
Prognostic value	Pre-RC or post-RC ctDNA+ status signals high relapse risk; clearance correlates with better outcomes	Intensify adjuvant therapy & surveillance for ctDNA+; use kinetics to monitor response
Predictive value for IO	**PENDING IMvigor011 prospective data to validate DFS/OS benefit in ctDNA+;** persistently ctDNA− do well with surveillance	**PENDING IMvigor011 data:** Adopt ctDNA-guided adjuvant IO for ctDNA+; consider de-escalation (surveillance) in consistently ctDNA− with shared decision-making
Perioperative integration	**NIAGARA** improves EFS/OS in cis-eligible MIUC; IO improves ctDNA clearance and retains benefit across ctDNA strata	Support perioperative IO + chemo as a standard backbone in cis-eligible pts; use ctDNA to flag persistent risk
Operations & caveats	Assay timing/thresholds vary; false negatives occur; outcomes maturing; logistics evolving	Standardize testing timepoints (baseline, pre-RC, post-RC); combine with clinicopathologic risk; maintain imaging even if ctDNA−

OUTLINE

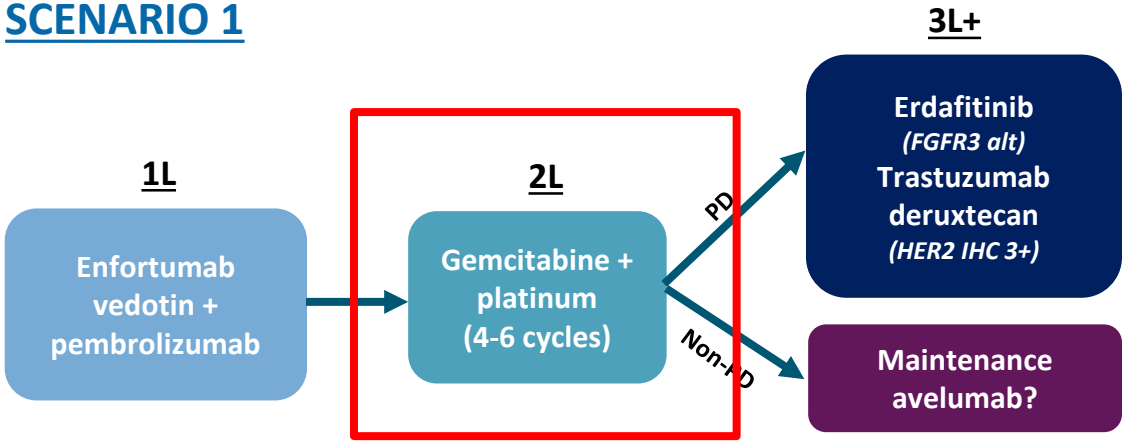
- Epidemiology & state of the field in 2025
- Locally advanced/metastatic urothelial carcinoma (La/mUC)
- Muscle-invasive urothelial carcinoma (MIUC)
- The emerging role of ctDNA & risk-adaptive strategies
- Future directions & summary

FUTURE DIRECTIONS

- Optimizing treatment sequence after EV+P and perioperative IO
- Risk-adaptive trials using clinical and molecular biomarkers to refine patient selection and guide personalized de-escalation and escalation strategies
- Defining the role of consolidative surgery or radiation in La/mUC disease states
- Improving therapeutic options and outcomes in histologic subtypes

