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PRESENCIAL RETRANSMITIDO EN DIRECTO
FACE-TO-FACE AND LIVE STREAMING

26-27 JUNIO 2025

Espacio Maldonado, Madrid



One line: Several options: Individualization of treatment in metastatic setting

Professor Syed A Hussain, University of Sheffield

Syed.Hussain@Sheffield.c.uk

X @ProfSyedHussain

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Disclosures

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Bladder Cancer Landscape in Numbers: A focus on UC¹⁻³

Urothelial carcinoma accounts for > 90% of bladder cancers and is strongly associated with frailty and old age^{1,2}

New cases³

614,000

In 2022, worldwide

Deaths⁴

~200,000

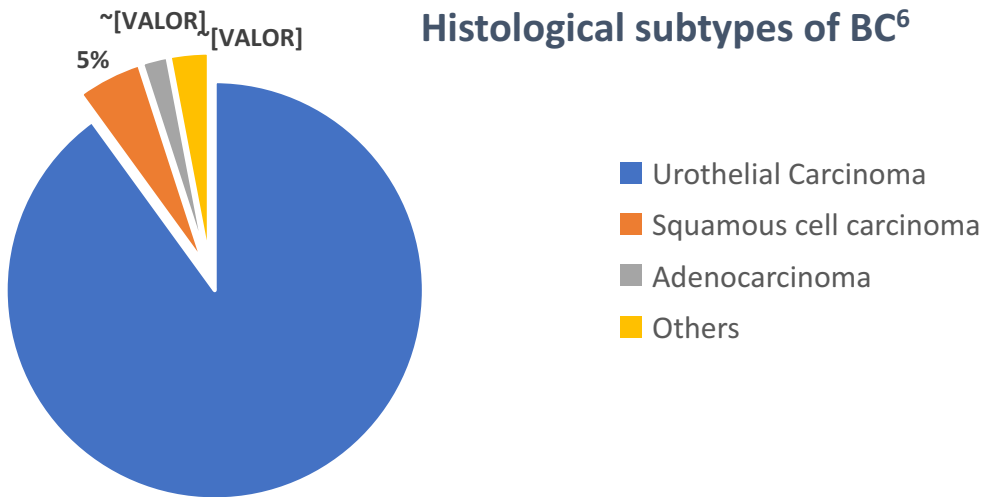
Median age²

~73
years old

5-year survival⁵

8%
In T4 UC

Histological subtypes of BC⁶



Emergency department visit

- Over **90%** of patients with mUC experience at least one hospitalisation during treatment⁷



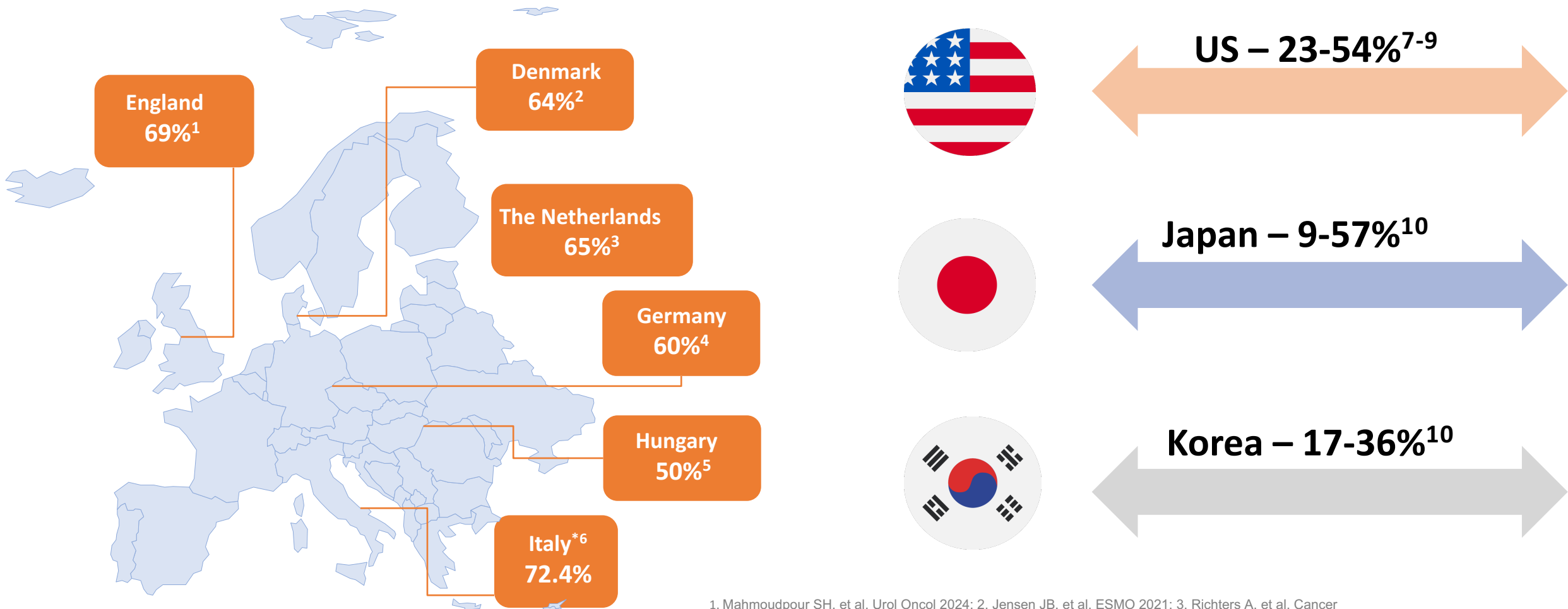
ICU admissions

- Over **50%** of patients with mUC had at least one ICU admission during treatment⁷

1. Grande E et al., Can Treat Rev 2025; 2. National Cancer Institute. "SEER cancer stat facts: bladder cancer." 2019; 3. Tonni E et al., Int J Mol Sci 2024; 4. Cleveland Clinic (2023) *A new standard emerges in advanced urothelial carcinoma after decades of first-line chemotherapy*. Available at: <https://consultqd.clevelandclinic.org/a-new-standard-emerges-in-advanced-urothelial-carcinoma-after-decades-of-first-line-chemotherapy>; Accessed: 23 April 2025; 5. Bladder Cancer Advocacy Network. (n.d.). *Survival rates for bladder cancer*. <https://bcan.org/survival-rates-for-bladder-cancer/>. Accessed on April 23, 2025; 6. Bilim V et al., J Pers Med 2022; 7. Aly A et al., J Med Econ 2019

Access to 1L Systemic Therapy for mUC Patients Remains Inconsistent Across the World¹⁻¹⁰

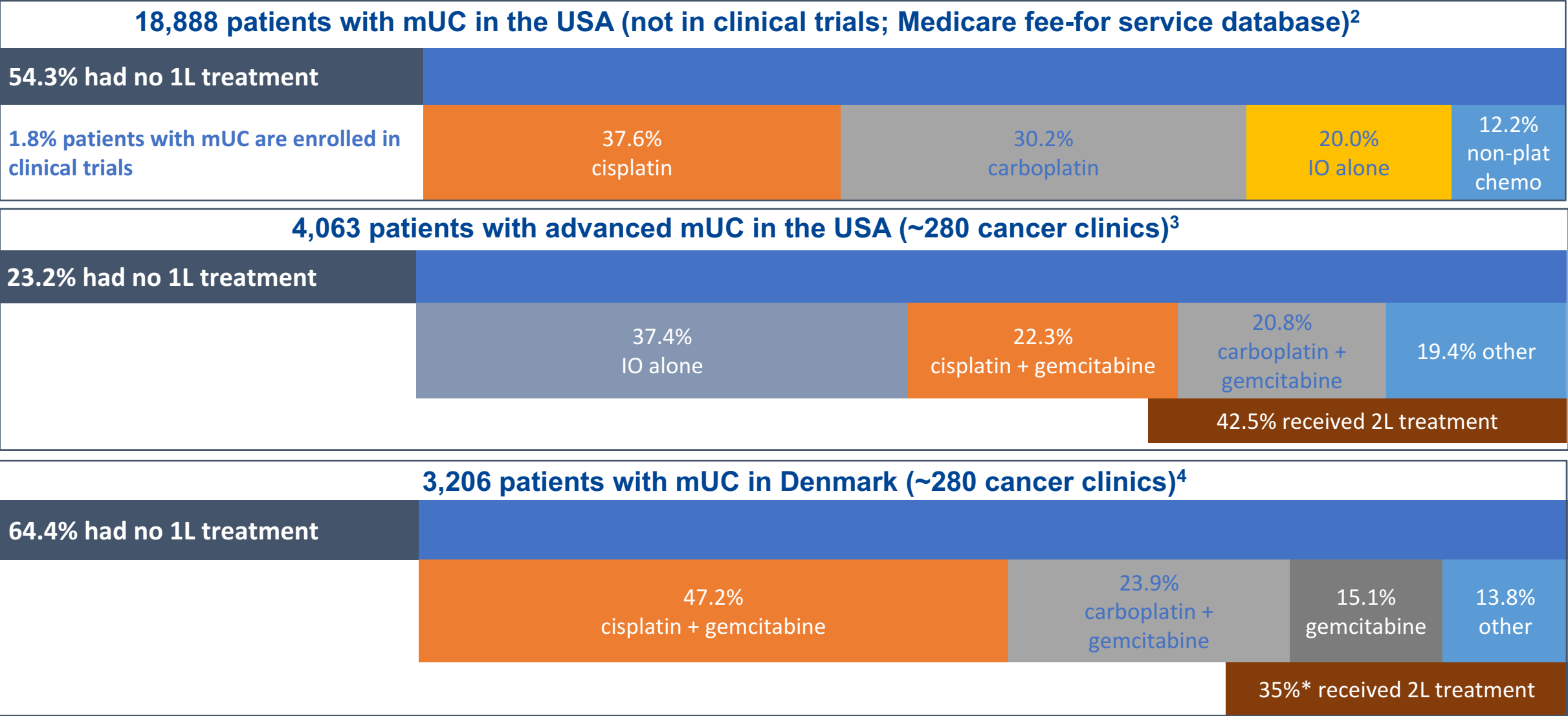
Percent of patients not receiving 1L treatment per country despite diagnosis



*In-patient rates only.
1L: first-line; mUC: metastatic urothelial carcinoma

1. Mahmoudpour SH, et al. Urol Oncol 2024; 2. Jensen JB, et al. ESMO 2021; 3. Richters A, et al. Cancer Treat Res Commun 2020; 4. Niegisch G, et al. Future Oncol 2024; 5. Maraz A, et al. Adv Ther 2023; 6. Kearney M, et al. ISPOR 2023; 7. Geynisman DM, et al. Urol Oncol 2022; 8. Bilen M, et al. Oncologist 2023; 9. Kearney M, et al. ASCO GU 2023; 10. Kearney M, et al. Future Oncol 2024.

