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Comprehensive Cancer Center

Treatment Updates in Urothelial Cancer

Debates and Didactics in Hematology and Oncology

July 20, 2023
Sea Island, GA

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Disclosures

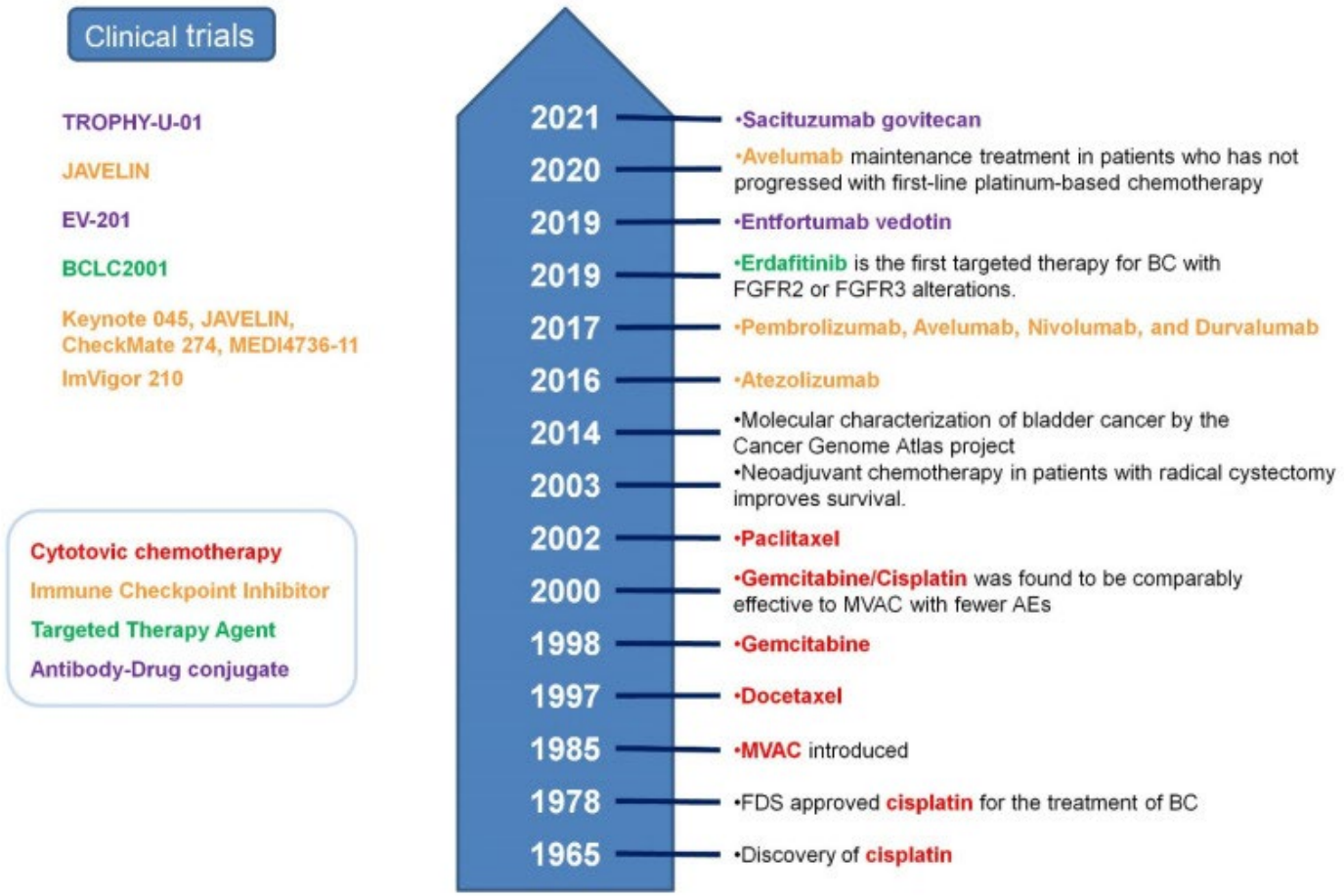
- Consultant:
  - Eisai
  - Bristol Myers-Squibb
  - Gilead

- Research funding to Institution:
  - Bristol Myers-Squibb
  - Immunomedics
  - AstraZeneca
  - Alkermes

Objectives

- Review of Treatment Landscape 2023
- Overview of Optimal and Novel Perioperative Approaches
- Recap Current Recommendations for Metastatic Setting
- Explore Promising Agents and Combinations In Advanced Urothelial Cancer

The Path From Cisplatin in Bladder Cancer



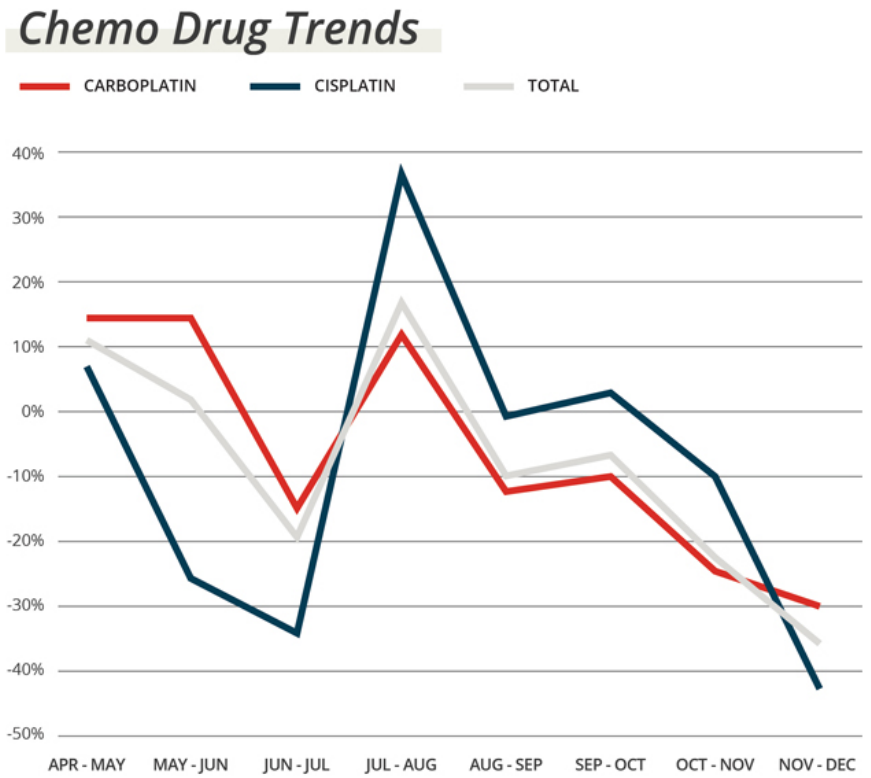
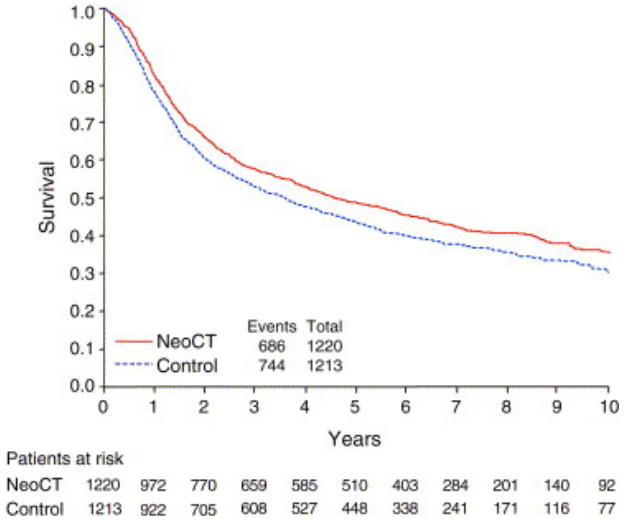


Figure 1: Drug availability in 2022. Permission granted to use graph data from Definitive Healthcare; Design: Nicole Bean, BioSpace.

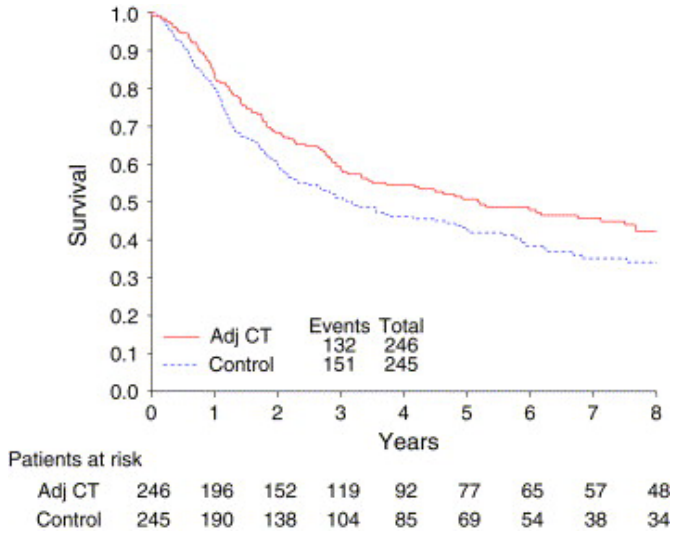
Rationale For Perioperative Chemotherapy For Muscle Invasive Bladder Cancer

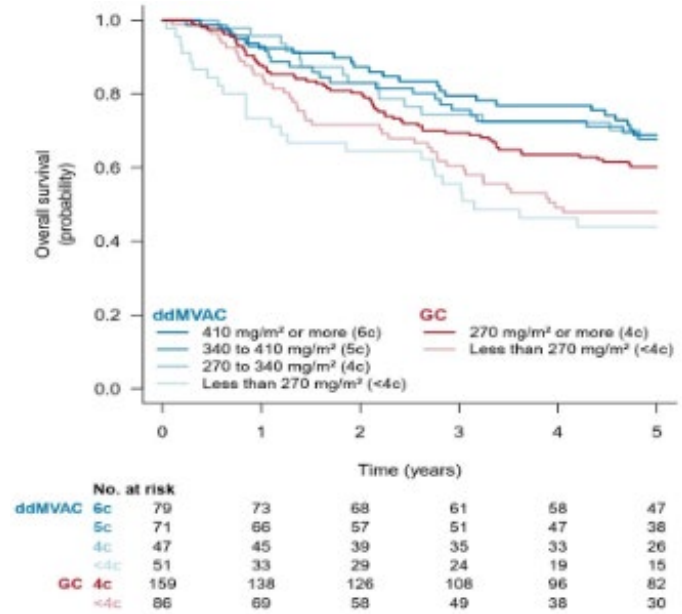
- Poor overall survival
- Few long-term survivors
- Treat occult micrometastases
- Improved survival
- ddMVAC > GC

Neoadjuvant



Adjuvant

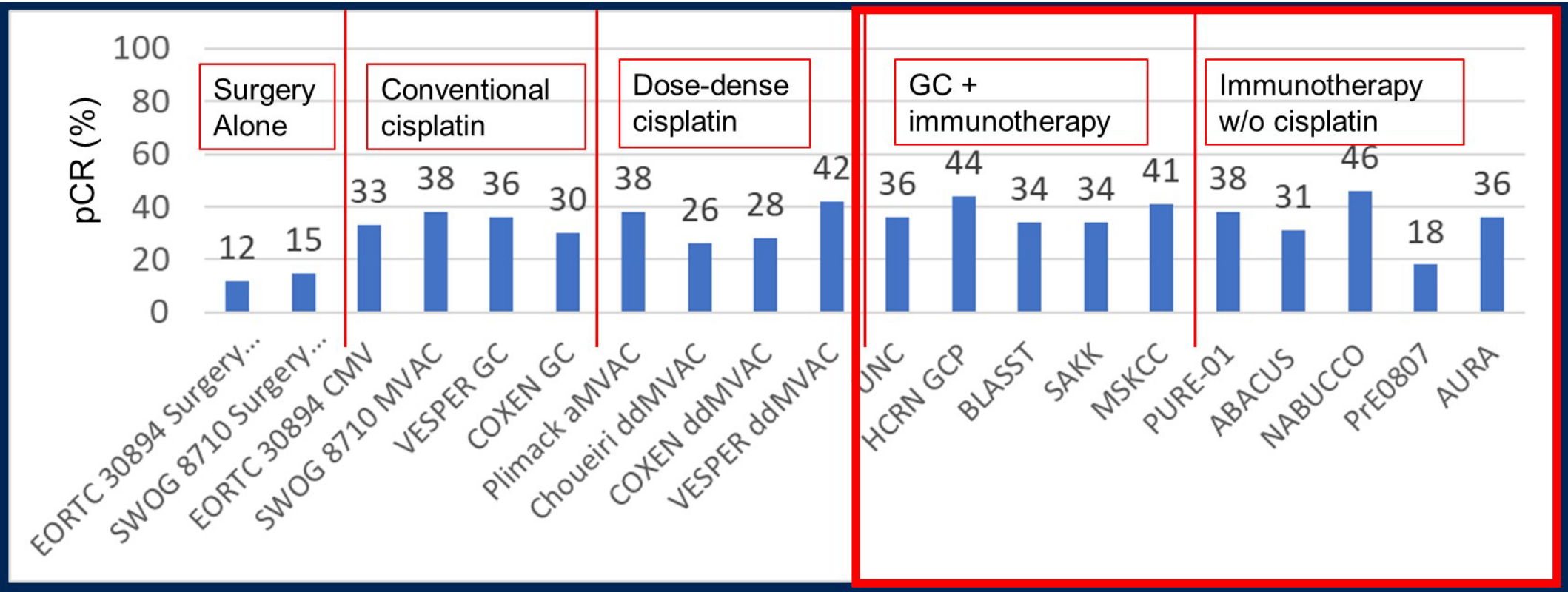




Vesper Trial 5 year Updates

Vale et al., Eur Urol 2005; 48:189-201; Vale et al., Eur Urol 2005; 48:202-206; Pfister et al ASCO 2023

Neoadjuvant Approach to Urothelial CA: Chemo, IO, or Both?