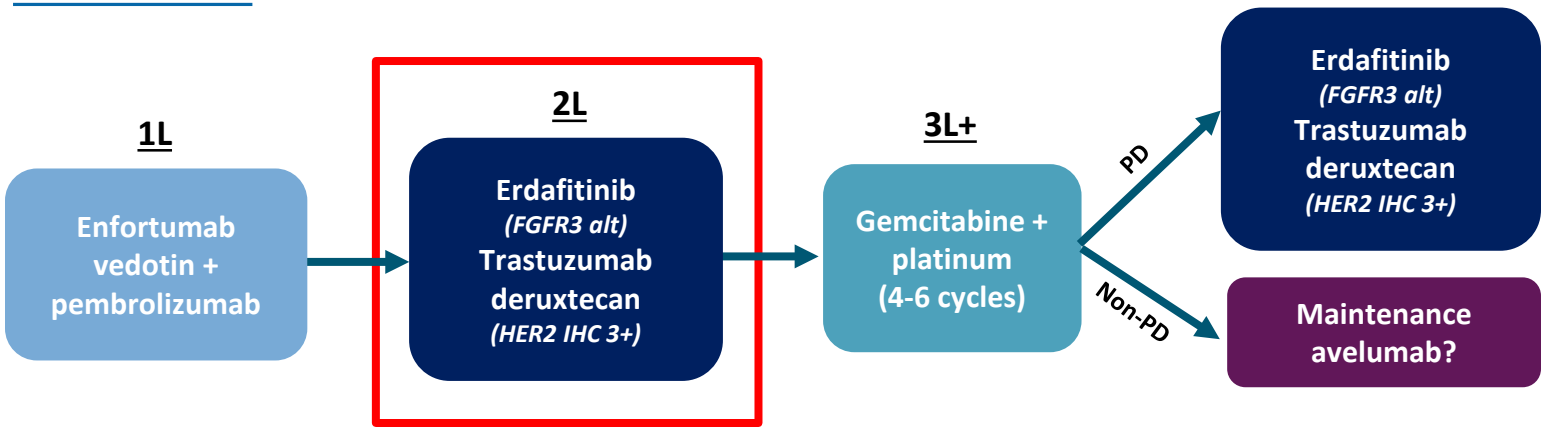
SEQUENCING AFTER EV+P

SCENARIO 1



	Gemcitabine + platinum (EV-302 control arm)[1]	Erdafitinib (THOR Cohort 1)[2]	Trastuzumab deruxtecan (DESTINY-PanTumor002)[3]
ORR	44%	46%	56% *(IHC 3+)*
DoR	7.0	5.6*	8.7
Median PFS, mos	6.3	5.6	7.4
Median OS, mos	15.9	12.1	13.4

SCENARIO 2



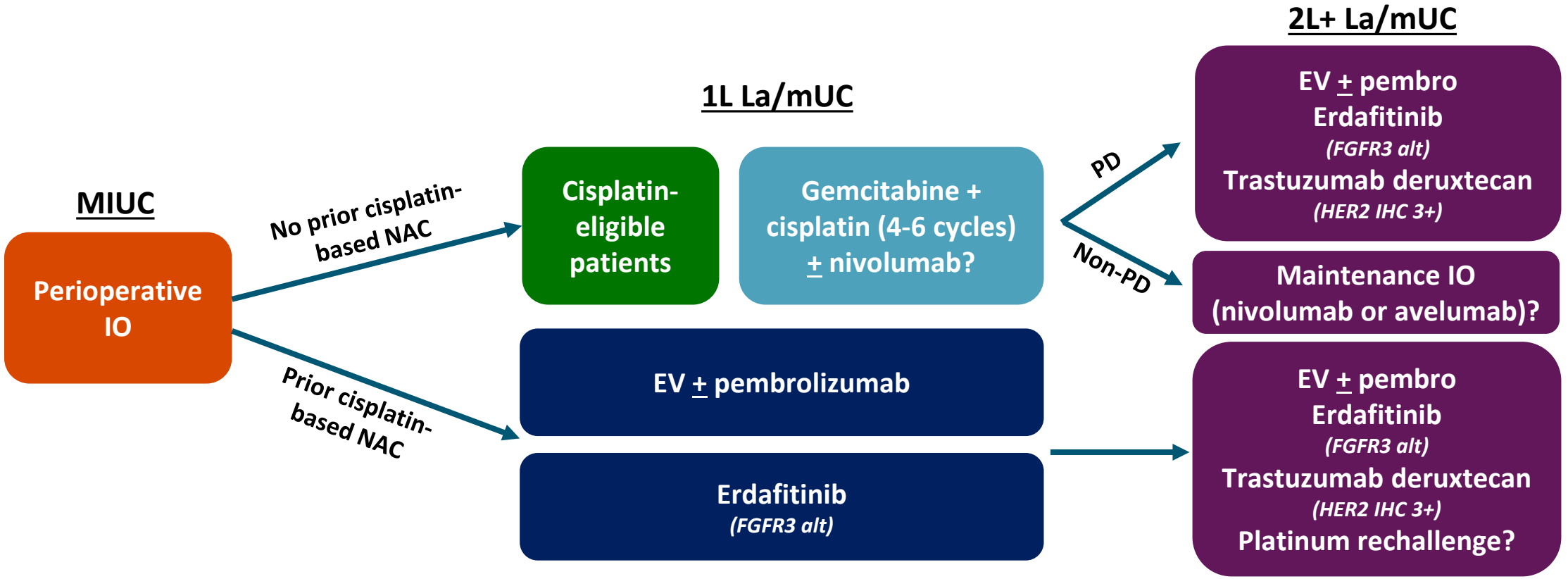
- Is there a role for IO rechallenge if PD on prior IO?
- Does time since last IO matter?
- Does intervening regimen matter?
- Toxicities with different sequences?
- Mechanisms of resistance?