Still too few Patients are Receiving Systemic Treatment for mUC¹



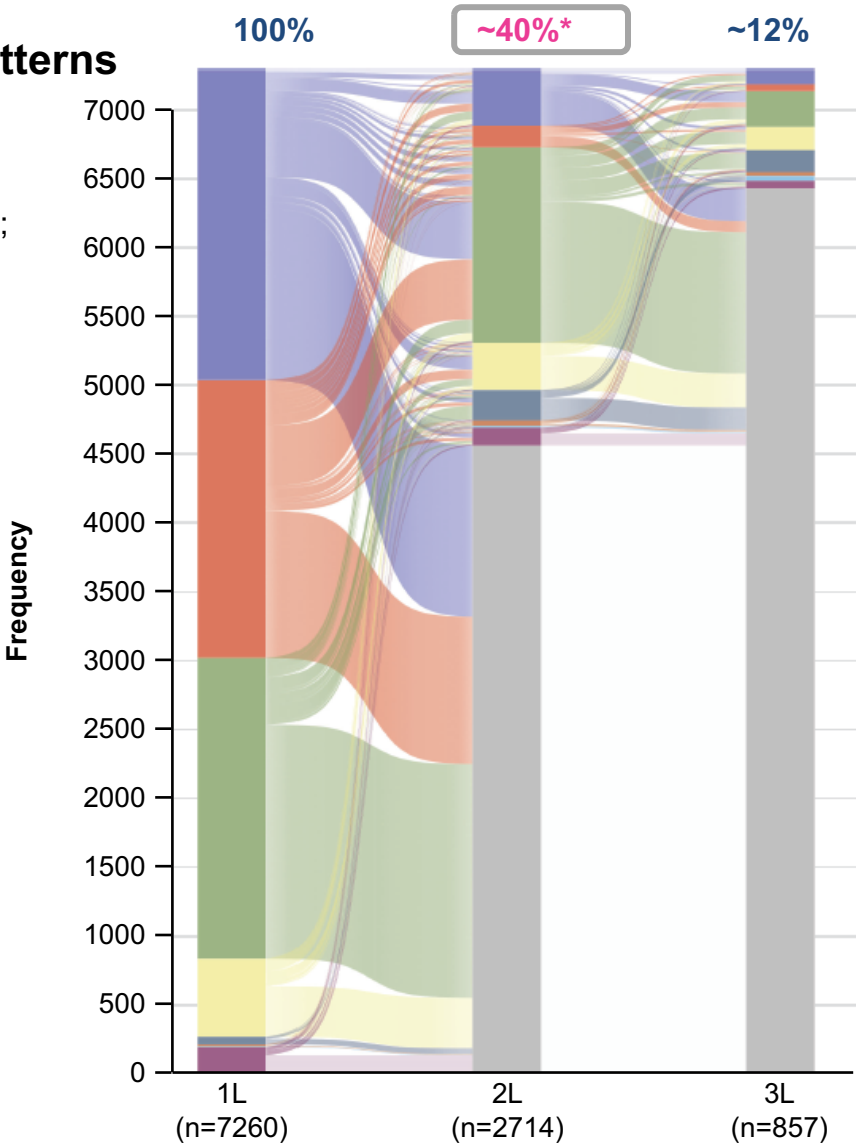
1L: first line; 2L: second line; IO: immunotherapy; mUC: metastatic urothelial carcinoma

1. Kearney M et al., Fut Oncol 2023; 2. Bilen M, et al., The Oncologist, 2023, 28, 790–798. Advance access publication 11 July 2023; 3. Morgans AK et al., Ann Oncol 2021; 4. Jensen JB et al., Ann Oncol 2021

Proportion of Treatment Across Therapy Lines: Historically high attrition rates

Treatment patterns across lines of therapy¹

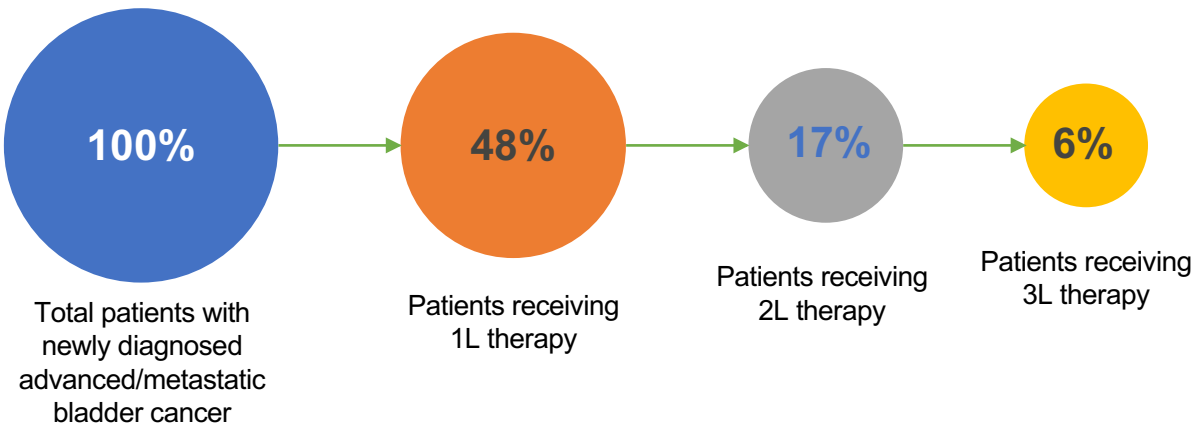
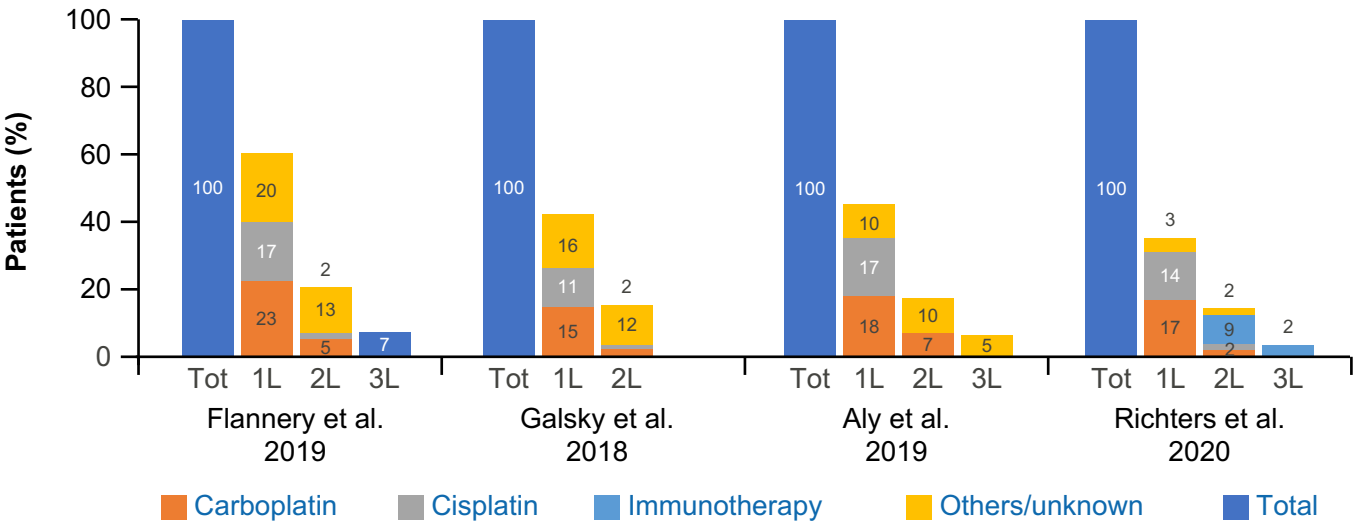
(US study; n=7260;
2011–2023)



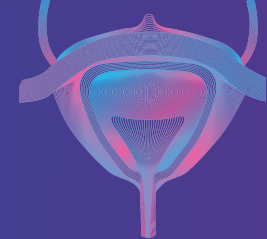
*37.4% of patients received 2L treatment (2714 out of 7260 patients).
1L, first-line; 2L, second-line; 3L, third-line; IO, immunotherapy; RW, real-world; Tot, total.

RW rate of systemic therapies and attrition rates²

(Five RW studies from the US and Netherlands with study periods between 2004 and 2017)



1. Thomas WM, et al. JAMA Network Open 2024;7:e249417; 2. Swami U, et al. Cancer Treat Res Commun 2021;27:100325.



Several factors may be relevant when personalizing 1L treatment for patients with advanced UC¹⁻¹⁰

Efficacy and safety of 1L treatment options

- OS
- PFS
- Response rates
- Treatment-related AEs
- PROs and quality of life

Disease characteristics

- Higher or lower tumor burden
- Visceral or nonvisceral metastases

Patient characteristics

- Fit or frail
- Clinically relevant comorbidities
- Eligible or ineligible for cisplatin and/or carboplatin

Patient or physician preferences

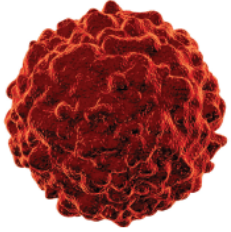
- Preference to avoid toxicity and maintain quality of life
- Preference to maximize efficacy
- Preference for a 1L treatment option that retains the possibility of 2L options with demonstrated efficacy

1L, first line; AE, adverse event; OS, overall survival; PFS, progression-free survival; PRO, patient-reported outcome; UC, urothelial carcinoma.