Grossman et al. NEJM 2003
Flaig et al, CCR 2021
Gupta et al, JCO 38,6_supp (Feb 2020).
Necchi et al, JCO 2018
Grivas et al, ASCO Annual Mtg 2021; abstr 4518

EORTC 30894, JCO 2011
Rose et al, GU ASCO 2021, abstr 396.
Cathomas et al, GU ASCO 2021, abstr 430.
Powles et al, Nat Med 2019
Kaimakliotis et al, ASCO Annual Mtg 2020;abstr 5019

Pfister et al, Euro Urol 2021
Hoimes et al, ESMO 2018, abstr 5681.
Funt et al, ASCO Annual Meeting, abstr 4517.
Van Dijk et al, ASCO Annual Mtg 2020;abstr 5020

Slide Courtesy Matt Milowsky, MD

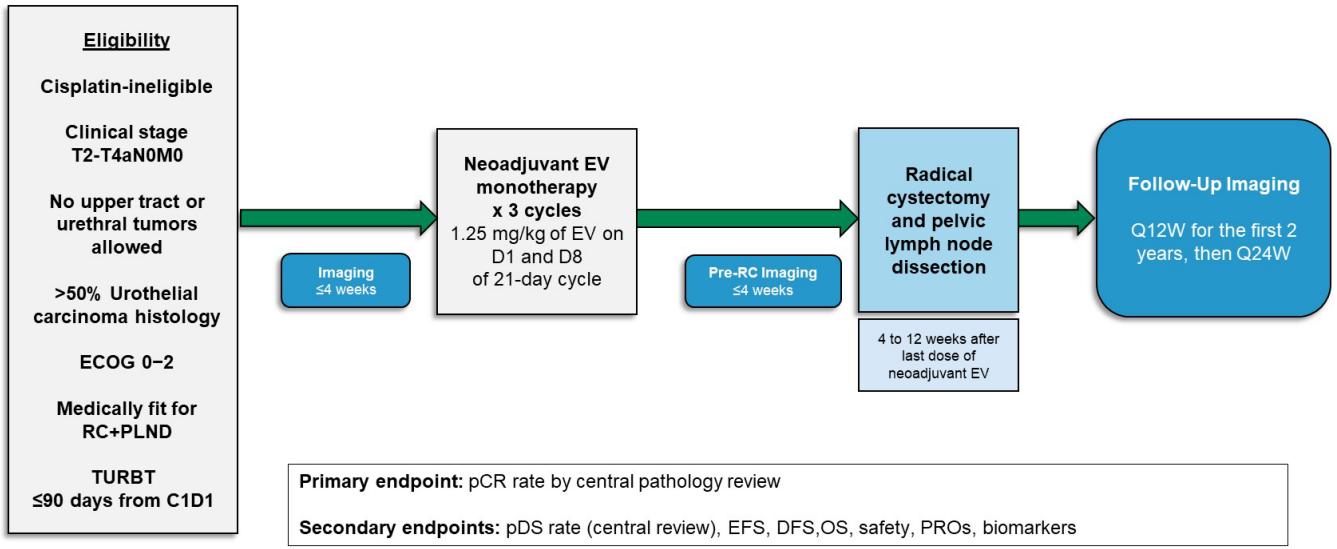
Ongoing Neoadjuvant Combination Trials in UC

	Clinical Trial	N	Treatment Arms
CISPLATIN ELIGIBLE	KEYNOTE-866	870	Pembro + GC vs GC
	KEYNOTE-B15/EV-304	784	Pembro +EV vs GC
	NIAGARA	1050	Durva+ GC vs GC
	ENERGIZE	1200	Nivo + GC vs GC ~~GC+ Nivo + Linrodostat~~
CISPLATIN-INELIGIBLE	KEYNOTE-905/ EV-303	836	RC vs Pembro+EV vs Pembro
	VOLGA	830	RC vs Druva/Tremi+EV vs Durva+EV
	SWOG GAP	196	Surgery vs Gem-Carbo+ Avelumab

Gupta, S. ASCO 2023; ClinicalTrials.gov

Study EV-103 Cohort H: Neoadjuvant EV in cisplatin-ineligible MIBC Patients

EV-103 Cohort H Study Design

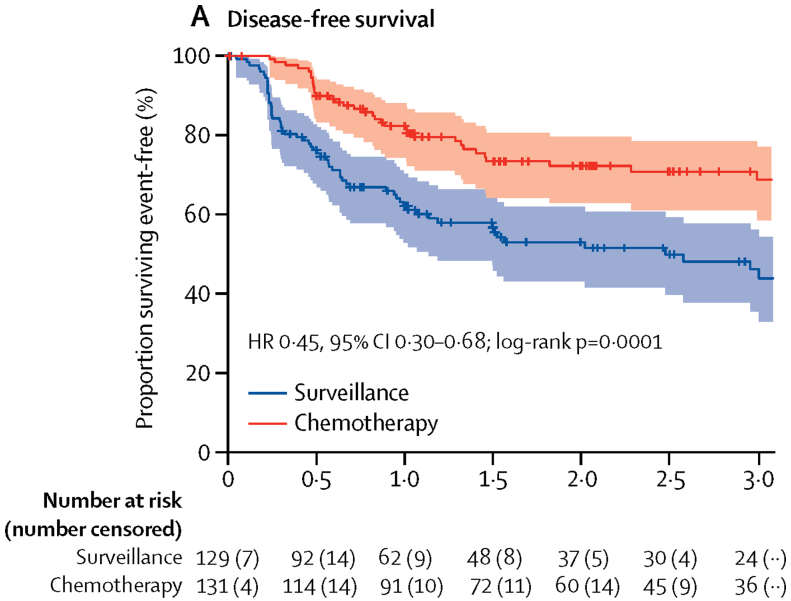


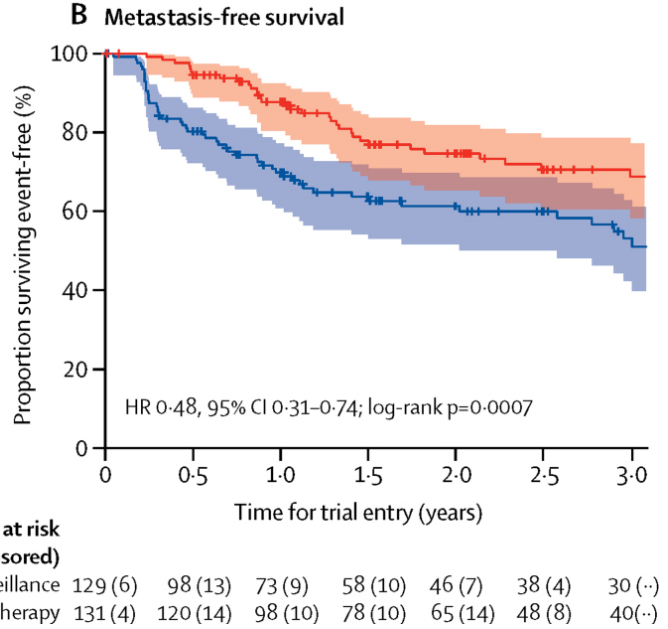
DFS: Disease-free survival; ECOG: Eastern Cooperative Oncology Group; EFS: Event-free survival; EV: Enfortumab vedotin; OS: Overall survival; pCR: pathological Complete Response rate; pDS: pathological Downstaging; RC+PLND: radical cystectomy + pelvic lymph node dissection; PROs: Patient-reported outcomes; TURBT: transurethral resection of bladder tumor

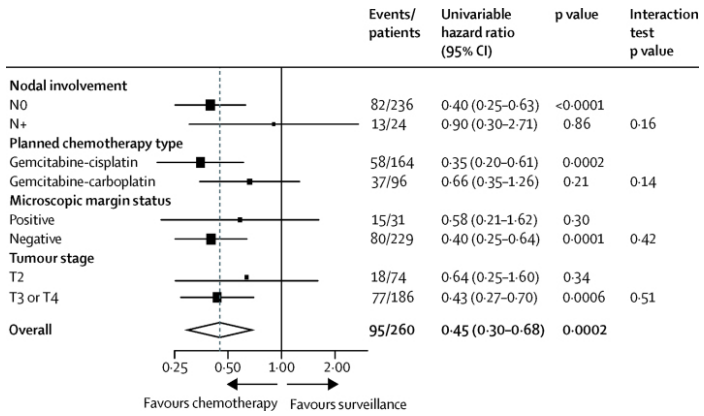
Pathological Response	Central Pathology Results (N=22) n (%) [95% Confidence Interval]
Pathological Complete Response Rate (defined as absence of any viable tumor tissue: ypT0 and N0)	**8 (36.4%)** [17.2–59.3]
Pathological Downstaging Rate (defined as presence of ypT0, ypTis, ypTa, ypT1, and N0)	**11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

Petrylak et al, GU ASCO 20222

Adjuvant Chemotherapy in UTUC: POUT Trial



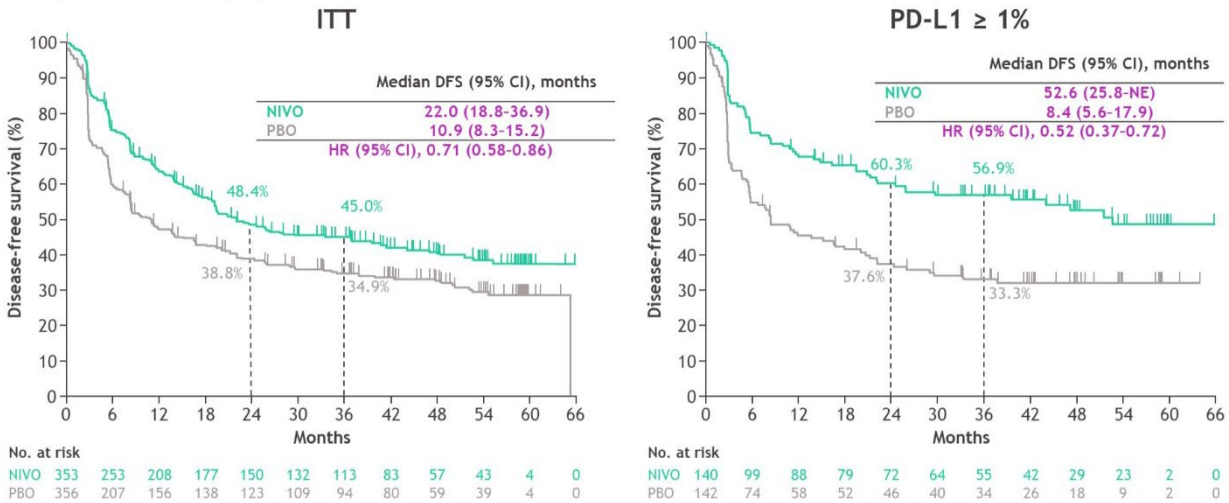




Birtle, et al. Lancet. 2020 Apr18; 395:1268-1277.

