Inaugural Southern California Genitourinary Cancer Research Forum

# Key Updates in Bladder Cancer

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Bladder Cancer
Can we finally make a difference ???
From NeoAdjuvant to Adjuvant to Metastatic,
and there is still a **Chance of Cure!!!**

# Disclosures

- Consultant for AstraZeneca, Eli Lilly, EMD Serono, Exelixis, Genentech, Merck, and Seagen.

*This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.*

*This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.*

*This presentation has been peer-reviewed and no conflicts were noted.*

**The off-label/investigational use of Durvalumab, Tremelimumab, Tiragolumab, Atezolizumab, and Enfortumab Vedotin will be addressed.**

# Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

**STATE LAW:**

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

*The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.*

***EXEMPTION:***

Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

***This presentation is dedicated solely to research or other issues that do not contain a direct patient care component.***

# Agenda

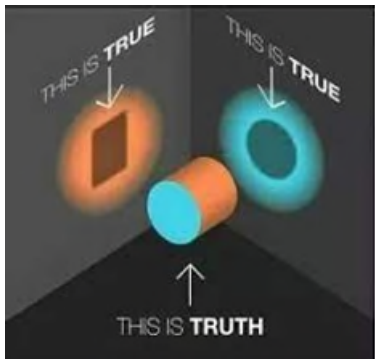
- NEOADJUVANT: Current SOC and Ongoing Needs / Studies
- ADJUVANT: Making science to make a difference!
- METASTATIC: Finally a step forward

# Basic Principle in Urothelial Cancer

## **Treat based on Cisplatin Eligibility**

## For Neoadjuvant-Adjuvant-1st Line Metastatic

1. Creatinine Clearance > 60  (Adjusting to Cr Cl 40-60)
2. Neuropathy  grade <2  (Subjective grade 1  vs 2)
3. Ototoxicity grade <2 (Subjective need vs use hearing aids)
4. NYHA class <3
5. ECOG 0-1



NEOADJUVANT

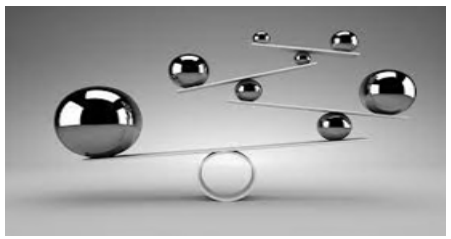
# Current SOC In Cisplatin Eligible

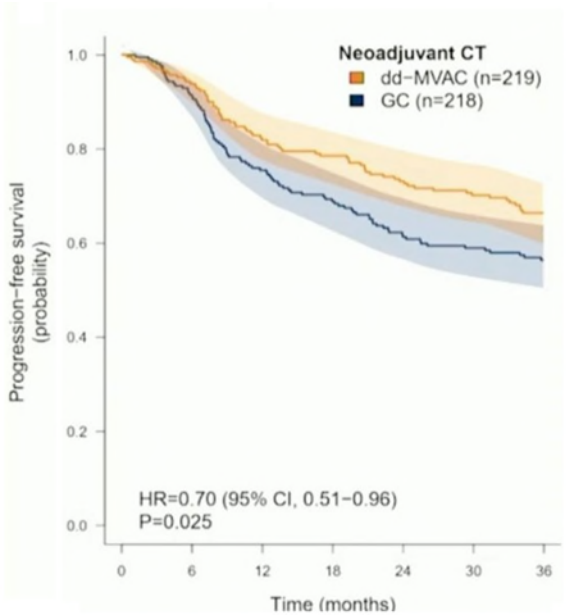
## MULTICENTER RANDOMIZED PHASE III TRIAL OF DOSE DENSE MVAC OR GC IN PERIOPERATIVE CHEMOTHERAPY FOR MUSCLE INVASIVE BLADDER CANCER GETUG/AFU VESPER PH III