1. Powles T, et al. Ann Oncol. 2024;35(6):485-90; 2. Cathomas R, et al. Eur Urol. 2021;81:95-103; 3. Benjamin DJ, et al. Nat Rev Urol. 2023;20:513-14; 4. Vuky J, et al. J Clin Oncol. 2020;38(23):2658-66; 5. Balar AV, et al. Lancet. 2017;389(10064):67-76; 6. Nassar AH, et al. Br J Cancer. 2020;122(4):555-63; 7. Hemenway G, et al. Am Soc Clin Oncol Educ Book. 2024;44(3):e432054; 8. Brown JR, et al. Eur Urol Focus. Published online May 5, 2024; 9. Vogl UM, et al. Eur Urol Focus. Published online April 5, 2024; 10. Benjamin DJ, et al. Eur Urol Oncol. 2024;7(3):313-15.

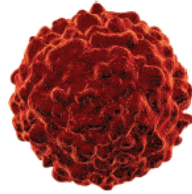


Long-term follow-up of the JAVELIN Bladder 100 trial continues to show prolonged OS with avelumab 1L maintenance^{1,2}



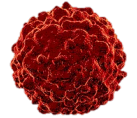
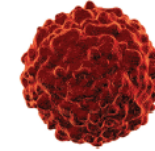
Chemotherapy

Decrease the tumor burden to achieve disease control and increase the immunogenicity of the tumor microenvironment¹⁶⁻²²



Avelumab

Immunotherapy is more effective in patients with reduced tumor burden and a high mutational burden like UC¹⁶⁻²²

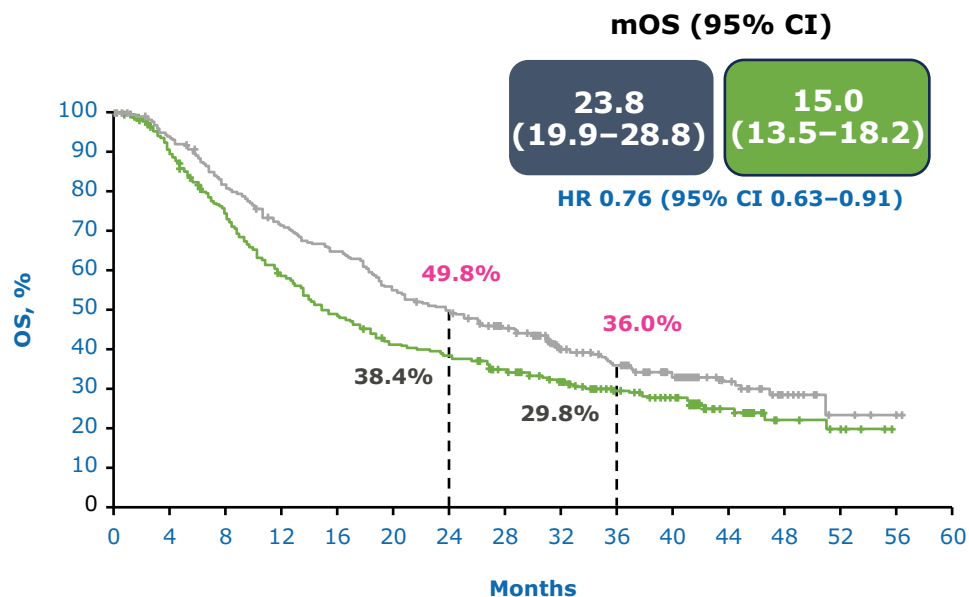


The cytotoxic and immunogenic effects of platinum-based chemotherapy provide the opportunity to enhance clinical efficacy with ICI maintenance therapy¹⁶



Long-term follow-up of the JAVELIN Bladder 100 trial continues to show prolonged OS with avelumab 1L maintenance^{1,2}

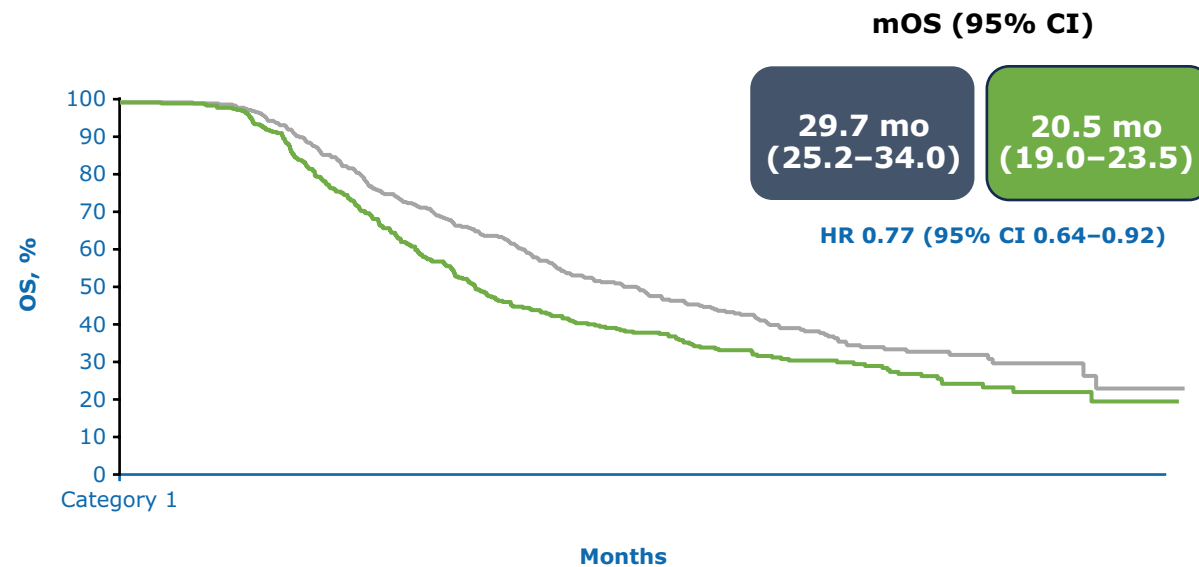
OS from start of randomization* (primary endpoint)



No. at risk

Avelumab + BSC	350	318	274	237	216	183	164	140	99	74	53	31	13	4	1	0
BSC alone	350	304	243	190	158	131	121	103	82	62	46	27	10	7	0	

Exploratory *post hoc* analysis of OS from the start of 1L PBC (in patients without PD after PBC)⁺³



No. at risk

Avelumab + BSC	350	350	334	288	247	220	191	171	145	114	86	58	36	17	7
BSC alone	350	349	317	255	207	168	141	125	111	89	68	54	33	12	8

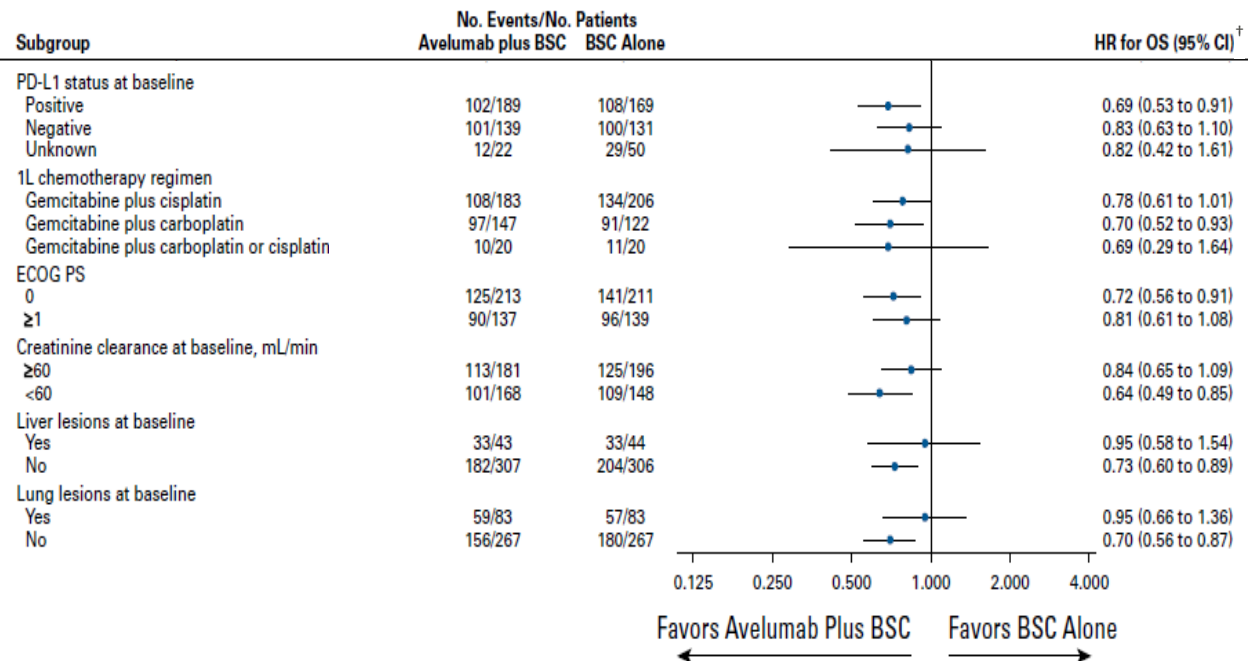
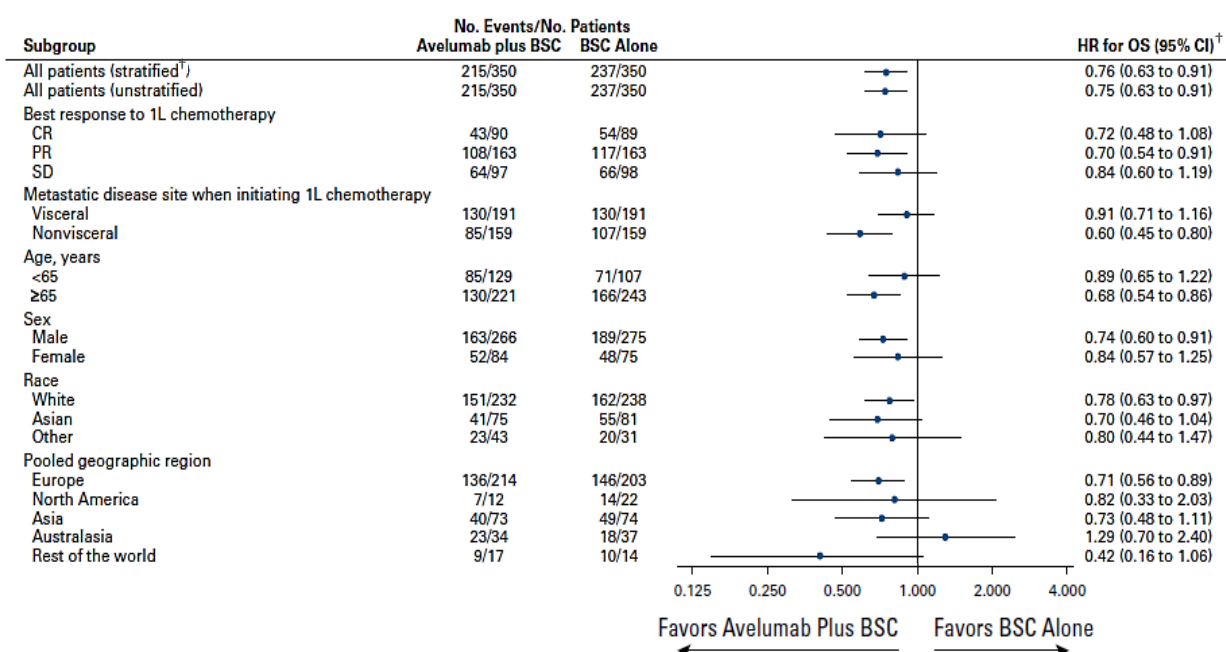
*Data cut-off: June 4, 2021. Median follow-up was 38.0 months with avelumab + BSC and 39.6 months with BSC alone (≥ 2 years in all patients); ⁺In select patients treated with avelumab 1L maintenance following no PD on 1L PBC. Median follow-up of ≥ 38 months. OS data calculated from the start of 1L CT is inclusive of 4–6 cycles of platinum-containing CT, 4–10 weeks of treatment-free interval, randomized study treatment with avelumab + BSC or BSC alone, and subsequent therapy. This is an exploratory, *post hoc* analysis of OS data calculated from the start of CT, and there are limitations to the interpretation of these data.