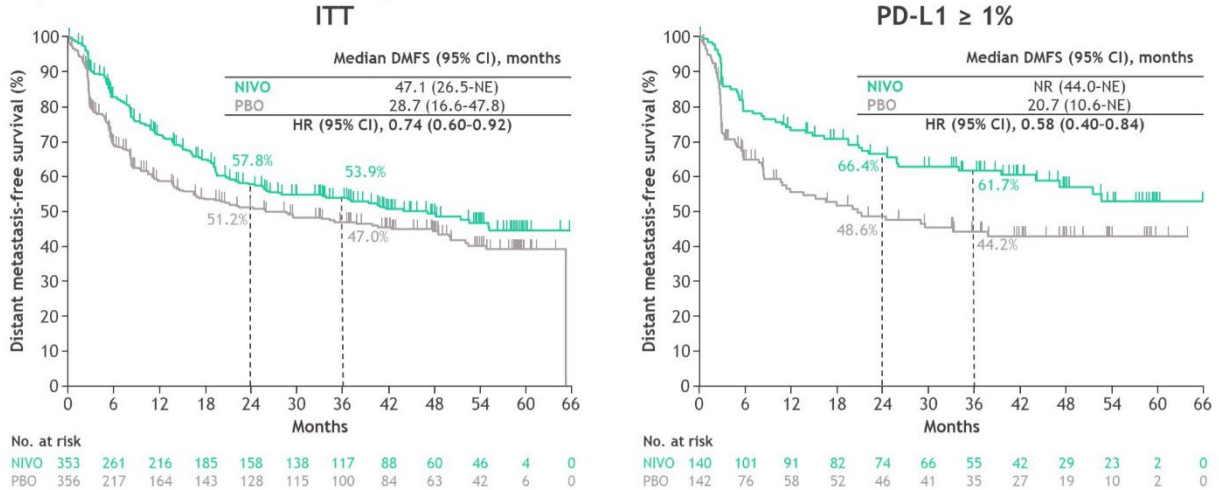
CheckMate 274 Adjuvant Nivolumab in MIBC

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



Minimum follow-up in the ITT population, 31.6 months. DFS was defined as the time between the date of randomization and the date of first recurrence (local urothelial tract, local non-urothelial tract or distant) or death.
NE, not estimable.

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



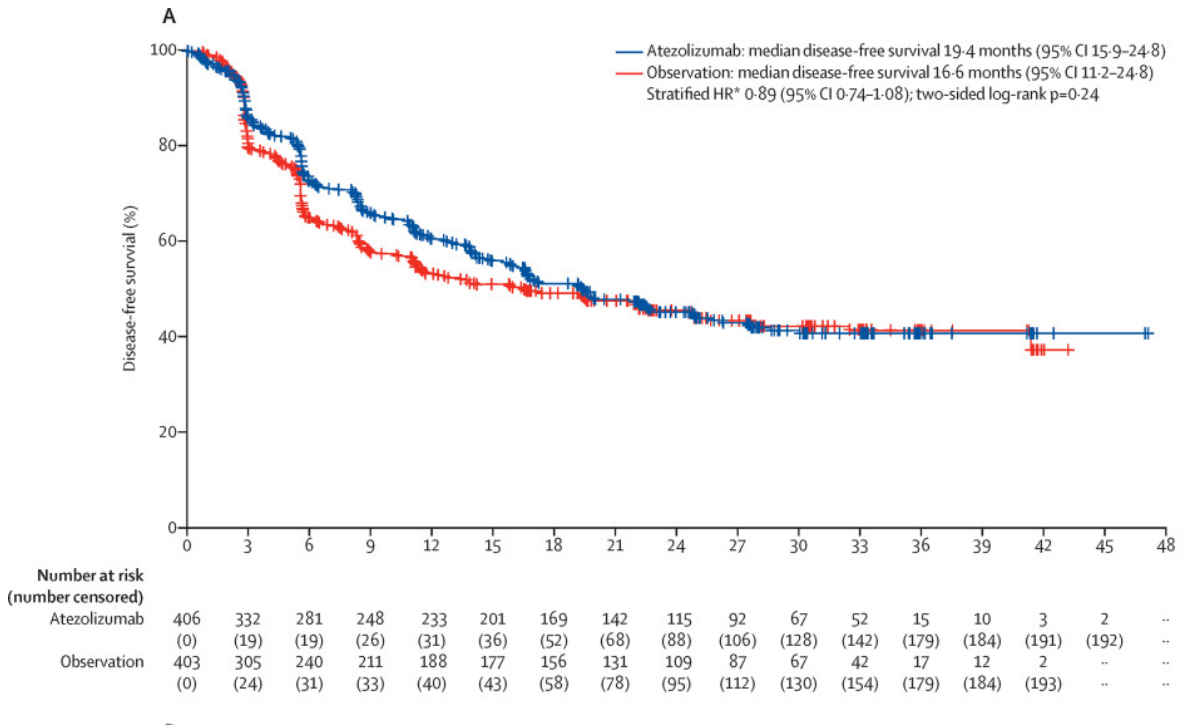
Minimum follow-up in the ITT population, 31.6 months. DMFS was defined as the time between the date of randomization and the date of first distant recurrence (non-local) or date of death.
NR, not reached.

Galsky, M. et al. GU ASCO 2023

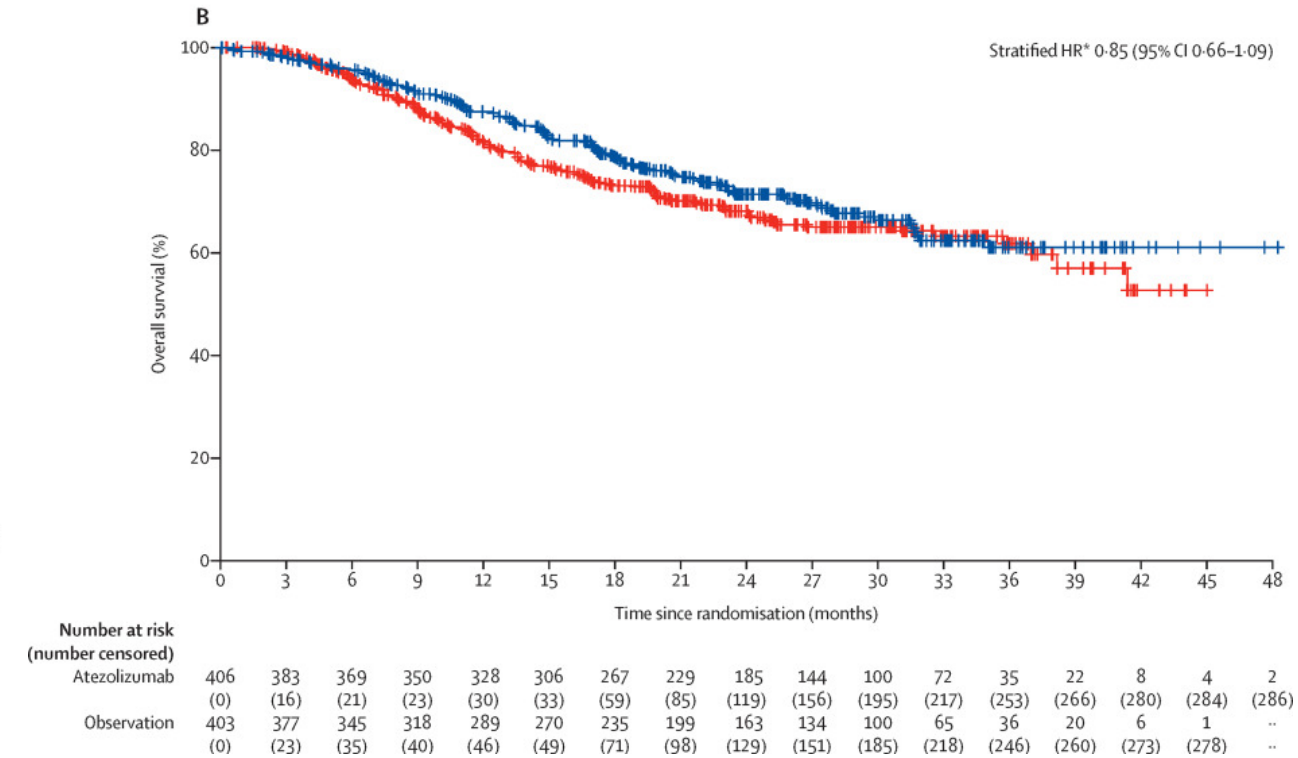
THE NEW ENGLAND JOURNAL of MEDICINE

DFS and OS with Adjuvant Immunotherapy in High Risk MIBC: Imvigor010

DFS in ITT Population



OS in ITT Population



Bellmunt, J, Hussain, M, et al. Lancet Oncology. April 2021, Pages 525-537

Best Practice in Metastatic UC Patients?

- Chemo → IO upon Progression?
- Chemo + IO Upfront?
- Chemo → IO Maintenance?

Immunotherapy	Atezolizumab	Pembrolizumab	Avelumab	Nivolumab	Durvalumab
Name of clinical trial	Imvigor 210	Keynote-045	JAVELIN Solid tumor	Checkmate 275	Study 1108
Phase	Phase II	III	Ib	II	I/II
N	310	266	44	270	182 PI
Overall Response Rate (ORR) All % (CI)	15%	21.10%	18.20%	19.60%	17%
	(11 - 20%)	(16.4 - 26.5%)	(8.2 - 32.7)	(15.1 - 24.9)	(11.9 - 23.3%)
ORR PD-L1+ (CI)	27% (19-37) IC2/3	21.6% (12.9 to 32.7)	53.8% (>/= 5%)	28.4% (18.9 - 39.5)	26.3% (17.8 - 36.4%)
ORR PD-L1- (CI)	18% (13-24) IC1/2/3	NR	4.20%	16.1% (10.5 - 23.1)	4.1% (0.9 - 11.5%)
PD-L1 Prevalence	33% (IC 2/3)	28% (>/= 10% CPS)	29.5% (>/= 5% TC)	46% (>/= 1%)	52% (TC or IC >/= 25%)
mOS All	7.9 mos	10.3 (8 - 11.8)	13.7 mos (8.5 - NE)	8.74 mos	18 mos
mPFS	2.1 mos (2.1-2.1 mos)	2.1 mos (2.0 to 2.2 mos)	11.6 weeks (6.1 to 17.4 weeks)	2 mos (1.87-2.63 mos)	2.2 mos (1.4 - 2.7 mos)
Dose (IV) and schedule	1200 mg q 3 weeks	200 mg q 3 weeks	10 mg/kg q 2 weeks	3 mg/kg q 2 weeks (label as 240 mg q 2 weeks	10 mg/kg q 2 weeks
References	Rosenberg Lancet 2016	Bellmunt NEJM 2017	Apolo JCO 2017	Sharma Lancet Oncol 2017	Powles ASCO GU 2017 and Durvalumab PI

Aragon-Ching J. Urol Oncol. 2017; 35(7):462-464

Best Practice in Metastatic UC Patients?