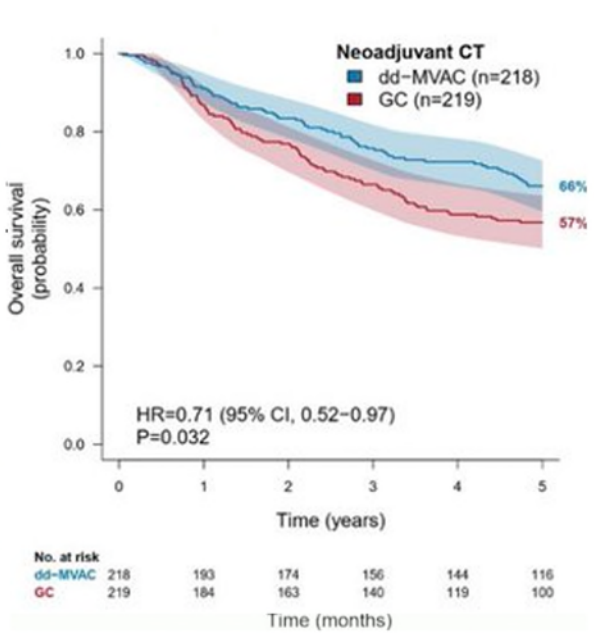
ASCO 2023

GC: Gemcitabine
Cisplatin

MVAC: Methotrexate
Vinblastine
Anthracycline
Cisplatin






GETUG/AFU VESPER Ph III

500 patients randomized to
ddMVAC * 6cy vs GC * 4cy

5yr OS
64% in dd MVAC vs 56% in GC

5yr DFS
72% in dd MVAC vs 59% in GC

NEOADJUVANT

# CISPLATIN ELIGIBLE TRIALS

**KEYNOTE-B15:** A Phase III study of Gemcitabine+Cisplatin vs Perioperative Enfortumab Vedotin (EV) Plus Pembrolizumab (PI: Chamie-urology)

**Patient Population**
- -Cisplatin Eligible
- -Stage cT2-T4aN0M0
- -Stage cT1-T4aN1M0
- -Any PD-L1 status

R (1:1) N=784

**Arm A**
EV 1.25 mg/kg Q3W on days 1 and 8 + Pembrolizumab 200 mg Q3W on day 1 (4 cycles)

**Arm B**
Gemcitabine 1000 mg/m² Q3W on days 1 and 8 + Cisplatin 70 mg/m² Q3W on day 1 (4 cycles)

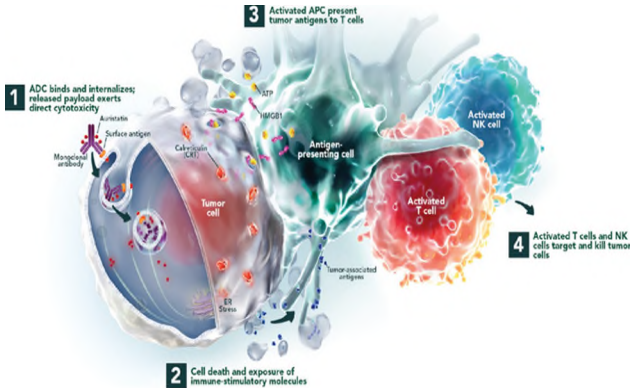
RC + PLND

EV 1.25 mg/kg Q3W on days 1 and 8 (5 cycles) + Pembrolizumab 200 mg Q3W on day 1 (13 cycles)[b]

Observation

Neoadjuvant Phase

Adjuvant Phase



# What is the SOC in Cisplatin Ineligible?

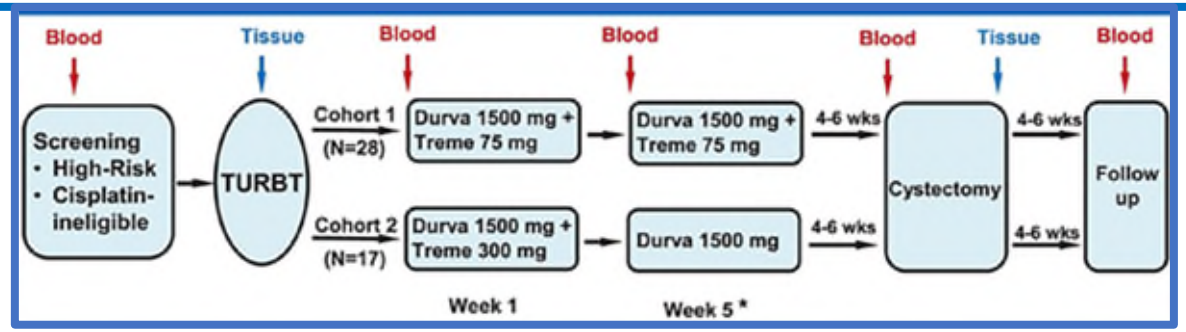
- Bladder Sparing: Chemo Radiation
- Surgical Candidates: Radical Cystectomy & LN Dissection → Adjuvant Tx