1L, first-line; Ave, avelumab; BSC, best supportive care; CI, confidence interval; CT, chemotherapy; HR, hazard ratio; (m)OS, (median) overall survival; PBC, platinum-based chemotherapy; PD, progressive disease.

1. Powles T, et al. N Engl J Med 2020;383:1218–1230; 2. Powles T, et al. J Clin Oncol 2023;41:3486–3492; 3. Grivas P, et al. ESMO Open 2023;8:6102050.



JAVELIN Bladder 100 long-term follow-up results show maintained OS benefit for avelumab + BSC vs BSC alone across



Results were maintained with ≥2-year follow-up data across all protocol-specified and prespecified subgroups¹

*At data cut-off (June 4, 2021), the median follow-up was 38.0 months and 39.6 months for avelumab + BSC vs BSC alone treatment arms, respectively; [†]HRs and CIs were calculated using a Cox proportional hazards model.

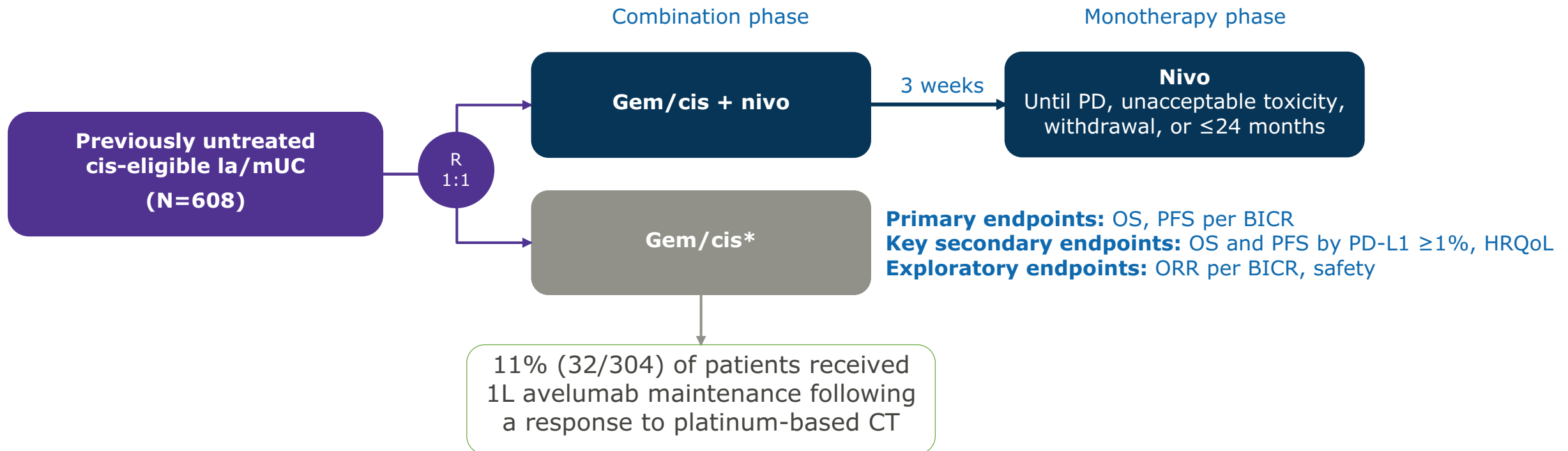
1L, first-line; BSC, best supportive care; CI, confidence interval; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; OS, overall survival; PD-L1, programmed death-ligand 1; PR, partial response; SD, stable disease.

1. Powles T, et al. J Clin Oncol 2023;41:3486–3492.



CheckMate 901 substudy: nivo + gem/cis vs gem/cis in la/mUC^{1,2}

Phase III, international, open-label, randomized trial to evaluate the efficacy and safety of nivo plus gem/cis vs gem/cis for previously untreated unresectable UC or mUC



*Patients who discontinued cisplatin could be switched to gem + carboplatin for the remainder of the platinum doublet cycles (≤6 total).
1L, first-line; BICR, blinded independent central review; cis, cisplatin; CT, chemotherapy; gem, gemcitabine; HRQoL, health-related quality of life;
la/mUC, locally advanced/metastatic urothelial carcinoma; nivo, nivolumab; ORR, overall response rate; OS, overall survival; PD, progressive disease;
PD-L1, programmed cell death protein-ligand 1; PFS, progression-free survival; R, randomization; UC, urothelial carcinoma.
1. Van der Heijden MS, et al. ESMO 2023 (Abstract No. LBA7 – presentation); 2. Van der Heijden MS, et al. N Engl J Med 2023;389:1778–1789.

ORIGINAL ARTICLE

Nivolumab plus Gemcitabine–Cisplatin
in Advanced Urothelial Carcinoma

Table 2. Objective and Best Overall Responses and Time to Response.*

Variable	Nivolumab plus Gemcitabine–Cisplatin (N = 304)	Gemcitabine–Cisplatin Alone (N = 304)
Objective response — % (95% CI)	57.6 (51.8–63.2)	43.1 (37.5–48.9)
Confirmed best overall response — no. (%)		
Complete response	66 (21.7)	36 (11.8)
Partial response	109 (35.9)	95 (31.2)
Stable disease	77 (25.3)	86 (28.3)
Progressive disease	29 (9.5)	39 (12.8)
Unevaluable	23 (7.6)	48 (15.8)

Of the patients enrolled into Nivo +
Gem-Cis or Gem-Cis

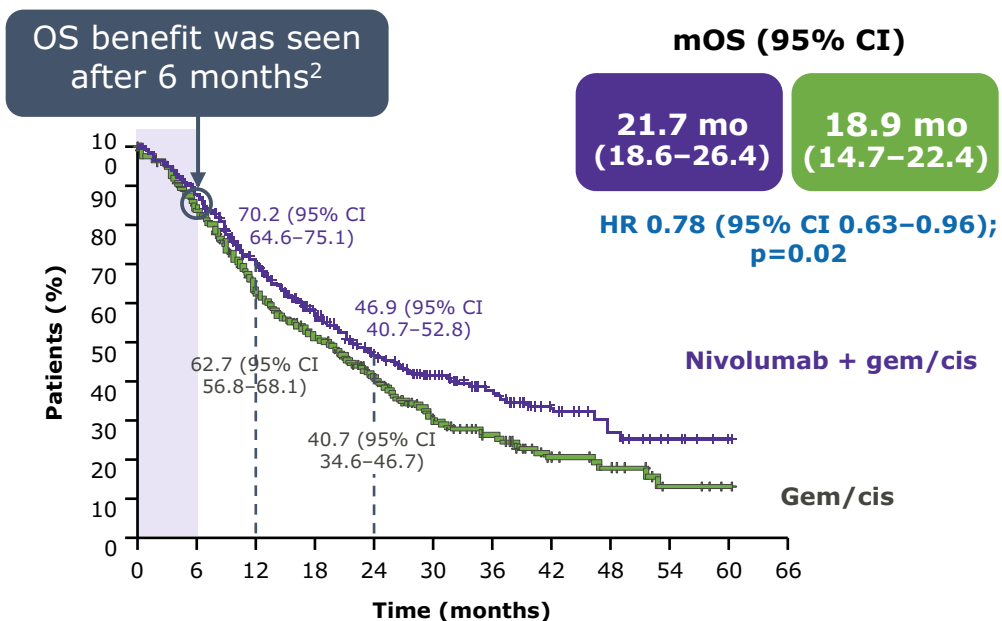
~10% patients have PD

Is there a benefit of upfront IO addition ???



CheckMate 901 substudy: OS, PFS, and TRAE outcomes – overall population¹

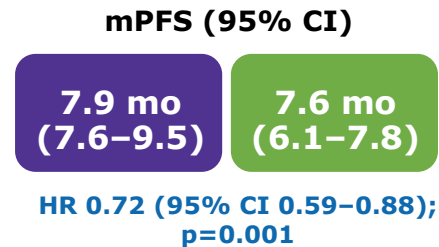
OS



No. at risk

Nivolumab + gem/cis	304	264	196	142	97	69	48	25	15	7	2	0
Gem/cis	304	242	166	122	82	49	33	17	13	4	1	0

PFS by BICR



Nivolumab + gem/cis was associated with improved OS (+2.8 months) and PFS (+0.3 months) vs gem/cis

*One grade 5 event occurred in each group (sepsis in the nivolumab plus gemcitabine–cisplatin group and acute kidney injury in the gemcitabine–cisplatin group).