- Chemo → IO upon Progression?
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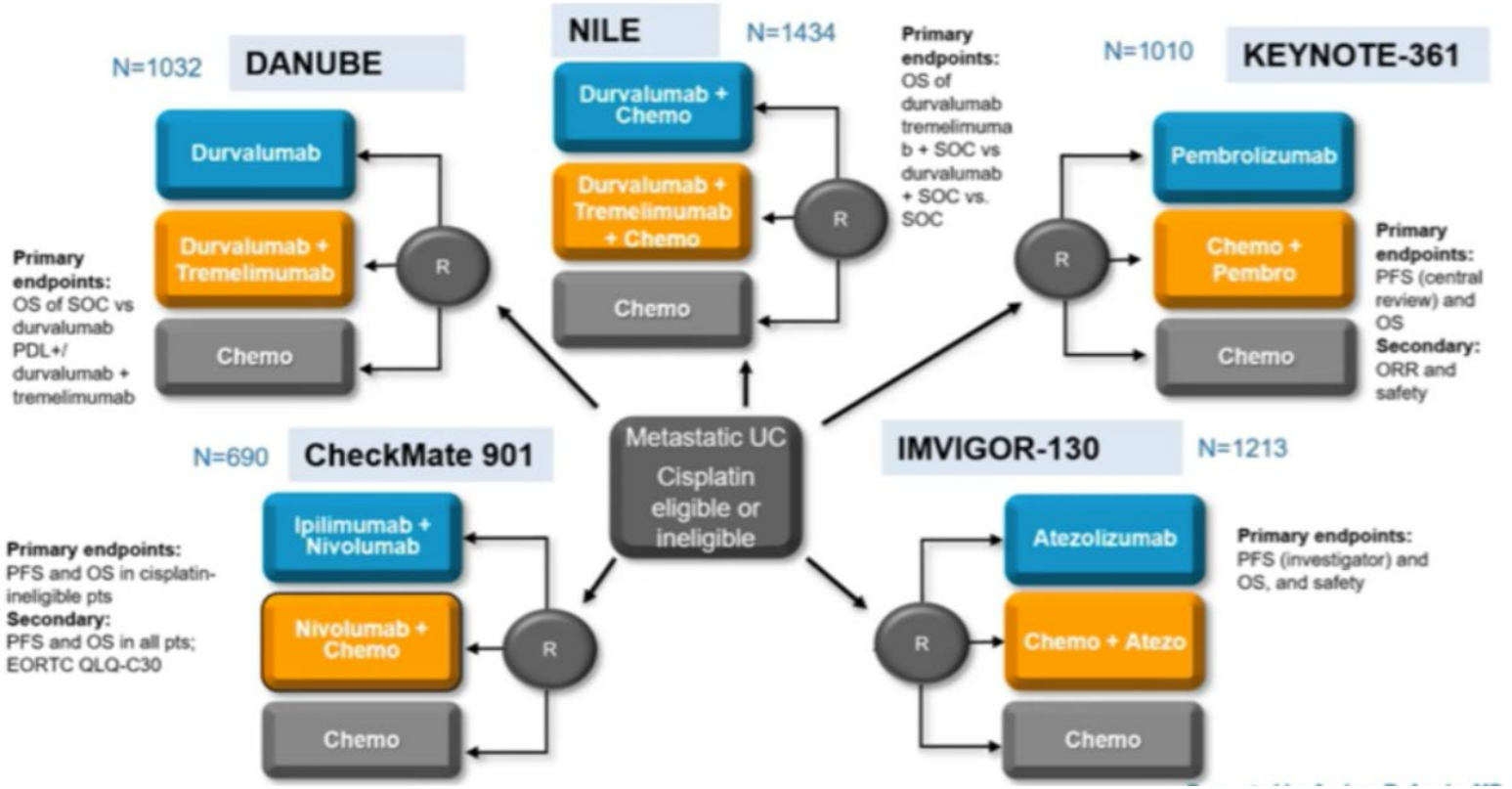
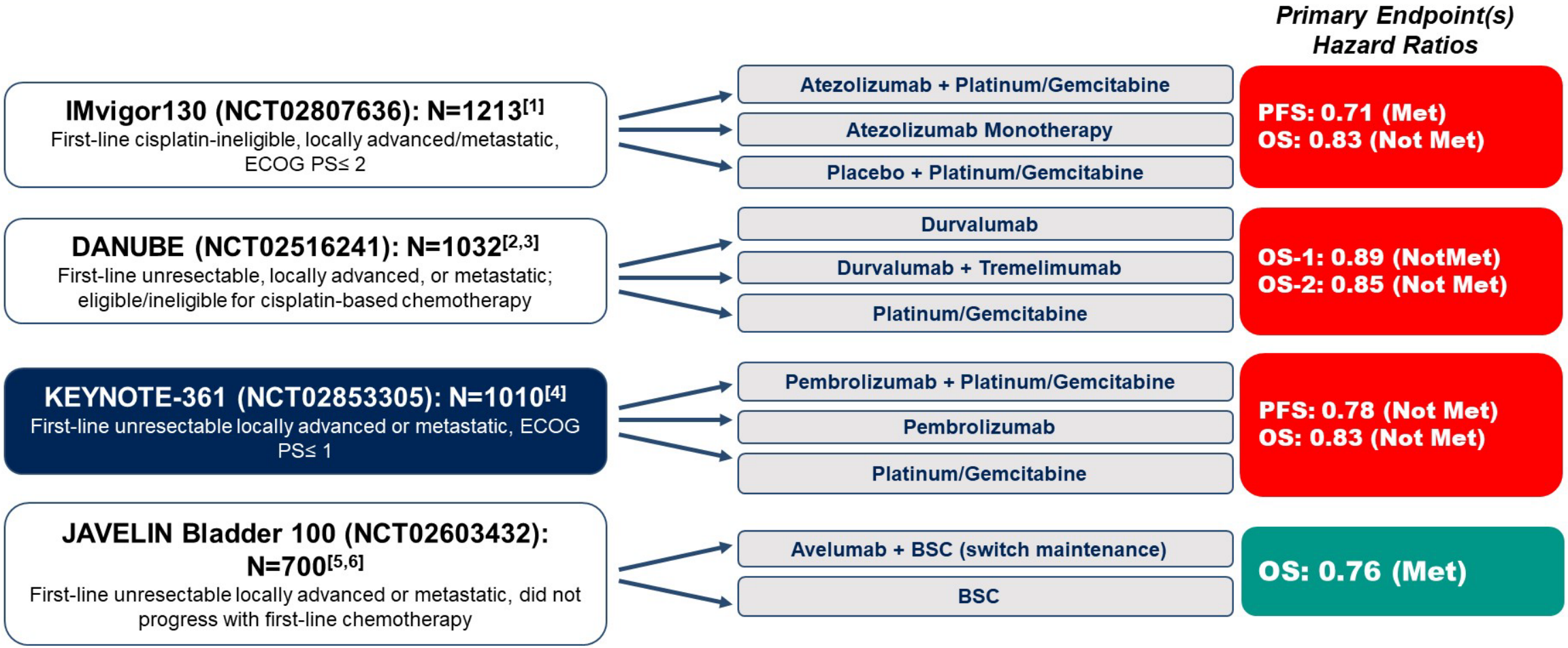


Apolo, A. GU ASCO 2021

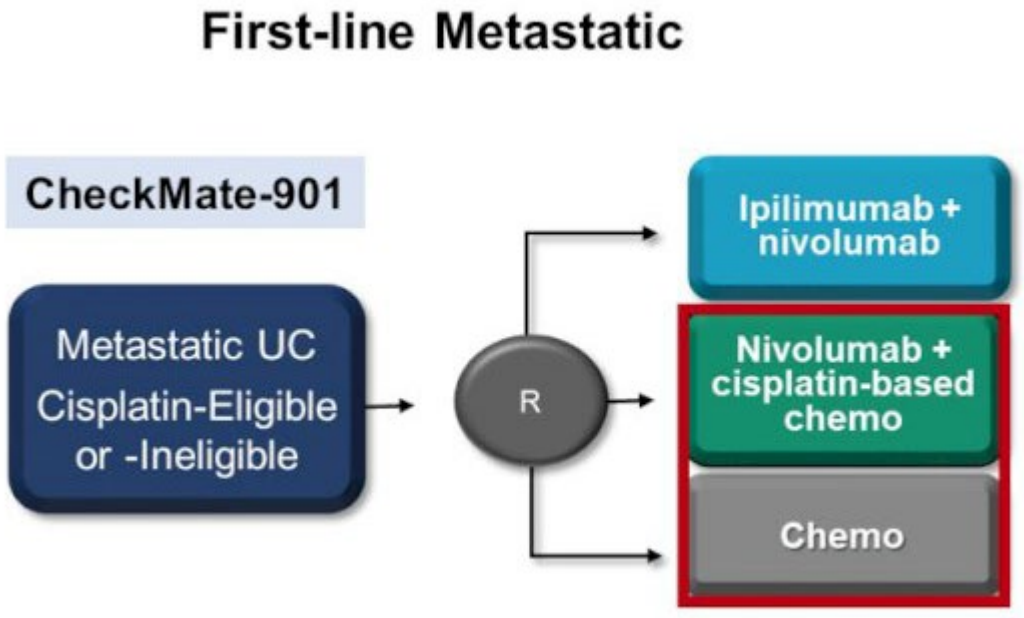
Combination IO & Chemotherapy in 1L Settings by Trial



1. Galsky. Lancet. 2020;395:1547. 2. Powles. ESMO 2020. Abstr 6790. 3. Powles. Lancet Oncol. 2020;21:1574. 4. Powles. Lancet Oncol. 2021;22:931. 5. Powles. NEJM. 2020;383:1218. 6. Powles. ASCO 2020. Abstr LBA1

Necchi, et al. ASCO 2023

CheckMate- 901:
Nivolumab + Cisplatin Based Chemo OS & PS Benefit



"Results of the sub-study showed that Opdivo (nivolumab) in combination with cisplatin-based chemotherapy followed by Opdivo monotherapy demonstrated statistically significant benefits in OS and PFS compared to standard-of-care cisplatin-based combinations as a first-line treatment for patients with unresectable or metastatic urothelial carcinoma who are eligible for cisplatin-based chemotherapy."

Check Mate -901 Fails to Meet Primary Endpoint of Overall Survival

May 18, 2022
Ashley Gallagher, Associate Editor

Independent committee recommends the phase 3 clinical trial continues to assess other primary and secondary endpoints for the treatment of unresectable or metastatic urothelial carcinoma.

announced that the phase 3 CheckMate -901 trial did not meet the primary endpoint of overall survival (OS) in individuals whose tumor cells express PD-L1 ≥1%, comparing nivolumab plus ipilimumab to the standard-of-care chemotherapy as a first-line treatment for individuals with untreated unresectable or metastatic urothelial carcinoma.

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(nivolumab) in Combination with Cisplatin-Based Chemotherapy Shows Overall Survival and Progression-Free Survival Benefit for Cisplatin-Eligible Patients with Unresectable or Metastatic Urothelial Carcinoma in the Phase 3 CheckMate -901 Trial

07/11/2023

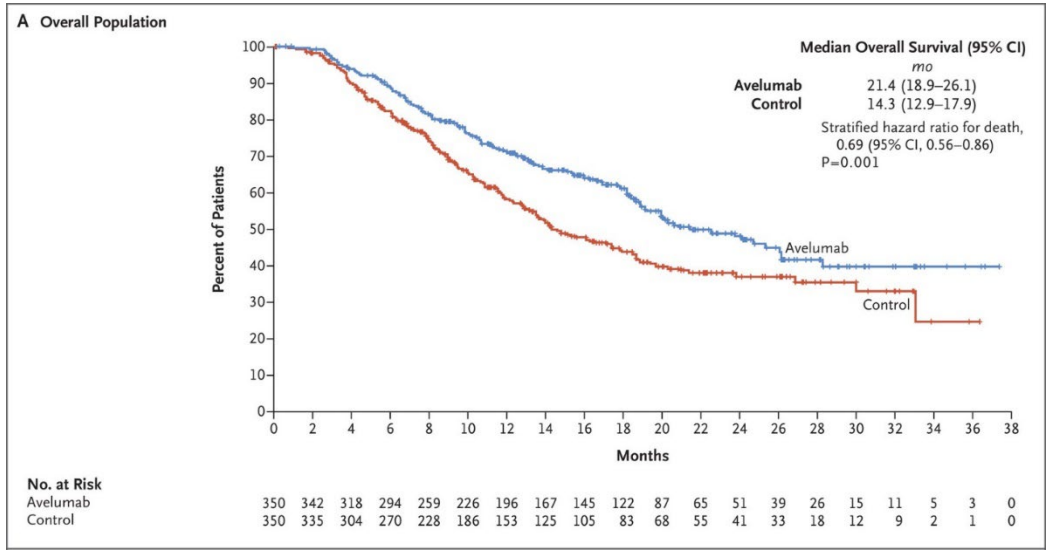
CATEGORY: Corporate/Financial News

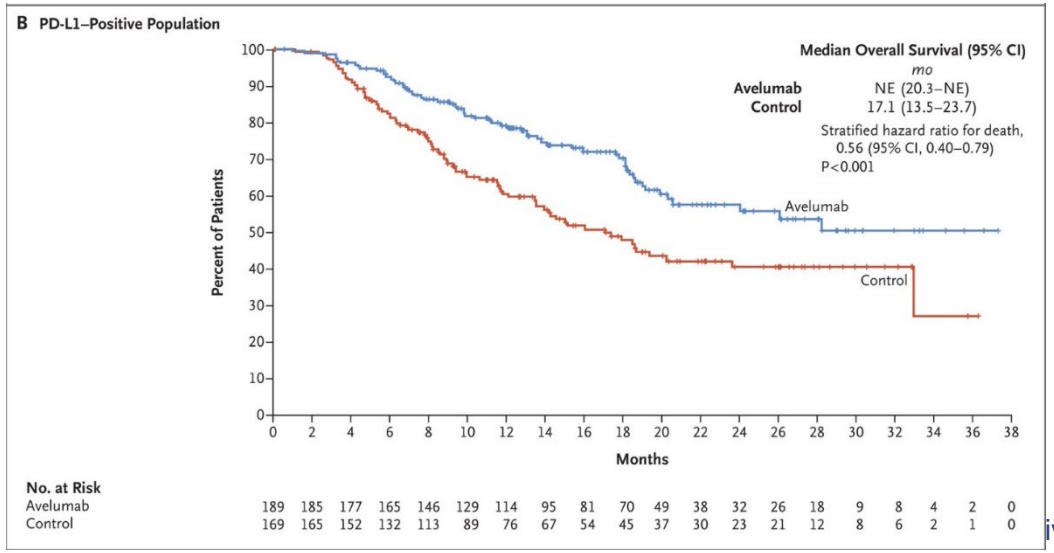
CheckMate -901 is the first and only Phase 3 trial with an immunotherapy-based combination to demonstrate a survival benefit compared to standard-of-care cisplatin-based combinations in the first-line treatment of this patient population

PRINCETON, N.J.--(BUSINESS WIRE)-- Bristol Myers Squibb (NYSE: BMY) today announced that the sub-study of the Phase 3 CheckMate -901 trial met the dual primary endpoints of overall survival (OS) and progression-free survival (PFS) as assessed by Blinded Independent Central Review (BICR) at final analysis. Results of the sub-study showed that (nivolumab) in combination with cisplatin-based chemotherapy followed by monotherapy demonstrated statistically significant benefits in OS and PFS compared to standard-of-care cisplatin-based combinations as a first-line treatment for patients with unresectable or metastatic urothelial carcinoma who are eligible for cisplatin-based chemotherapy. The combination of *Opdivo* with cisplatin-based chemotherapy in first-line urothelial carcinoma had a tolerable safety profile consistent with the known safety profiles of the individual components of the regimen. No new safety concerns have been identified.