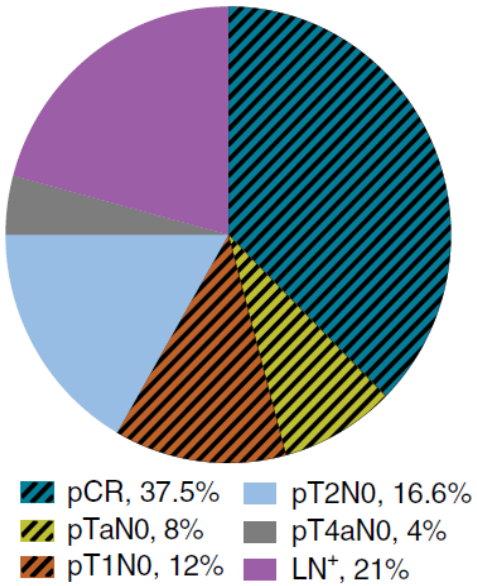
Neoadjuvant therapy is the SOC in MIBC
If that holds true for CISPLATIN ELIGIBLE,
is probably true for CISPLATIN INELIGIBLE
IF we can give Effective Drugs Safely

NEOADJUVANT

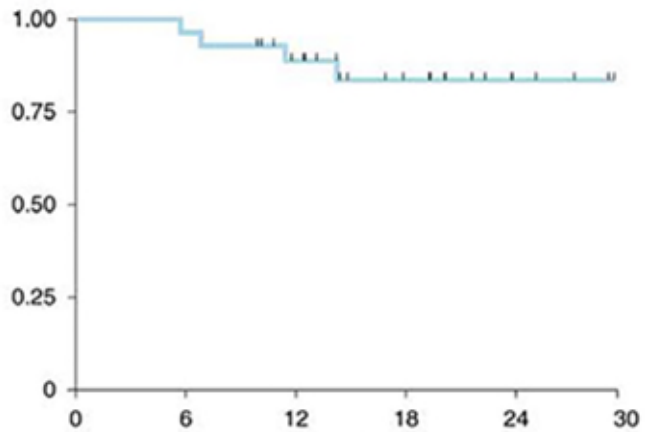
# Neoadjuvant PD-L1 plus CTLA-4 blockade in patients with cisplatin-ineligible operable high-risk urothelial carcinoma