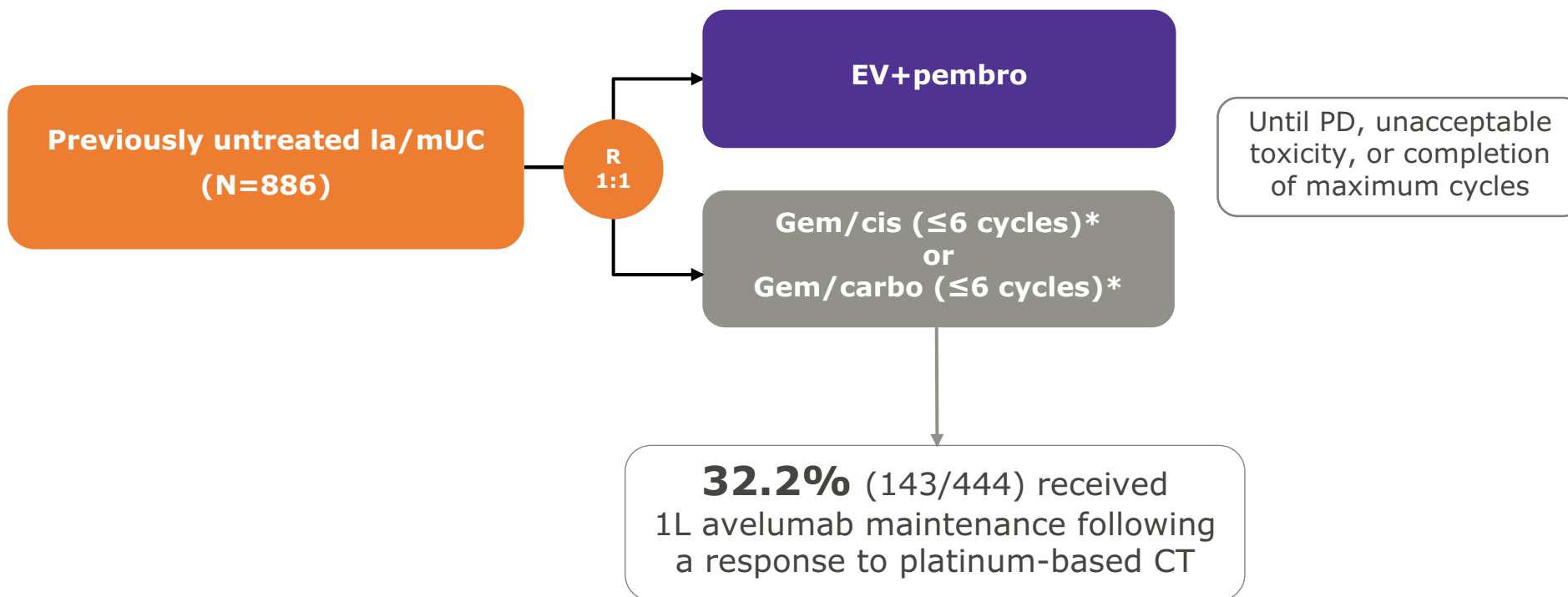
AE, adverse event; BICR, blinded independent central review; CI, confidence interval; cis, cisplatin; gem, gemcitabine; HR, hazard ratio; mo, months; (m)OS, (median) overall survival; (m)PFS, (median) progression-free survival; TRAE, treatment-related adverse event.

1. Van der Heijden MS, et al. N Engl J Med 2023;389:1778–1789; 2. Dr Birtle. Personal opinion/experience.



EV-302: EV+pembro vs PBC in la/mUC^{1,2}

A Phase III open-label study of EV+pembro in untreated la/mUC^{1,2}



Dual primary endpoints

- PFS by BICR; OS

Key secondary endpoints

- ORR per RECIST v1.1 by BICR and investigator assessment
- Safety

*Maintenance therapy could be used following completion or discontinuation of platinum-containing therapy – this amendment to the protocol was made late in the enrollment period.

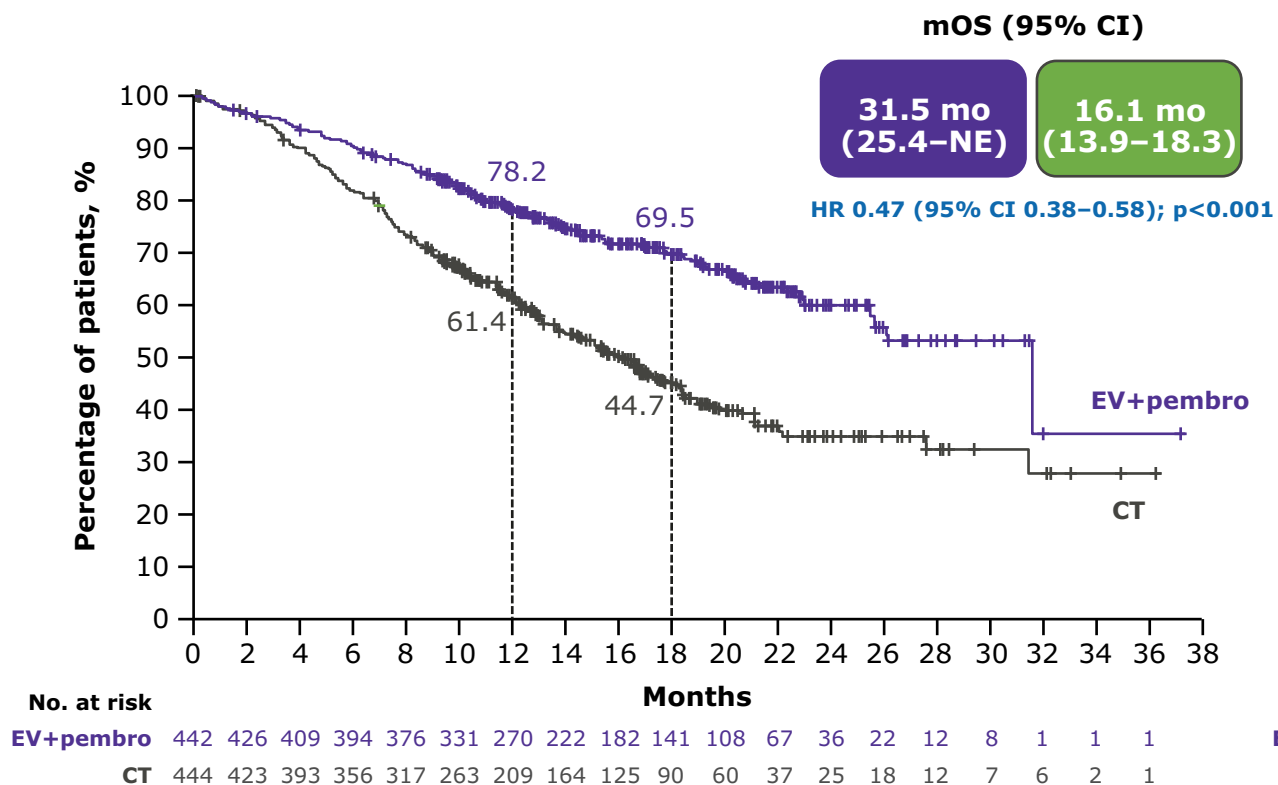
1L, first-line; 2L, second-line; BICR, blinded independent central review; carbo, carboplatin; cis, cisplatin; CT, chemotherapy; EV, enfortumab vedotin; gem, gemcitabine; la/mUC, locally advanced/metastatic urothelial carcinoma; ORR, overall response rate; OS, overall survival; PBC, platinum-based chemotherapy; PD, progressive disease; pembro, pembrolizumab; PFS, progression-free survival; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors.