Best Practice in Metastatic UC Patients?

- Chemo → IO upon Progression?
- Chemo + IO Upfront?
- Chemo (+/- IO)→ IO Maintenance?
  - ***Javelin Bladder 100***
  - ***CheckMate-901***





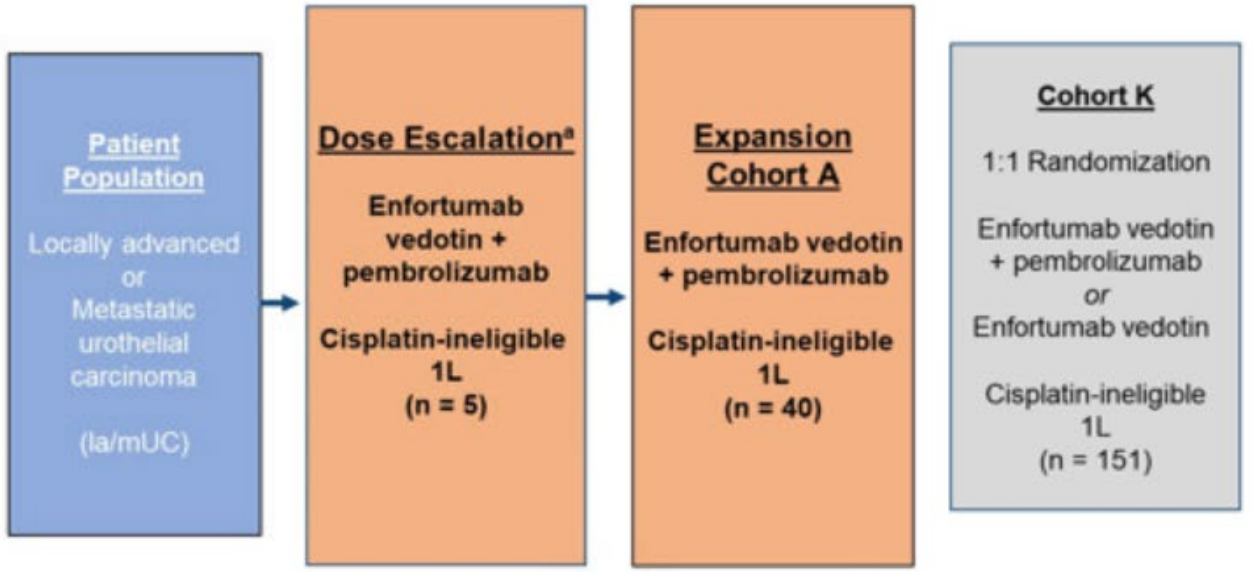
PD-L1 +

Powles, T, et al. N Engl J Med 2020; 383:1218-1230

Enfortumab Vedotin + Pembrolizumab in Front Line Setting

Study Design – EV+P Cohorts

EV-103 is an open-label, multiple cohort, phase 1b/2 study



- **Dosing:** EV 1.25 mg/kg IV on Days 1 and 8, and P 200 mg IV on day 1 of every 3-week cycle
- **Primary endpoints:** AEs, lab abnormalities
- **Key secondary endpoints:** confirmed ORR, DOR, DCR, and PFS per RECIST v1.1 by BICR[b] and investigator; OS, plasma/serum PK of EV

AE = adverse events; BICR = blinded independent central review; DCR = disease control rate; DOR = duration of response; EV = enfortumab vedotin; ORR = objective response rate; OS = overall survival; P = pembro; PFS = progression-free survival; PK = pharmacokinetics; 1L = first-line

Exploratory endpoints: biomarkers of activity including baseline PD-L1 status and Nectin-4 expression; **Dose Escalation/Cohort A** completed enrollment in Jan 2019; **Data cutoff** was 16 Sep 2022

[a]Patients assigned to EV 1.25 mg/kg + pembro and for whom study treatment was administered as 1L therapy

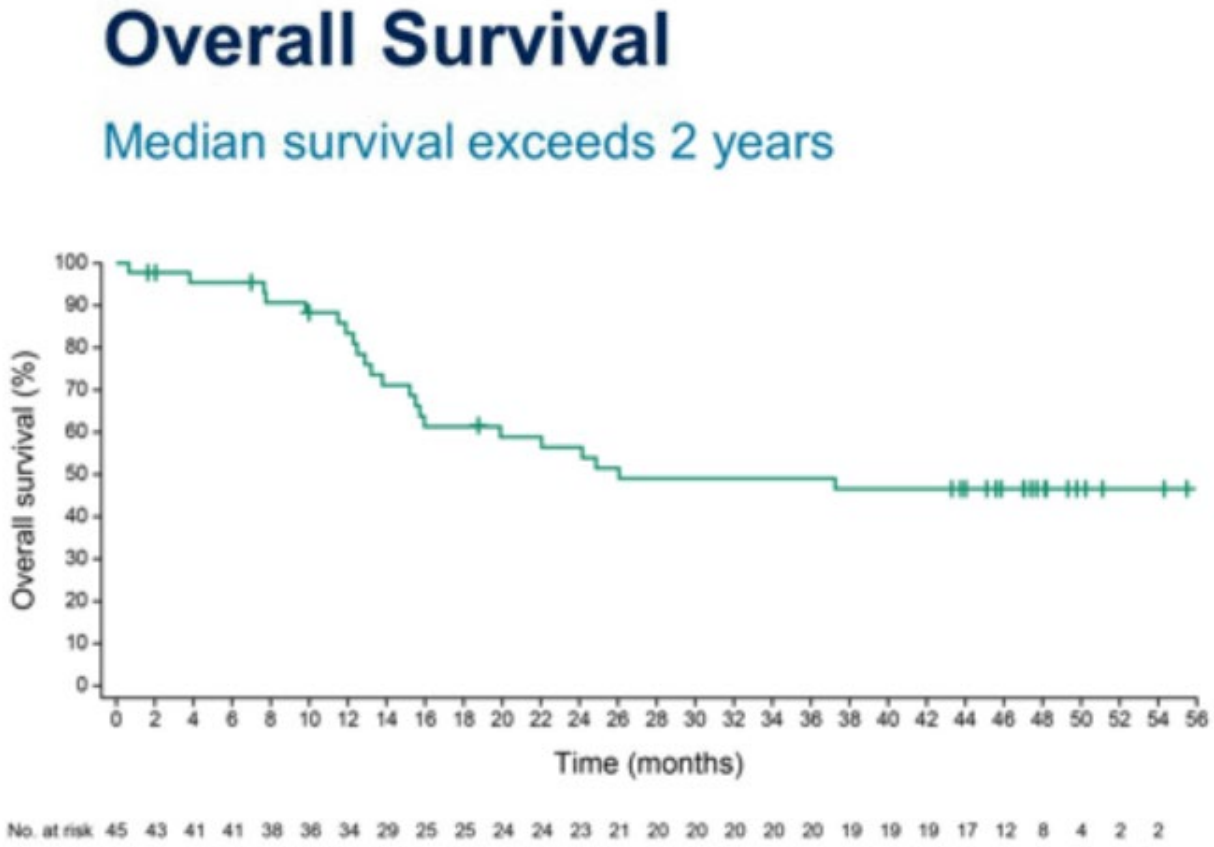
[b]The efficacy endpoints per RECIST v1.1 by BICR are presented for the first time herein. Results by investigator assessment have been previously published (Homes CJ, et al. JCO 2022).

Gupta, S. et al. ASCO 2023

EV 103 – Cohort A: Long Term Follow Up

	Dose Escalation + Cohort A (N = 45)
Objective Response Rate, n (%)	33 (73.3)
95% CI[a] for ORR	58.1-85.4
Best Overall Response, n (%)	
Complete response	7 (15.6)
Partial response	26 (57.8)
Stable disease	5 (11.1)
Progressive disease	5 (11.1)
No assessment[b]	2 (4.4)
Disease Control Rate, n (%)	38 (84.4)
95% CI[a] for DCR	70.5-93.5
Concordance rate of BOR between BICR and INV[c] assessment	95.3%

BICR = blinded independent central review; BOR = best overall response; CI = confidence interval; DCR = disease control rate; INV = investigator; ORR = objective response rate
[a]CI was computed using the Clopper-Pearson method (Clopper 1934)
[b]Patients had no response assessment post-baseline
[c]ORR per INV assessment was 33/45 (73.3%)



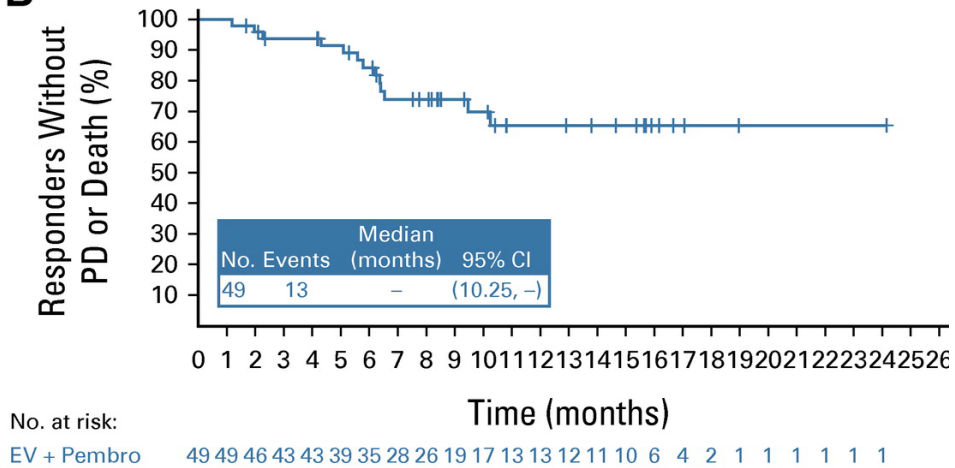
Gupta, S. et al. ASCO 2023

1L Enfortumab Vedotin + Pembrolizumab: Cohort K

A

	EV + Pembro (N = 76)	EV Monotherapy (N = 73)
Confirmed ORR, No. (%) (95% CI)	49 (64.5) (52.7, 75.1)	33 (45.2) (33.5, 57.3)
Best overall response		
CR	8 (10.5)	3 (4.1)
PR	41 (53.9)	30 (41.1)
Stable disease	17 (22.4)	25 (34.2)
PD	6 (7.9)	7 (9.6)
Not evaluable	3 (3.9)	5 (6.8)
No assessment	1 (1.3)	3 (4.1)
Time to objective response, months, median (range)	2.07 (1.1, 6.6)	2.07 (1.9, 15.4)
Treatment cycles, No., months, median (range)	11.0 (1, 29)	8.0 (1, 33)