*Median DoR in Phase II BLC2001

1. Powles T. Ann Oncol. 2025. 2. Loriot Y. N Engl J Med. 2023. 3. Meric-Bernstam F. J Clin Oncol. 2024.

SEQUENCING AFTER PERIOPERATIVE IO

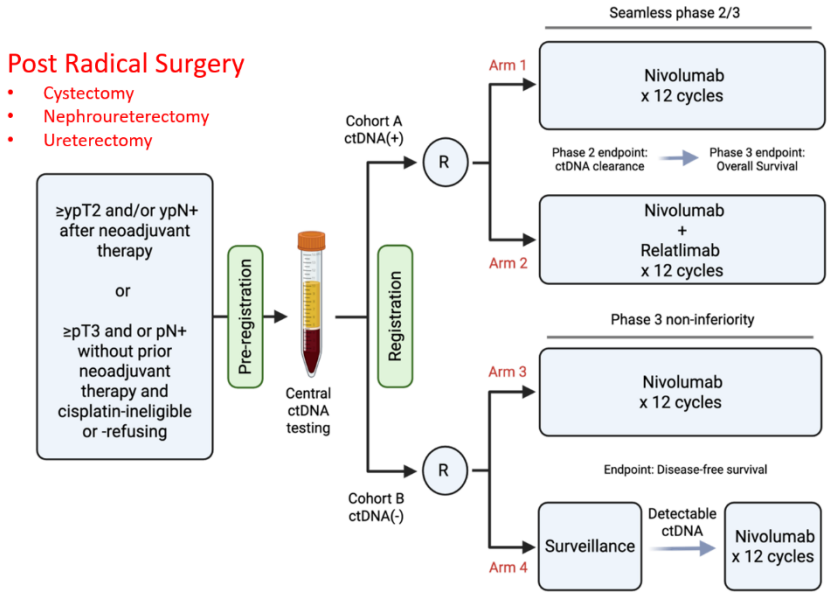
- Neoadjuvant cisplatin-based chemotherapy within the preceding 12 months? If so, do we move straight to EV? Erdafitinib?
- Does timing of disease progression matter? (While on adjuvant IO? Within ≤ 12 or > 12 months of completion?)
- Is there a role for IO rechallenge?



SELECT RISK-ADAPTIVE PERIOPERATIVE TRIALS IN MIUC

A0327103 (MODERN)