nature medicine LETTERS
https://doi.org/10.1038/s41591-020-1086-y

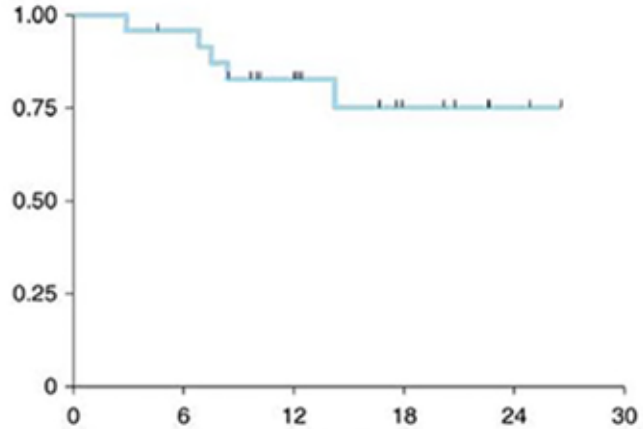



**Pathologic Responses post cystectomy**




**Overall Survival**



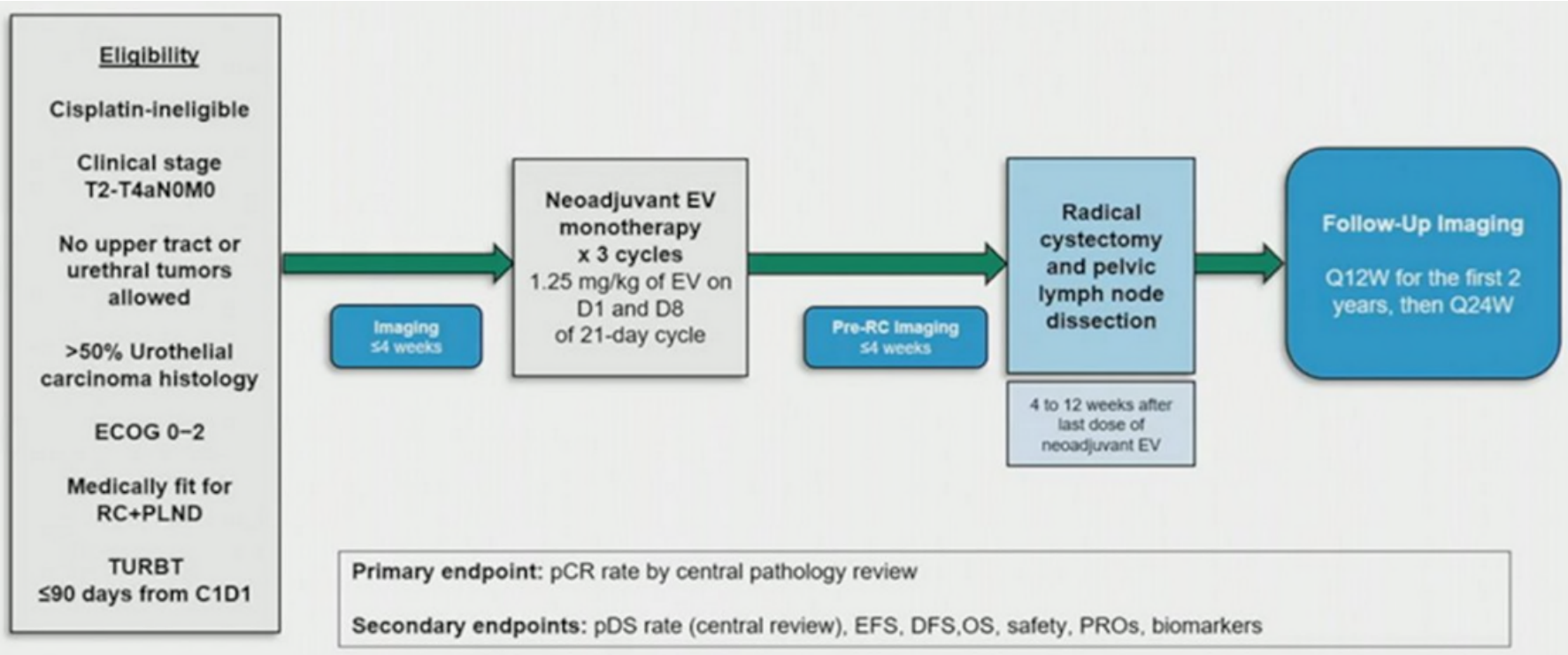

**Relapse Free Survival**

*Gao et al 2020*

NEOADJUVANT

# EV-103 Cohort H: Neoadjuvant Enfortumab Vedotin in patients Cisplatin Ineligible MIBC

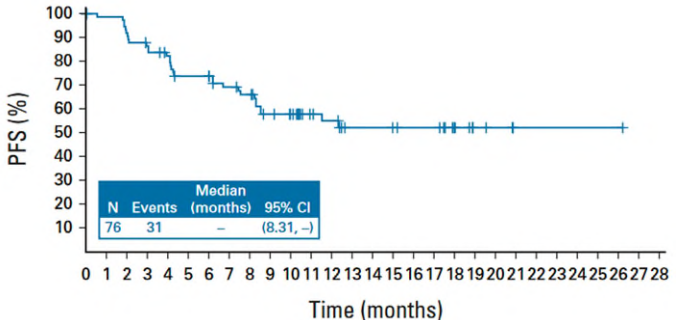
*J Clin Oncol*. 40, 2022 (suppl 6; abstr 435)