B



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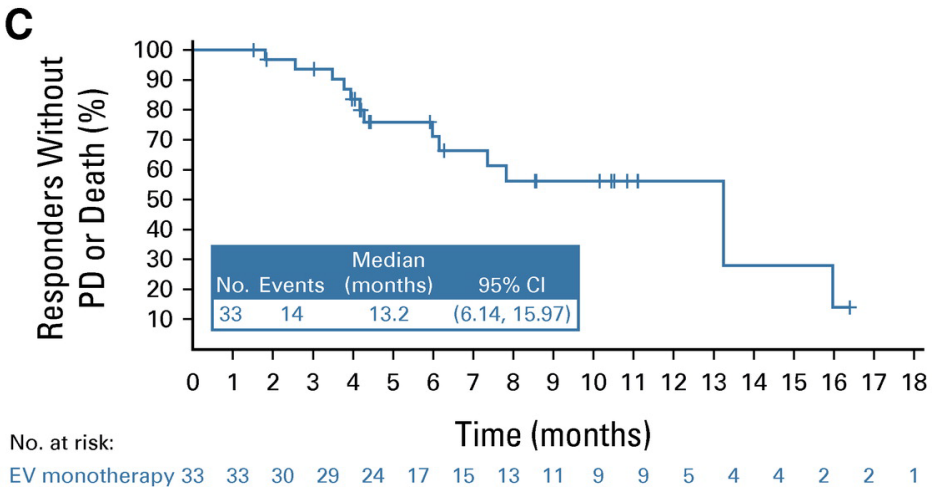
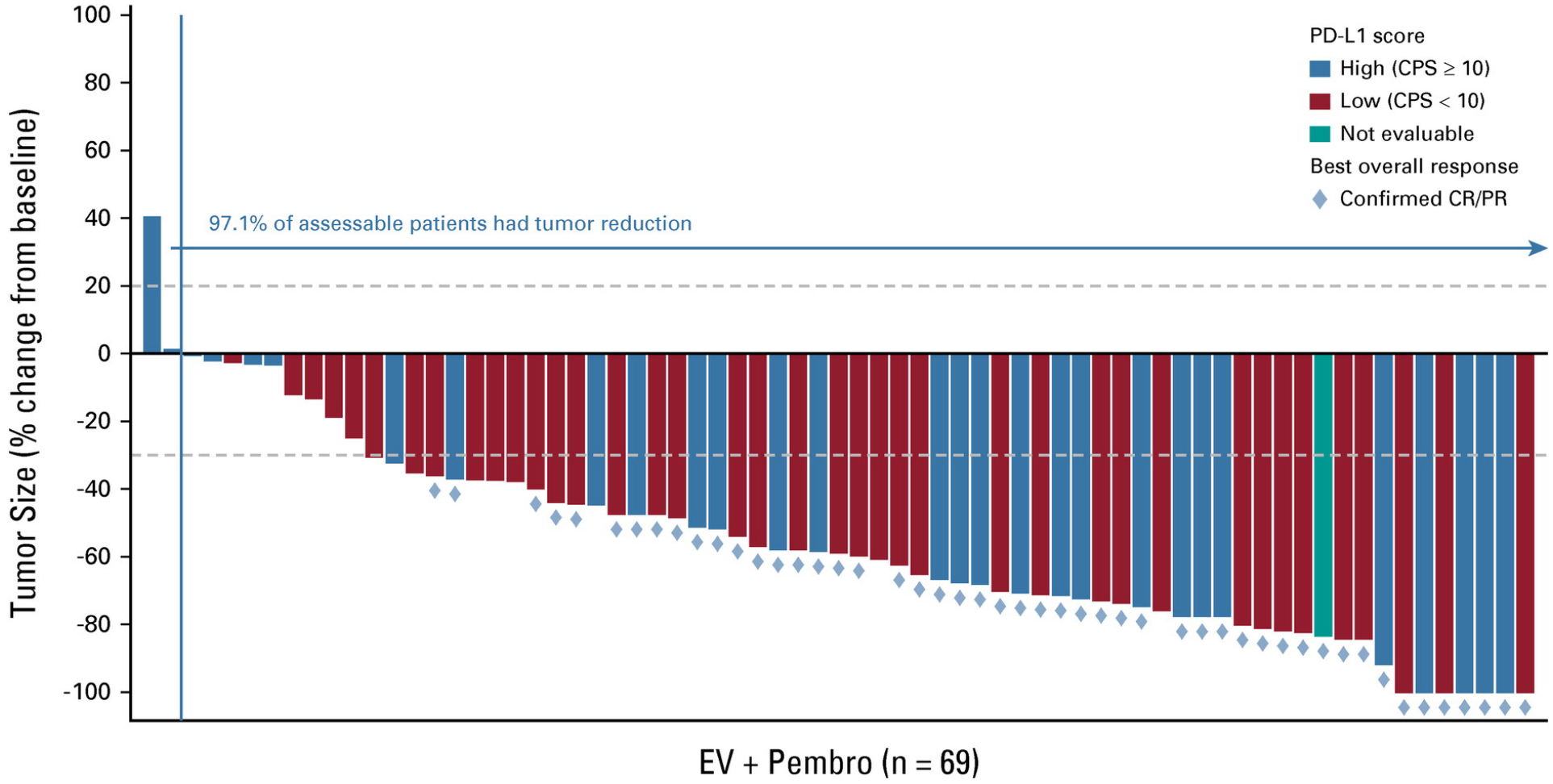


Enfortumab Vedotin + Pembrolizumab in Front Line Setting: Cohort K



O'Donnell, P.H. et al. JCO. 2023 Jun 27:JCO2202887.

FDA grants accelerated approval to enfortumab vedotin-ejfv with pembrolizumab for locally advanced or metastatic urothelial carcinoma

On April 3, 2023, the Food and Drug Administration granted accelerated approval to enfortumab vedotin-ejfv with pembrolizumab for patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy.

View full prescribing information

Efficacy was evaluated in EV-103/KEYNOTE-869 (NCT03288545), a multi-cohort (dose escalation cohort, Cohort A, Cohort K) study. The dose escalation cohort and Cohort A were single-arm cohorts treating patients with enfortumab vedotin-ejfv plus pembrolizumab while patients on Cohort K were randomized to either the combination or to enfortumab vedotin-ejfv alone. Patients had not received prior systemic therapy for locally advanced or metastatic disease and were ineligible for cisplatin-containing chemotherapy. A total of 121 patients received enfortumab vedotin-ejfv plus pembrolizumab.

The major efficacy outcome measures were objective response rate (ORR) and duration of response (DoR) determined by blinded independent central review using RECIST v1.1. The confirmed ORR in 121 patients was 68% (95% CI: 59, 76), including 12% with complete responses. The median DoR for the dose escalation cohort + Cohort A was 22 months (range: 1+ to 46+) and for Cohort K was not reached (range: 1 to 24+).

Content current as of:
04/03/2023

Regulated Product(s)
Drugs

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-enfortumab-vedotin-ejfv-pembrolizumab-locally-advanced-or-metastatic

1st Line Systemic Therapy

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2023
Bladder Cancer

NCCN Guidelines Index
Table of Contents
Discussion

PRINCIPLES OF SYSTEMIC THERAPY

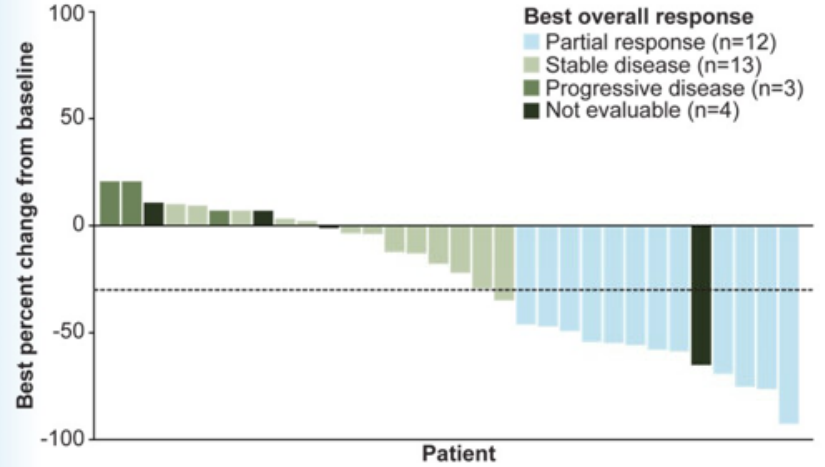
First-Line Systemic Therapy for Locally Advanced or Metastatic Disease (Stage IV)	
Cisplatin eligible	Preferred regimens • Gemcitabine and cisplatin[4] (category 1) followed by avelumab maintenance therapy (category 1)[a,11] • DDMVAC with growth factor support (category 1)[2,8] followed by avelumab maintenance therapy (category 1)[a,11]
Cisplatin ineligible	Preferred regimens • Gemcitabine and carboplatin[12] followed by avelumab maintenance therapy (category 1)[a,11] • Pembrolizumab[14] (for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy) • Pembrolizumab and enfortumab vedotin-ejfv[17] Other recommended regimens • Gemcitabine[15] • Gemcitabine and paclitaxel[16] • Atezolizumab[13] (only for patients whose tumors express PD-L1[b]) (category 2B) Useful under certain circumstances • Ifosfamide, doxorubicin, and gemcitabine[18] (for patients with good kidney function and good performance status) • Atezolizumab[13] (only for patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression) (category 3)

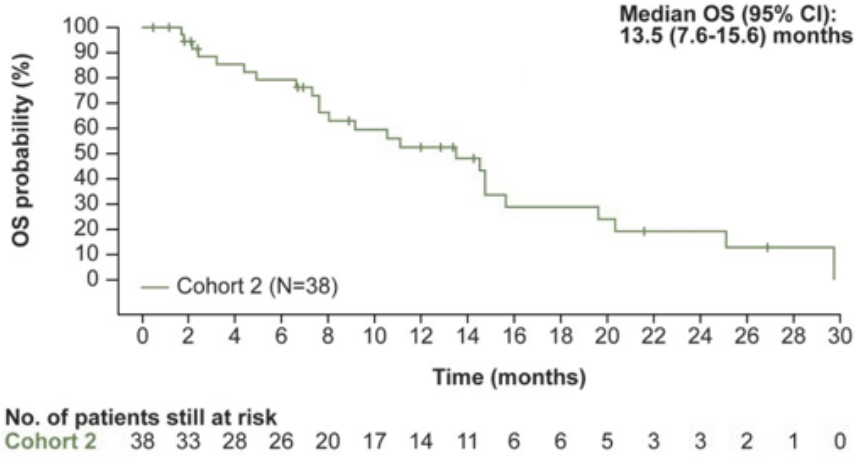
NCCN, Bladder Cancer 2023.

Trophy U-01 Cohort 2 – Status Post CPI, Platinum Ineligible

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

[a]Accelerated FDA approval for treatment of patients with LA or mUC who previously received PT-containing chemotherapy and PD-1/L1 inhibitor9. [b]Patients will complete randomized.
carbo, carboplatin; CBR, clinical benefit rate; cis, cisplatin; CPI, checkpoint inhibitor; CrCl, creatinine clearance; D, day; dom, domvanalimab; DOR, duration of response; F gemcitabine; LA, locally advanced; mUC, metastatic urothelial cancer; ORR, objective response rate; PD-1, programmed death-1; PD-L1, programmed death-ligand 1; PF patients; SG, sacituzumab govitecan; UC, urothelial cancer; zim, zimberelimab.

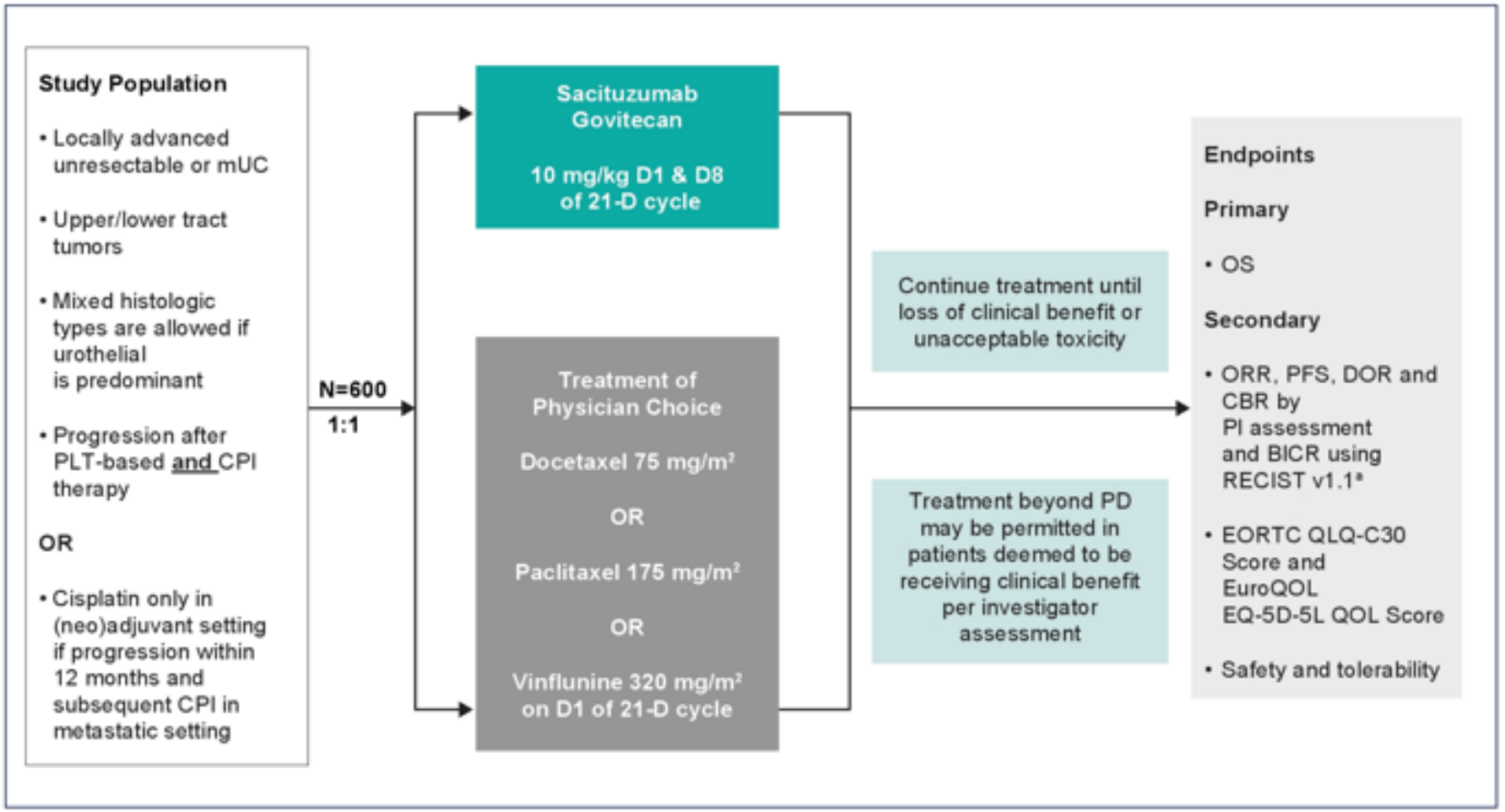




Petrylak et al, GU ASCO 2023

Study of Sacituzumab Govitecan (IMMU-132) in Metastatic or Locally Advanced Unresectable Urothelial Cancer (TROPiCS-04)