1. Powles T, et al. ESMO 2023 (Abstract No. LBA6 – presentation); 2. Powles T, et al. N Engl J Med 2024;390:875–888;

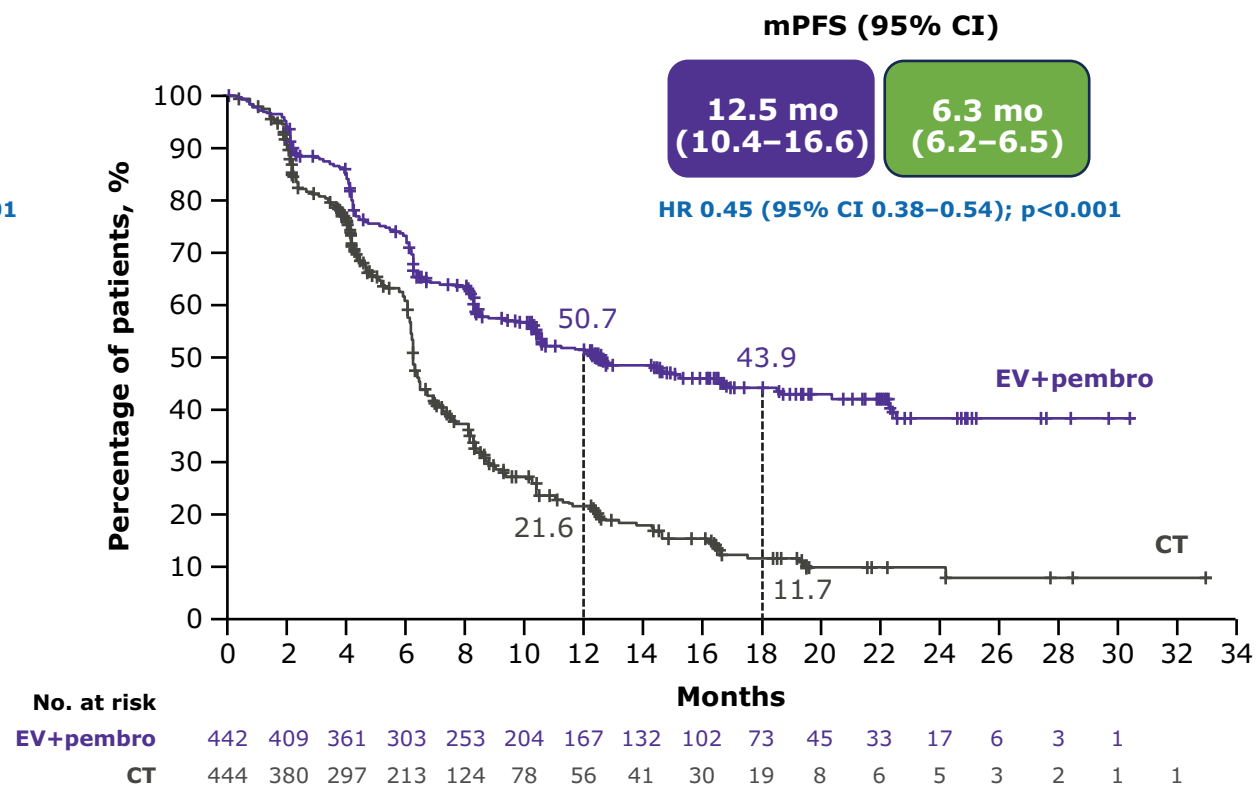


EV-302: OS and PFS outcomes¹

OS*†1



PFS by BICR^{†1}



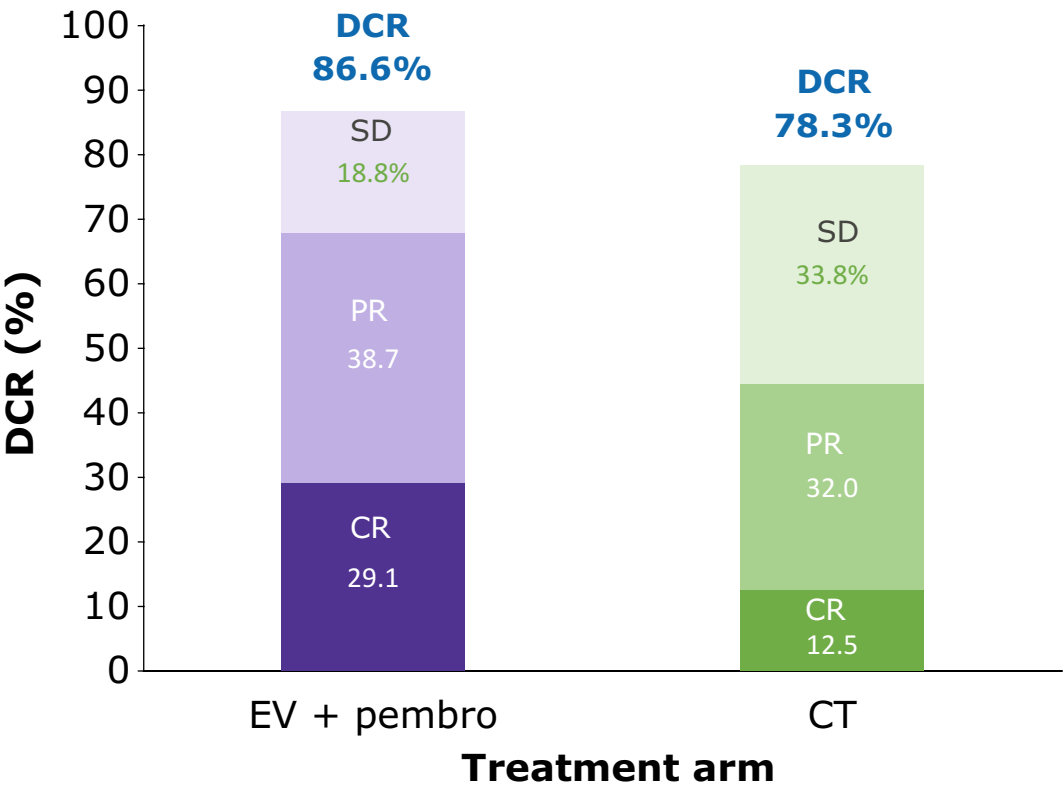
EV+pembro vs CT demonstrated increased OS and PFS outcomes

*Median follow-up: 17.2 months; †Data cut-off: August 8, 2023.

BICR, blinded independent central review; CI, confidence interval; CT, chemotherapy; EV, enfortumab vedotin; HR, hazard ratio; mo, months; NE, not estimable; (m)OS, (median) overall survival; pembro, pembrolizumab; (m)PFS, (median) progression-free survival.

1. Powles T, et al. N Engl J Med 2024;390:875–888.

EV-302: response rates¹



	EV+pembro (n=437)	CT (n=441)
Confirmed overall response,* % (95% CI)	67.7 (63.1–72.1)	44.4 (39.7–49.2)
p value	<0.001	
Confirmed best overall response, n (%)		
CR	127 (29.1)	55 (12.5)
PR	169 (38.7)	141 (32.0)
SD	82 (18.8)	149 (33.8)
PD	38 (8.7)	60 (13.6)
Could not be evaluated [†]	0	4 (0.9)
No assessment [‡]	21 (4.8)	32 (7.3)
mDoR,* months (95% CI)	NR (20.2–NE)	7.0 (6.2–10.2)
Median time to response, months (range)	2.1 (1.3–12.3)	2.1 (1.6–8.3)



DCR rate: EV+pembro vs CT, 86.6% vs 78.3%

*Overall response and DoR, as assessed by blinded independent central review according to the RECIST v1.1, were evaluated in all the patients in the ITT population who had measurable disease at baseline according to RECIST v1.1; [†]Patients had a post-baseline assessment of response, but the best overall response could not be evaluated according to RECIST v1.1; [‡]Patients had no post-baseline assessment of response.
CI, confidence interval; CR, complete response; CT, chemotherapy; DCR, disease control rate; EV, enfortumab vedotin; ITT, intention-to-treat; (m)DoR, (median) duration of response; NE, not evaluable; NR, not reported; PD, progressive disease; Pembro, pembrolizumab; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.
1. Powles T, et al. N Engl J Med 2024;390:875–888.



EV-302: PROs show no observed detriment in overall QoL in either arm^{1,2}

Time to pain progression

**No statistically significant
difference between
EV+pembro vs CT**

HR 0.92
(95% CI 0.72–1.20)

Change in worst pain (BPI-SF)

**Predefined clinically
meaningful thresholds were
not met in either arm**

Numerically greater
improvements in
EV+pembro vs CT arm

Change in worst pain and HRQoL in patients with moderate-to-severe pain (BPI-SF and EORTC QLQ-C30)

**Clinically meaningful
improvements in both arms**

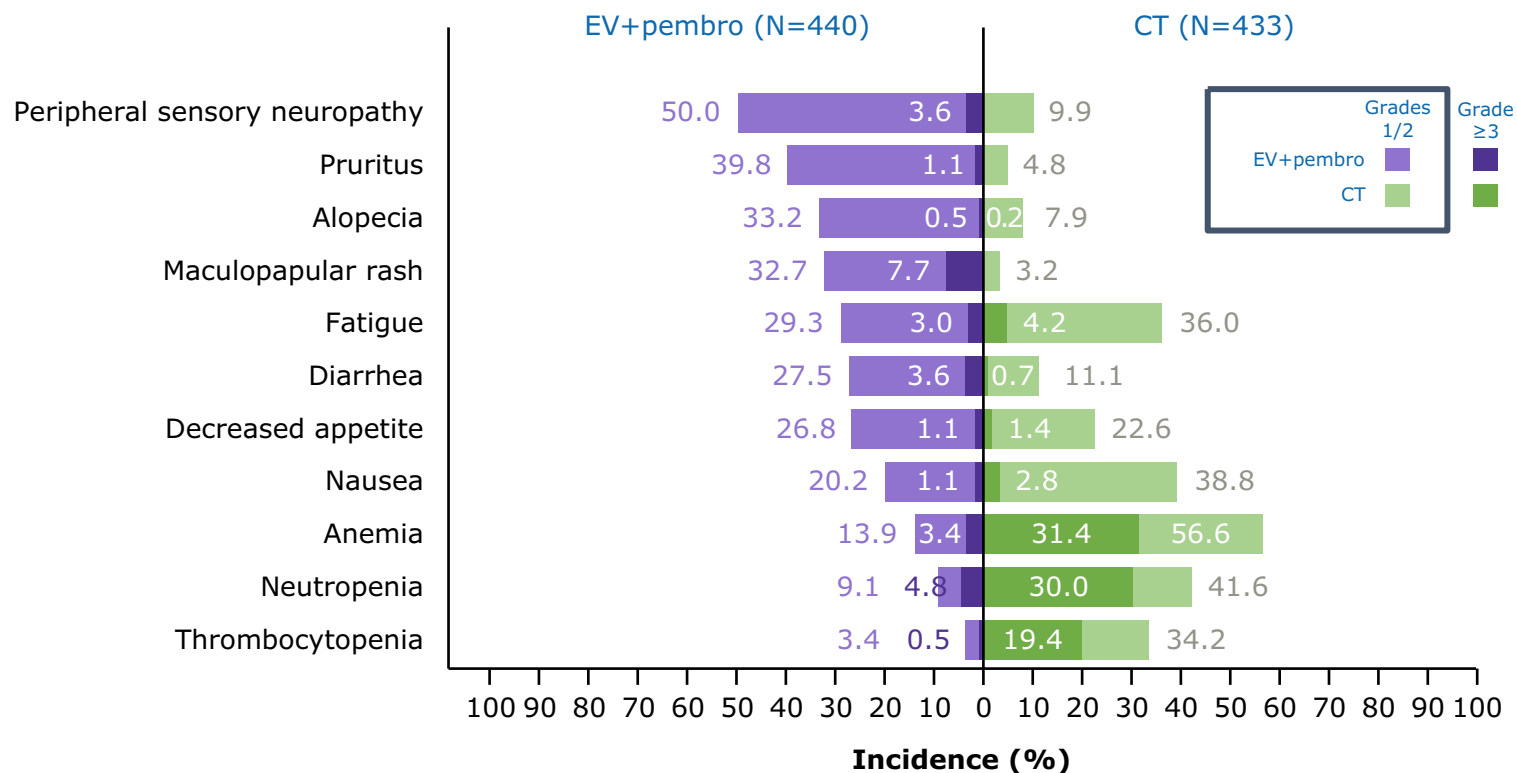
Numerically greater
improvements in
EV+pembro vs CT arm



- **More research is needed to assess PRO endpoints further to include impact of EV+pembro treatment-related toxicities**

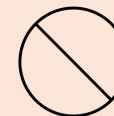


EV-302: safety outcomes – TRAEs^{1,2}



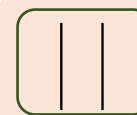
Patients with any grade AE

- EV+pembro: 427 (97%)
- CT: 414 (95.6%)



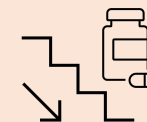
TRAEs leading to discontinuation

- EV+pembro: 154 (35%)
- CT: 80 (18.5%)



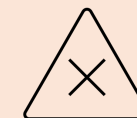
TRAEs leading to interruption

- EV+pembro: 299 (68%)
- CT: 229 (52.9%)



TRAEs leading to dose reduction

- EV+pembro: 179 (40.7%)
- CT: 164 (37.9%)



TRAEs leading to death

- EV+pembro: * 4
- CT: † 4



- Grade 1/2 events occurred more frequently with EV+pembro vs CT
- EV+pembro was associated with a high incidence of AEs, treatment interruption, dose reduction, and discontinuation

Data cut-off: August 8, 2023. TRAEs are any grade by preferred term in ≥20% of patients for any grade in either arm.