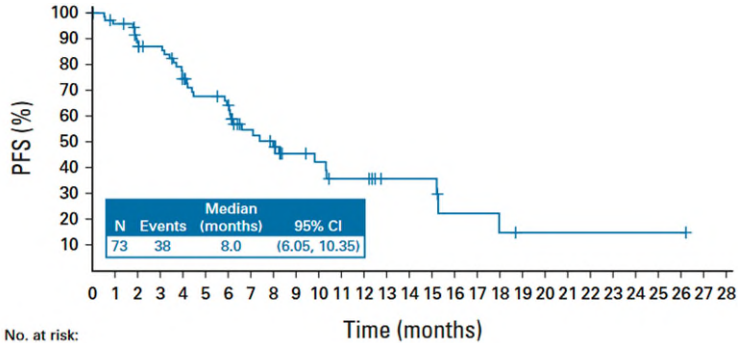


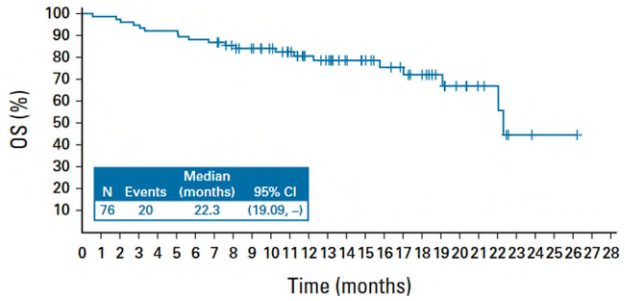

| Pathological Response | Central Pathology Results (N=22) n (%) [95% Confidence Interval] |
|---|---|
| **Pathological Complete Response Rate** (defined as absence of any viable tumor tissue: ypT0 and N0) | **8 (36.4%)** [17.2–59.3] |
| **Pathological Downstaging Rate** (defined as presence of ypT0,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

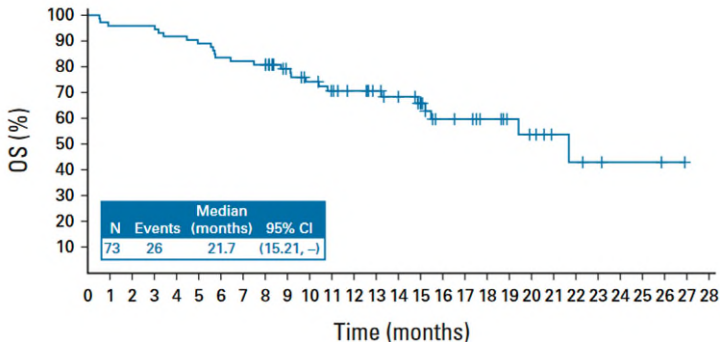
# Enfortumab Vedotin With or Without Pembrolizumab in Cisplatin Ineligible Untreated Advanced Bladder Cancer