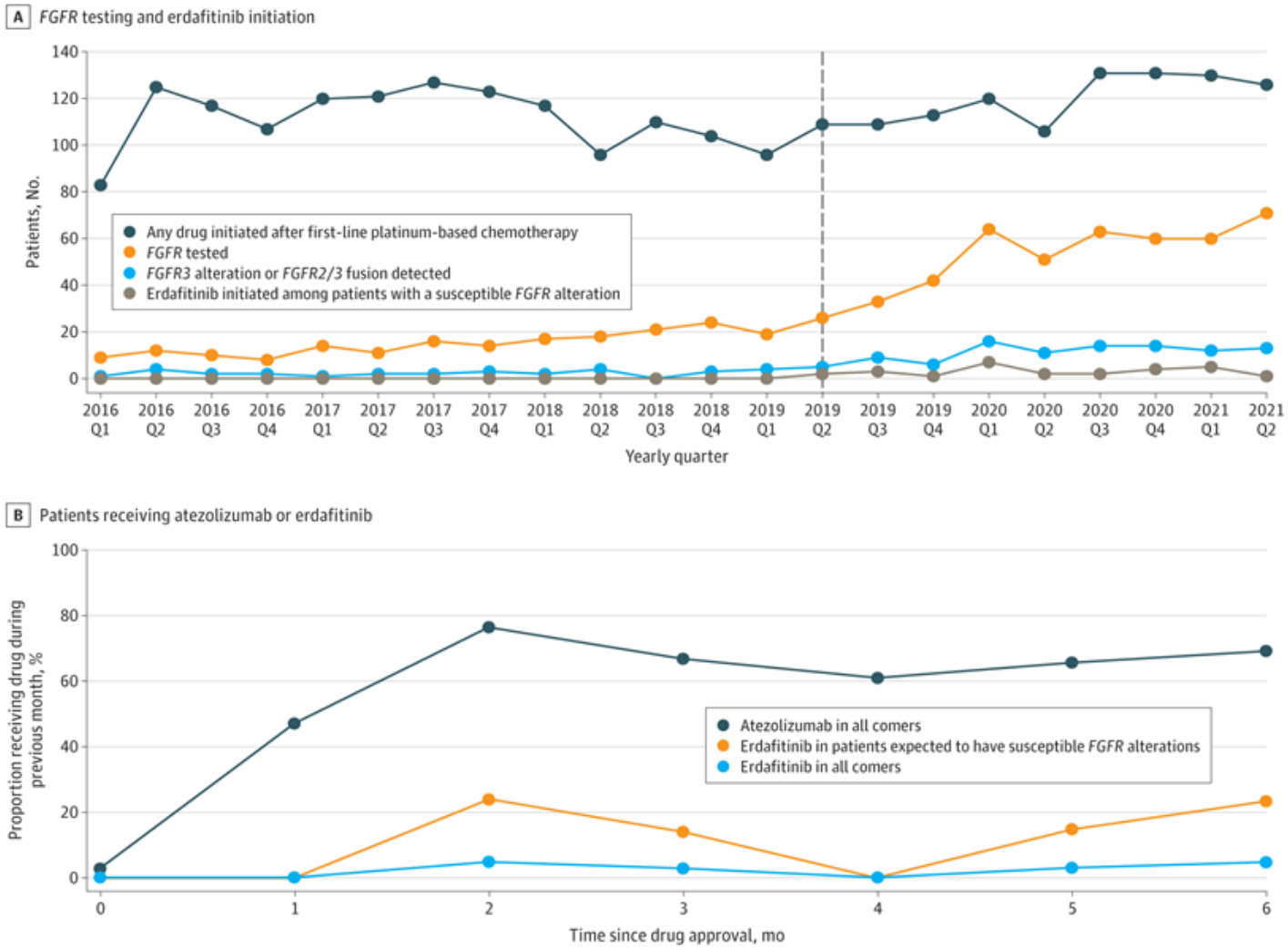
Figure 3. TROPiCS-04: A Phase 3 Confirmatory Study of SG in mUC Progressing After Prior PLT-Based and CPI Therapies (NCT:04527991)



[a]Assessed every 6 weeks for the first 12 months and every 9 weeks thereafter until there is evidence of progressive disease (PD), including patients who discontinue prematurely due to toxicity.
BICR, blinded independent central review; CBR, clinical benefit rate; CPI, checkpoint inhibitor; D, day; DOR, duration of response; EORTC QLQ-C30, European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30; EuroQOL EQ-5D-5L QOL, European Quality of Life 5-dimensions 5-levels; mUC, metastatic urothelial carcinoma; ORR, objective response rate; OS, overall survival; PD-1, programmed death-1; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PI, Principal Investigator; PLT, platinum; QOL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors.

Vulsteke, C. GU ASCO 2022.

FGFR Testing, Alterations, and Real World Utility



Nimgaonkar, V. et al. JAMA Oncol. 2022 Jul 1;8(7):1070-1072

THOR Phase 3 Study: Erdafitinib vs. Chemo in FGFR Mutated

Cohort 1

Key eligibility criteria
- Age ≥18 years
- Metastatic or unresectable UC
- Confirmed disease progression
- Prior tx with anti–PD-(L)1
- 1-2 lines of systemic tx
- Select *FGFR3/2alt* (mutation/fusion)[a]
- ECOG PS 0-2

1:1
N=266[b]
R

Erdafitinib
(n=136)
Once-daily erdafitinib 8 mg with pharmacodynamically guided uptitration to 9 mg

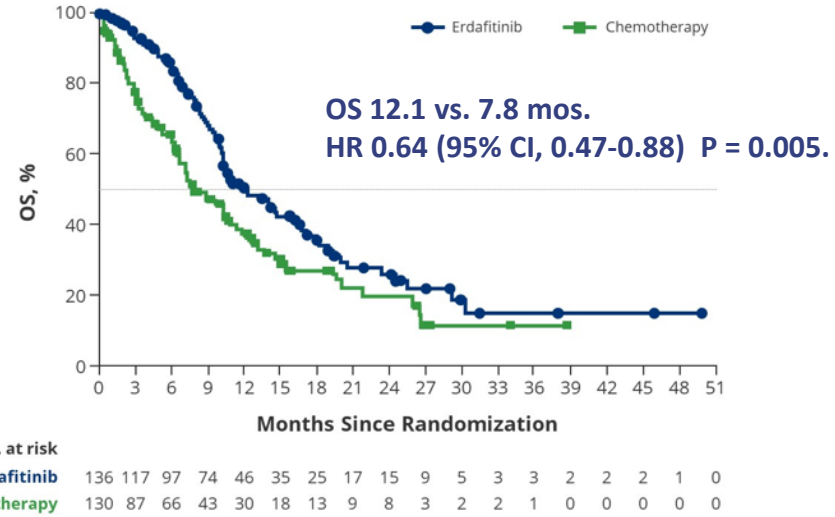
Chemotherapy of Choice
(n=130)
docetaxel or vinflunine once every 3 weeks

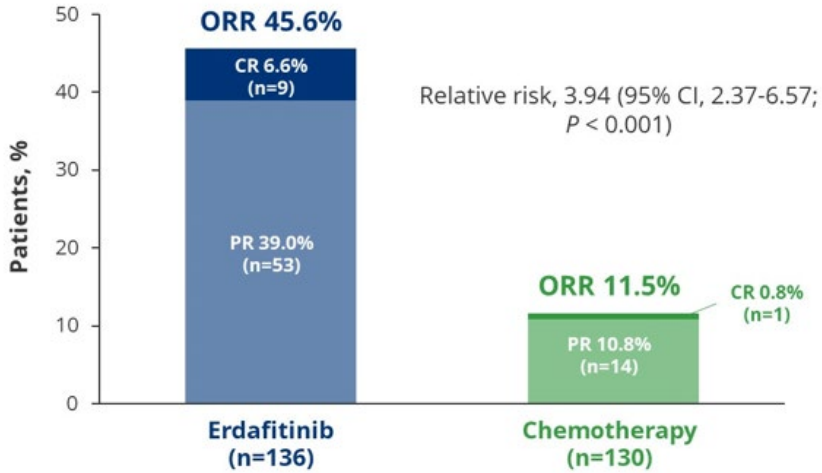
Stratification factors: region (North America vs European Union vs rest of world), ECOG PS (0 or 1 vs 2), and disease distribution (presence vs absence of visceral [lung, liver, or bone] metastases)