NCT05987241



PI: M. Galsky

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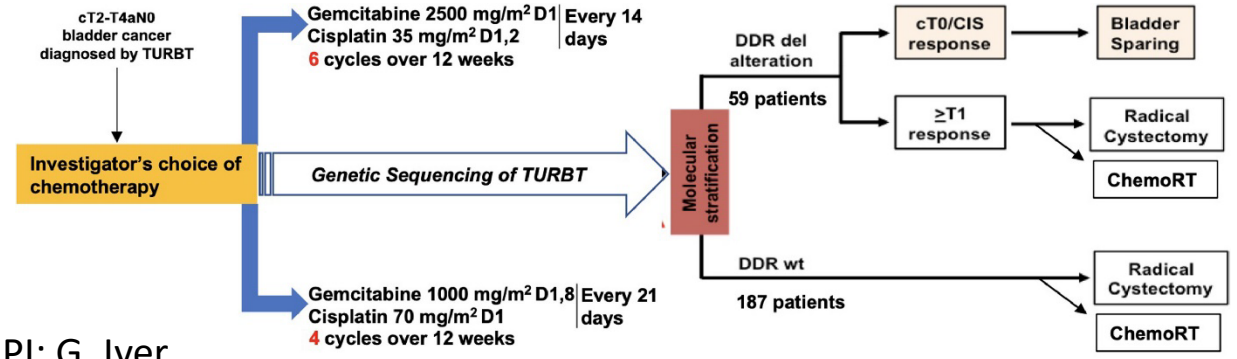

PI: G. Iyer

RETAIN-2

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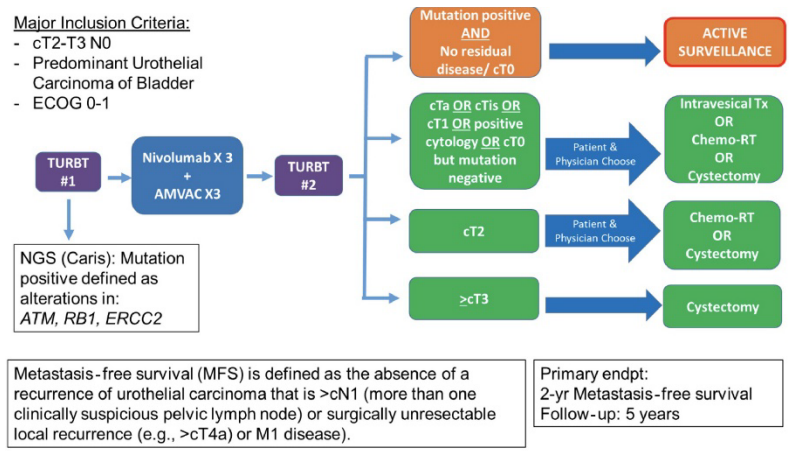

PI: P. Ghatalia

SUMMARY: UROTHELIAL CANCERS IN 2025

- EV + pembrolizumab established as SOC in 1L La/mUC; long-term data reinforce durability
- Perioperative chemo + IO remains the SOC for MIUC, but ADC + IO regimens and ctDNA-guided strategies are poised to reshape MIUC care soon → downstream implications on La/mUC treatment
- Integration of NGS + ctDNA collection into multidisciplinary workflows is essential for personalized care
- Treatment regimens & their associated toxicities are increasingly complex & shifting to earlier treatment settings → proactive management & multidisciplinary collaboration are crucial
- Optimal therapy sequence decisions should be patient-centric with consideration of prior therapies, potential toxicities, and patient- and disease-related factors
- Clinical trials in refractory treatment settings and in histologic subtypes remain key unmet needs for improving outcomes

THANK YOU!

Our patients, families, patient advocates, & cancer advocacy organizations!

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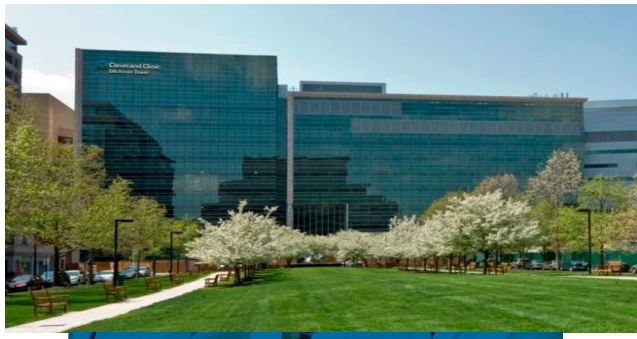

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