*Per investigator, and cause of EV+pembro deaths included asthenia, diarrhea, immune-mediated lung disease, multiple organ dysfunction syndrome. †Cause of CT deaths included febrile neutropenia, myocardial infarction, neutropenic sepsis, sepsis.

AE, adverse event; CT, chemotherapy; EV, enfortumab vedotin; pembro, pembrolizumab; TRAE, treatment-related adverse event.

1. Powles T, et al. ESMO 2023 (Abstract No. LBA6 – presidential symposium); 2. Powles T, et al. N Engl J Med 2024;390:875–888.



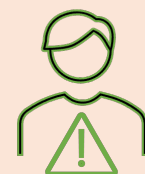
EV-302: safety outcomes – TRAEs of special interest*^{1,2}

TRAEs of special interest for EV, n (%)	EV+pembro (n=440)		CT (n=433)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Skin reactions	294 (66.8)	68 (15.5)	60 (13.9)	1 (0.2)
Peripheral neuropathy	278 (63.2)	30 (6.8)	53 (12.2)	0
Ocular disorders	94 (21.4)	0	12 (2.8)	0
Hyperglycemia	57 (13.0)	27 (6.1)	3 (0.7)	0
Infusion-related reactions	9 (2.0)	0	9 (2.1)	0



TRAEs of special interest for pembro

- Severe skin reactions
 - Any grade, 17.0%
 - Grade ≥3, 11.8%



Serious TRAEs

- EV+pembro: 122 (27.7%)
- CT: 85 (19.6%)



- Skin reactions and peripheral neuropathy were the most common TRAE of special interest with EV
- A higher rate of serious TRAEs was observed with EV+pembro vs CT

*There are differences in the rates of skin reactions reported for EV treatment-related AESIs and pembro TEAEs of special interest because these adverse events were reported via different methodologies developed for EV and pembro monotherapies, respectively.
AESI, adverse events of special interest; CT, chemotherapy; EV, enfortumab vedotin; pembro, pembrolizumab; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

1. Powles T, et al. ESMO 2023 (Abstract No. LBA6 – presidential symposium); 2. Powles T, et al. N Engl J Med 2024;390:875–888.



Future perspectives: Biomarker development^{1–6}

Biomarkers predictive of response are under investigation
to individualize treatment for each patient with la/mUC



FGFR3

Erdafitinib



HER2/3

**Trastuzumab
deruxtecan
(US only) and
disitamab vedotin**



TROP-2

**Sacituzumab
govitecan**



NECTIN-4

**Enfortumab
vedotin**

ADC, antibody drug conjugate; FGFR, fibroblast growth factor receptor; HER2/3, receptor tyrosine-protein kinase erbB-2/3; la/mUC, locally advanced metastatic urothelial carcinoma; TROP2, trophoblast cell surface antigen 2.
1. Dr Grande, personal opinion; 2. Witjes J, et al. European Association of Urology Guidelines on Metastatic Urothelial Carcinoma. 2024. Available at: <https://uroweb.org/guidelines/muscle-invasive-and-metastatic-bladder-cancer> (last accessed September 2024); 3. Meric-Bernstam F, et al. ASCO 2023 (Abstract No. LBA3000 – presentation); 4. Klümper N, et al. J Clin Oncol 2024;42:2446–2455; 5. Vranic S and Gatalica Z, Bosn J Basic Med Sci 2022;22:14–21; 6. The FDA has granted a priority review designation to a supplemental Biologics License Application (sBLA) for trastuzumab deruxtecan (Enhertu) for the treatment of adult patients with unresectable or metastatic HER2-positive solid tumors—including bladder cancer—who have received prior treatment or who have no satisfactory alternative treatment options. Available at: <https://www.urologytimes.com/view/fda-fast-tracks-trastuzumab-deruxtecan-for-her2-tumors-including-bladder-cancer> (last accessed September 2024).



1L treatment choices should be based on discussions between HCP and the patient, as well as family/caregivers



Treatment attributes

- Efficacy
- Safety/toxicity
- Effects on QoL
- Treatment regimen (number/frequency of infusions)



Patient characteristics

- Ineligibility criteria
- Comorbidities
- Frailty
- Patient priorities
- Social factors (e.g. caregiver support, urban/rural location)



Disease characteristics

- Site of metastases
- High/low tumour burden
- Biomarkers
- Histology
- Treatment for earlier disease stages



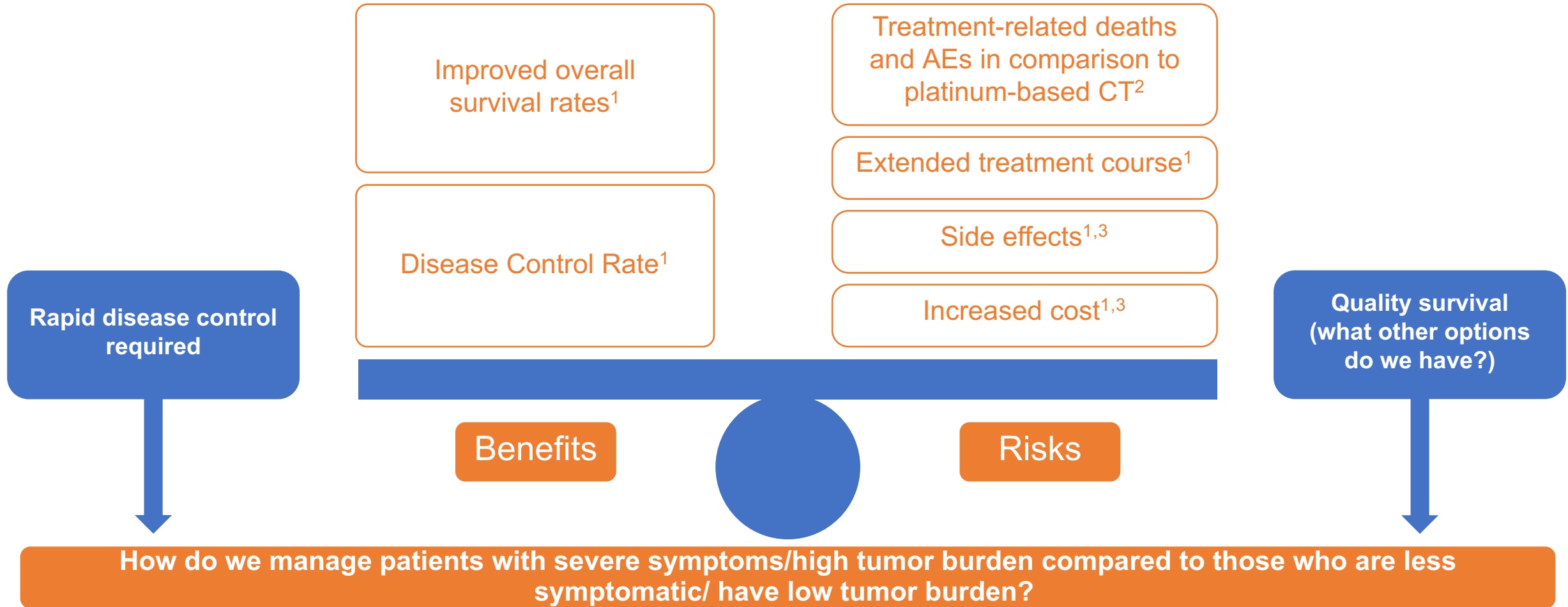
Access & cost

- Regulatory approval
- Local reimbursement
- Healthcare and/or personal costs





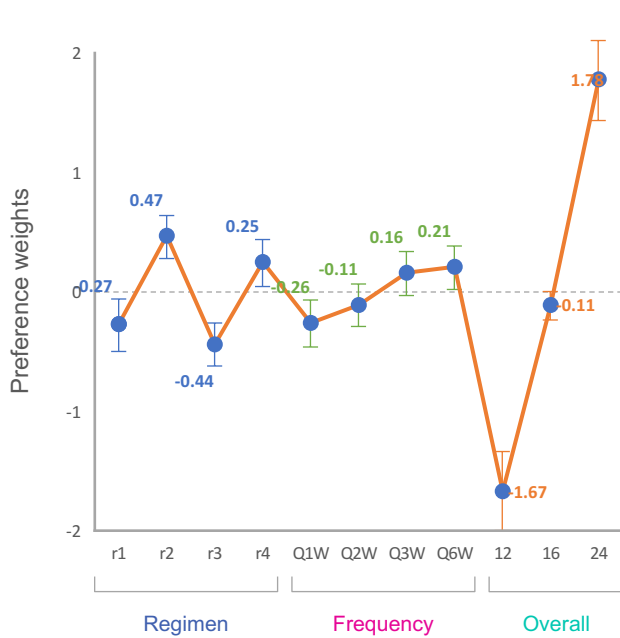
Balancing risks and benefits



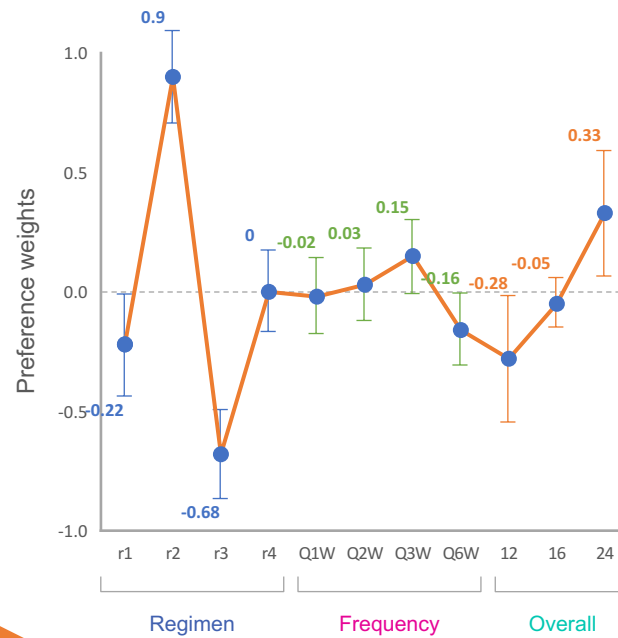
HCP treatment goals are driven by OS whilst patients prioritize their treatment experience¹