Primary end point:
- OS

Key secondary end points:
- PFS
- ORR
- Safety

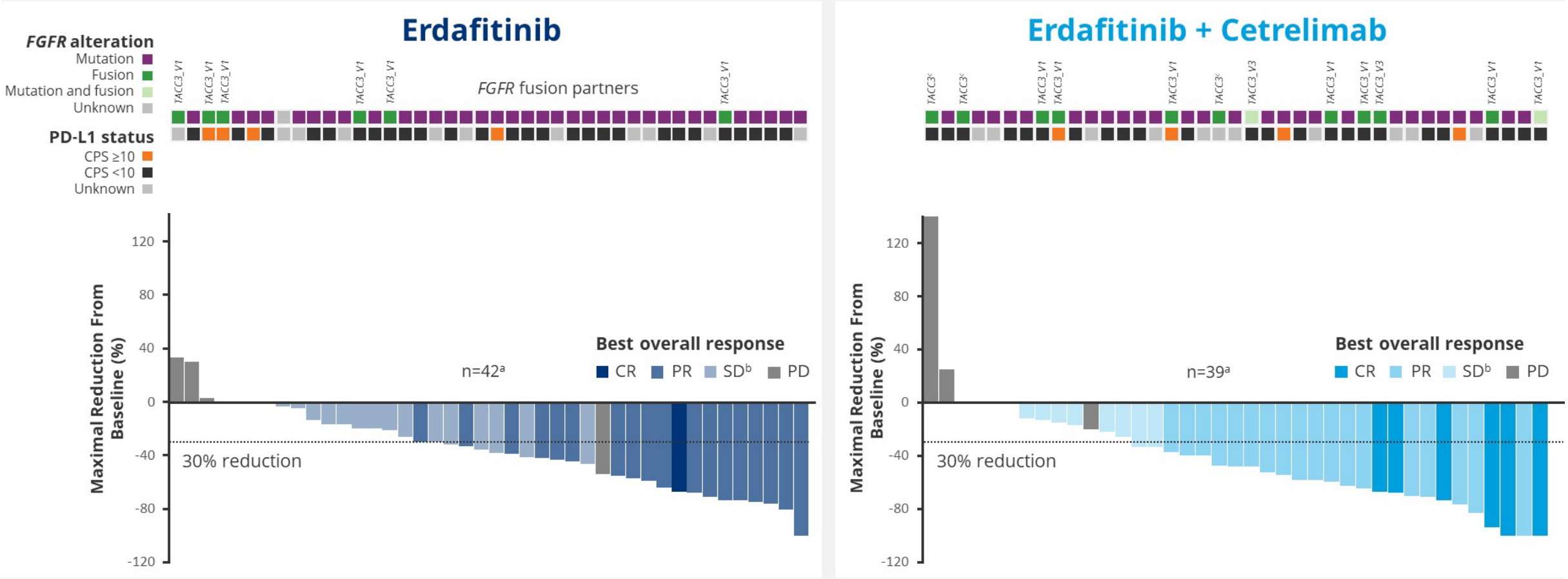
NCT03390504





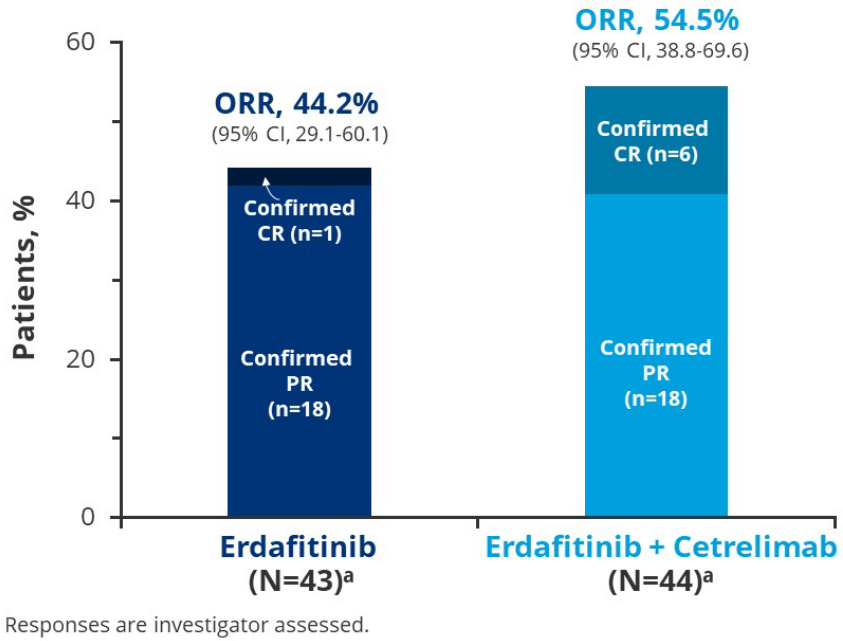
Loriot Y, et al. ASCO 2023.

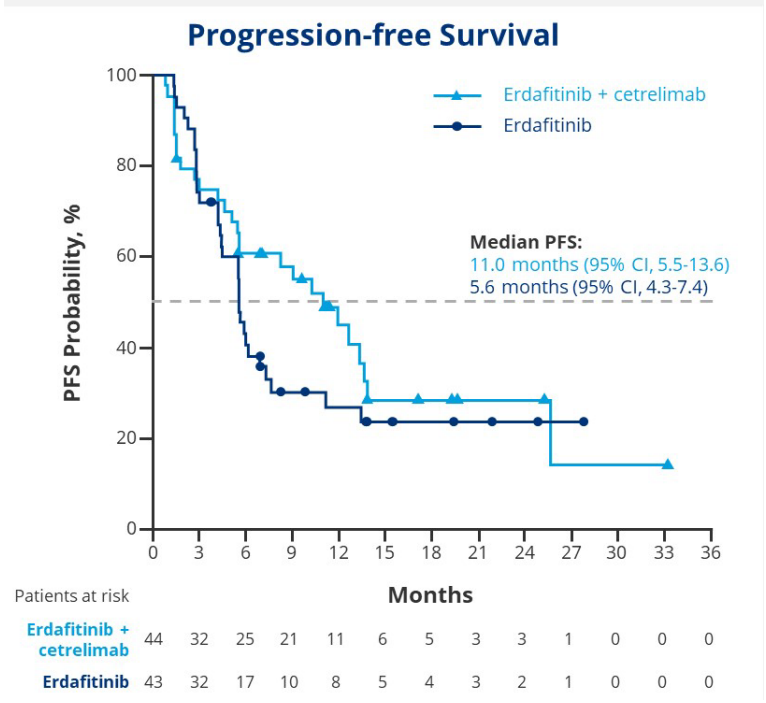
Phase 2 NORSE Study: Erdafitinib vs. Erdafitinib Plus Cetrelimab

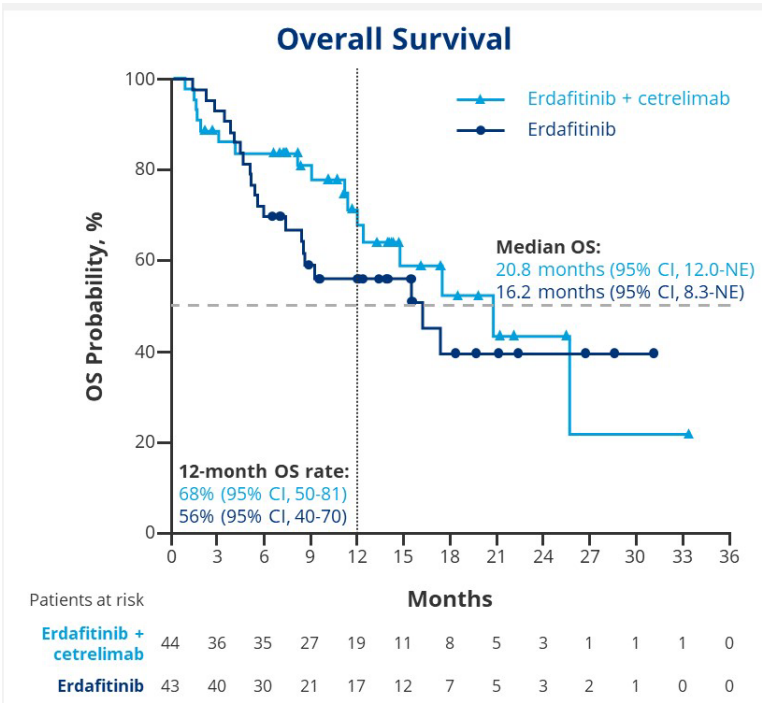


Siefker-Radtke, A. et al. ASCO 2023

Phase 2 NORSE Study: Erdafitinib vs. Erdafitinib Plus Cetrelimab







Siefker-Radtke, A. et al. ASCO 2023

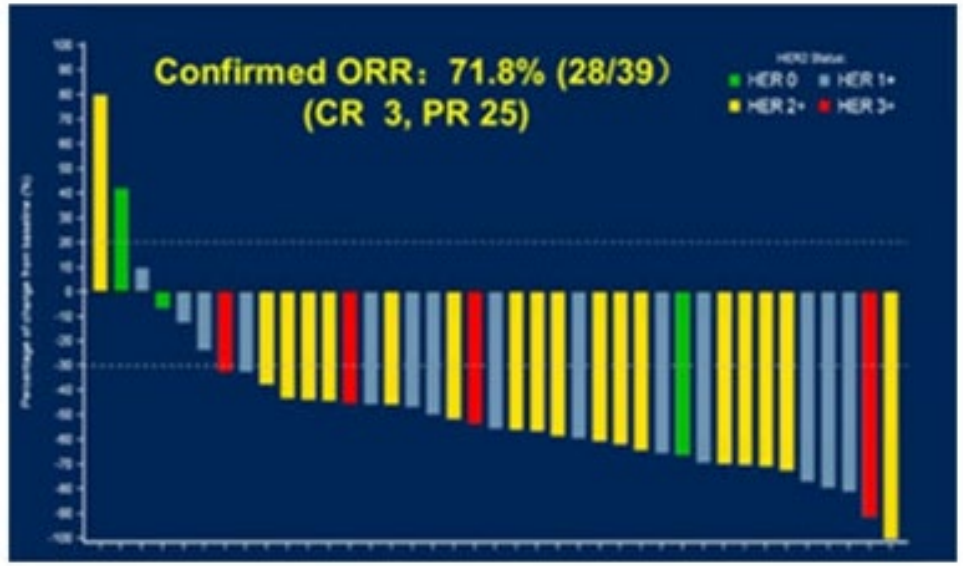
Her 2 ADC + Check Point Inhibitor Combinations

RC48 + toripalimab

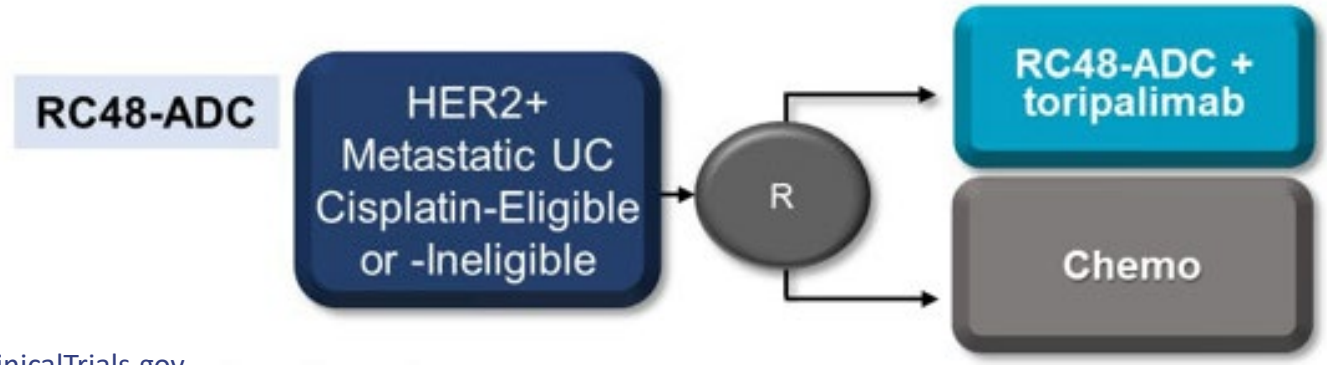
Phase II

ORR 71.8%

N=41



Phase III
N=452



Sheng, X. et al, ASCO 2023; Jan 1;27(1):43-51. ClinicalTrials.gov

Antibody Drug Conjugate Combinations in Advanced UC

Early Phase

Combination	Population	ORR	DOR
Enfortumab Vedotin + Pembrolizumab[1] N=45	1L cisplatin ineligible	73.3%	25.6 mos
Sacituzumab Govitecan + Pembrolizumab[2] N=41	≥2L post chemotherapy Checkpoint naïve	34% -prelim analysis 41% - primary analysis[3]	NR 11.1 mos
*Disitamab Vedotin (RC48) + Toripalimab[4] N=41	1L 61% ≥2L 39%	71.8% 73.9% tx naive	PFS 9.2 mos
Trastuzumab Deruxtecan (TDXD) + Nivolumab[5] N=30	≥2L post chemotherapy	36.7% HER2 IHC 3+/2+	13.1 mos

1. Holmes C et al J Clin Oc 2023
2. Grivas P et al ASCO GU 2022 3. Grivas P et al GU ASCO 2023 Abstract 518
4. Sheng X et al ASCO 2022
5. Galsky M et al GU ASCO 2022

Phase III

Combination	N	Initiated
Enfortumab Vedotin + Pembrolizumab vs Cisplatin / Carboplatin + Gemcitabine	990	March 2020
Disitamab Vedotin + Toripalimab (anti-PD-1) vs Cisplatin / Carboplatin + Gemcitabine (HER2-expressing status by IHC 1+, 2+ or 3+)	452	June 2022

Hoffman-Centsis, GU ASCO 2023.

Take Home Points:

- 1st line landscape is changing, particular in cisplatin ineligible patients
- IO and Chemo IO highly active in perioperative setting (upper and lower tract)
- Chemo + IO data shows multiple negative trials, but maintenance IO may be key
- Novel ADC conjugates and IO Combinations Will likely shape future Advanced Urothelial Cancer Therapies

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  - Sagar Lonial, MD
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  - Bassel Nazha, MD
  - Jackie Brown, MD
  - GU Clinical Trials & Office Staff
  - Urology and Radiation Oncology Colleagues

- Participating Patients and Clinician Researchers

Patient Case

A 62 year old male with hx of HTN, chronic kidney disease (Creatinine Clearance 39), hearing loss (uses hearing aids) and pre-diabetes presents with hematuria. He has a cystoscopy and is diagnosed with high grade muscle invasive urothelial cell carcinoma of the bladder. Imaging shows widespread metastases, involving bilateral pelvic and retroperitoneal lymph nodes as well as bone. Biopsy of a lymph node confirms metastatic urothelial carcinoma.

Labs and exam are otherwise unremarkable. Patient performance status is 1. Although he is hesitant to be on traditional chemotherapy, the patient is motivated to begin an effective therapy. What would be your recommendation for this patient?

a. Single agent Carboplatin followed by Avelumab maintenance
b. Gemcitabine and Cisplatin
c. Sacituzumab Govitecan
d. Enfortumab Vedotin and Pembrolizumab
e. Durvalumab

Patient Case

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