Distinct preference between oncologists and patients when considering 1L treatment options for aUC¹

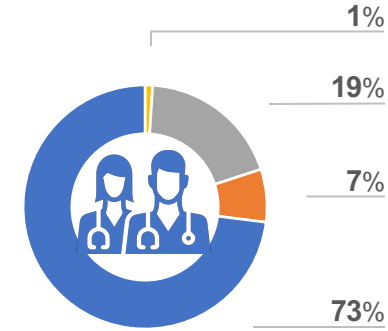
Oncologists' preference weights



Patients' preference weights

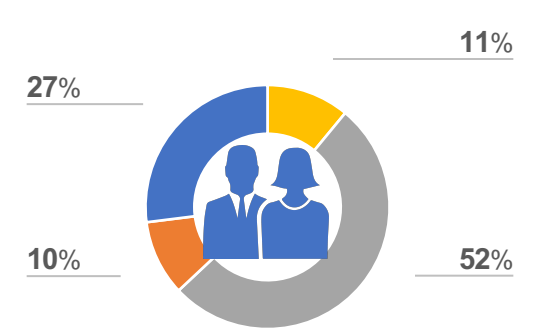


Oncologists' preference shares



- **Oncologists** had strong preference for treatments that improve **overall survival**

Patients' preference shares



- **Patients** preferred a **better treatment experience**, with lower TRAEs and lower medication frequencies

- One medication taken for 4 months with moderate grade 3–4 TRAE, 12 months of survival, Q1W.
- One medication until disease progression or unacceptable toxicity with low grade 3–4 TRAE, 16 months of survival, Q3W.
- Two medications for 4 months then one medication until disease progression or unacceptable toxicity with high then low grade 3–4 TRAE, 16 months of survival, Q1W and Q3W.
- One medication for 4 months then one medication until disease progression or unacceptable toxicity with moderate then low grade 3–4 TRAE, 24 months of survival, Q1W and Q2W.



R1: One medication taken for 4 months with moderate grade 3/4 TRAEs; r2: One medication until disease progression or unacceptable toxicity with low grade 3/4 TRAEs; r3: Two medications for 4 months then one medication until disease progression or unacceptable toxicity with high then low grade 3/4 TRAEs; r4: One medication for 4 months then one medication until disease progression or unacceptable toxicity with moderate then low grade 3/4 TRAEs.

1L: first-line; aUC: advanced urothelial carcinoma (includes locally advanced or metastatic UC); HCP: healthcare professional; OS: overall survival; Q#W: every # weeks; r=regimen; TRAE: treatment-related adverse event.

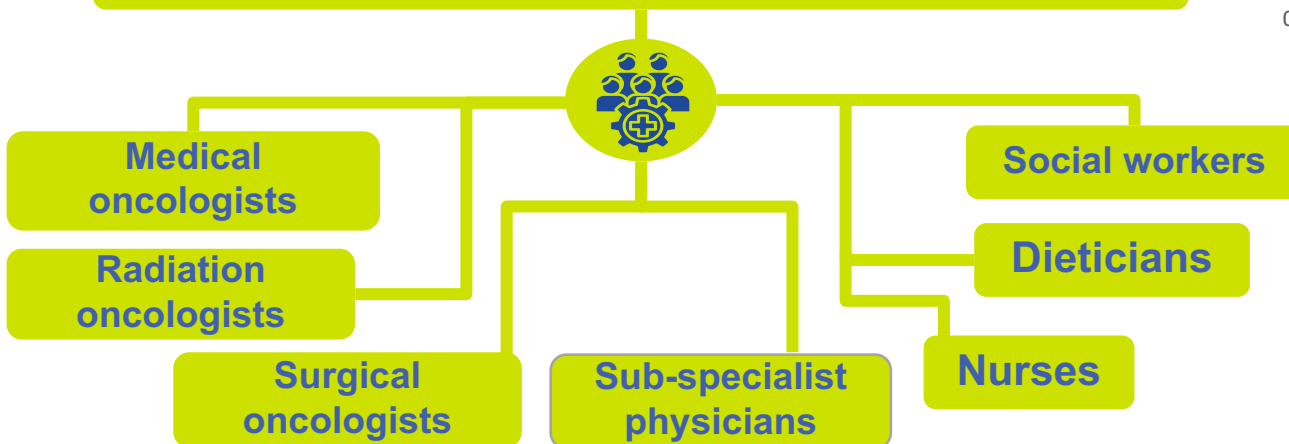
Managing AEs: Multidisciplinary Team (MDT) Approach

MDTs can facilitate comprehensive treatment planning, ensuring that patients receive optimal, individualized care

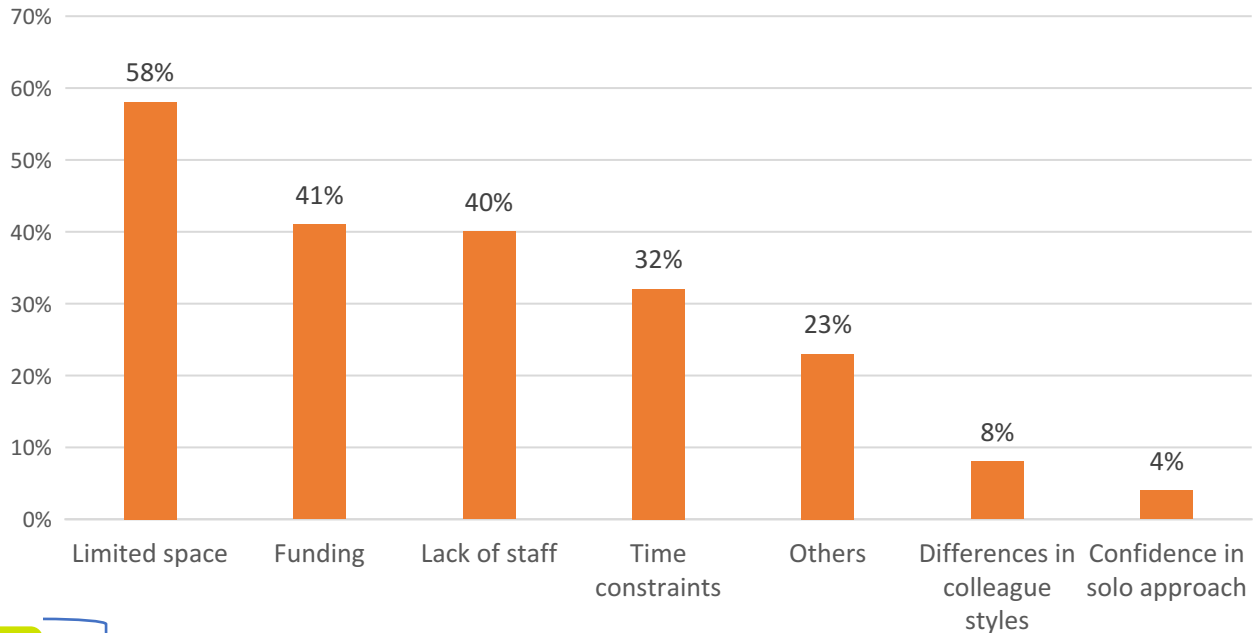
Patients discussed in MDT meetings are more likely to receive curative treatments

- Changes in diagnosis in 23% and changes in treatment in 44% of BC patients¹
- Treatment with curative intent was more often given to patients discussed in a MDTM compared to those not discussed
 - 67% vs 26%²

MDT approach is often required to manage AEs³



Perceived barriers to implementation of MDT include¹:



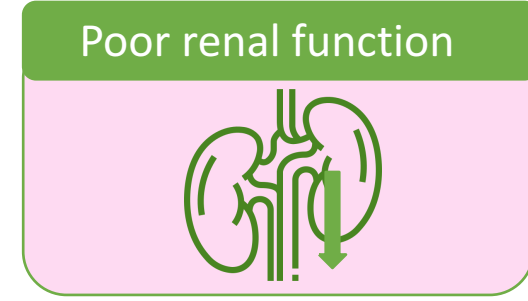
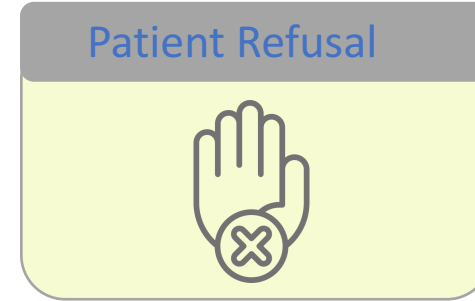
Lack of access to members of an MDT may impact selection and safe delivery of cancer therapies³:

e.g. management of skin toxicities from emerging cancer drugs without a dermatologist may negatively impact clinical care

Age and Other Criteria Influencing Non-Treatment of Patients with Locally Advanced or Metastatic Urothelial Carcinoma

Results of a Physician Survey in Five European Countries (France, Germany, Italy, Spain, UK) - ASCO 2024

- Most commonly reported factors influencing decisions on whether to treat a patient with 1L systemic treatment



The majority of physicians (78.1%) reported having an **age threshold for not offering systemic treatment**. The mean age threshold (**≈75 years**) is relatively low compared with the senior age profile of the la/mUC population

Physicians who reported using an explicit age threshold may be inappropriately excluding otherwise eligible patients from treatment; **this could be a driver of underutilization of systemic treatment in la/mUC, resulting in poor patient outcomes**

¡Gracias!