*O'Donnell et al, J Clin Oncol 2023*



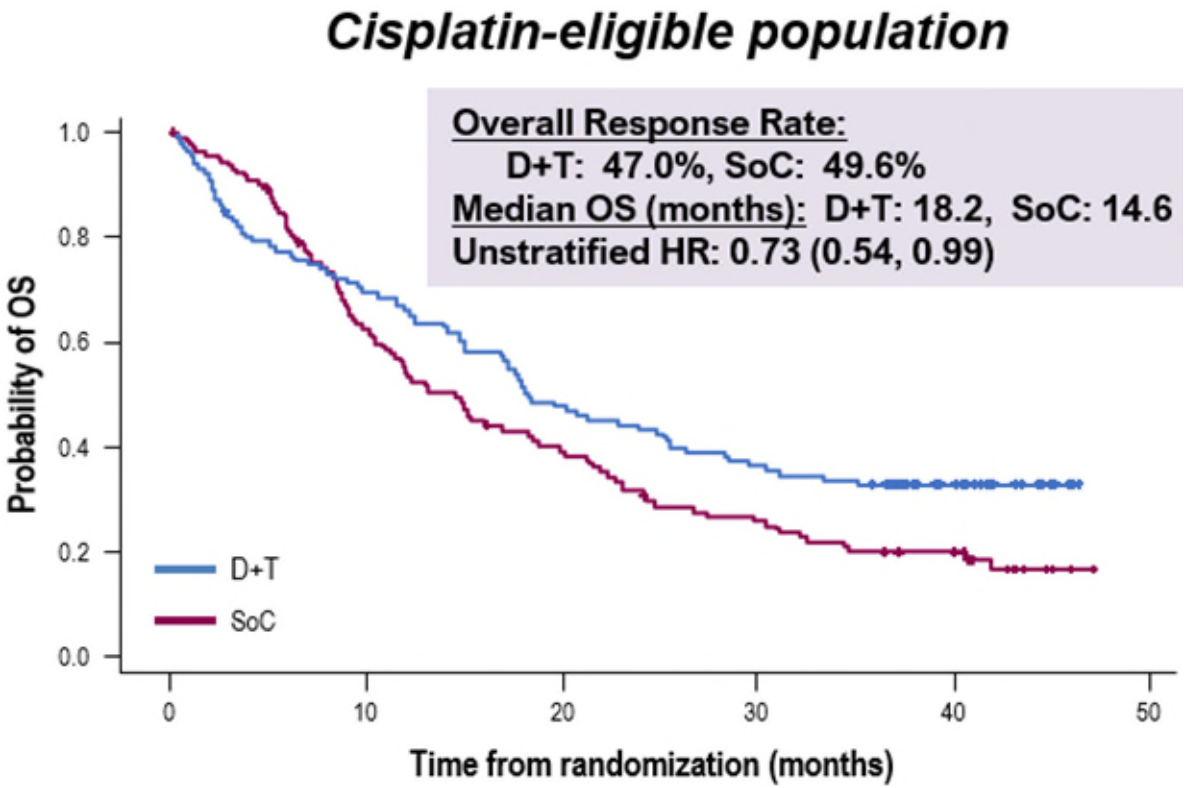

| | EV + Pembro (N = 76) |
|---|---|
| mPFS, months<br>95% CI | –<br>(8.31, –) |
| mOS, months<br>95% CI | 22.3<br>(19.09, –) |

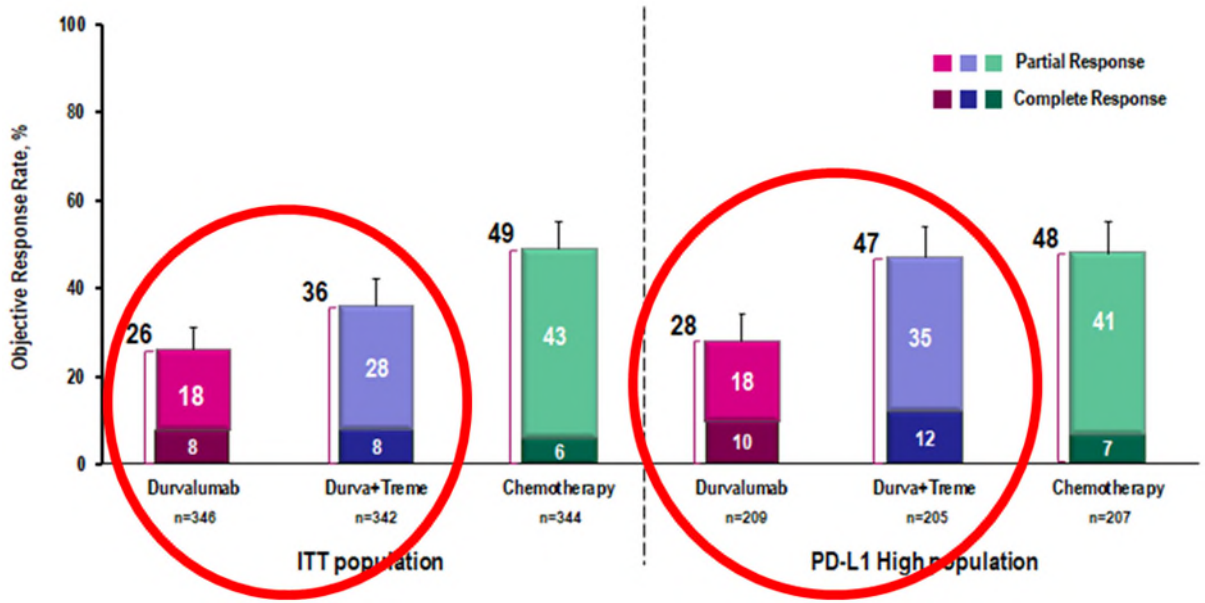
| | EV Monotherapy (N = 73) |
|---|---|
| mPFS, months<br>95% CI | 8.0<br>(6.05, 10.35) |
| mOS, months<br>95% CI | 21.7<br>(15.21, –) |

| | EV + Pembro (N = 76) | EV Monotherapy (N = 73) |
|---|---|---|
| Confirmed ORR, No. (%)<br>(95% CI) | 49 (64.5)<br>(52.7, 75.1) | 33 (45.2)<br>(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) |

Journal of Clinical Oncology®
An American Society of Clinical Oncology Journal

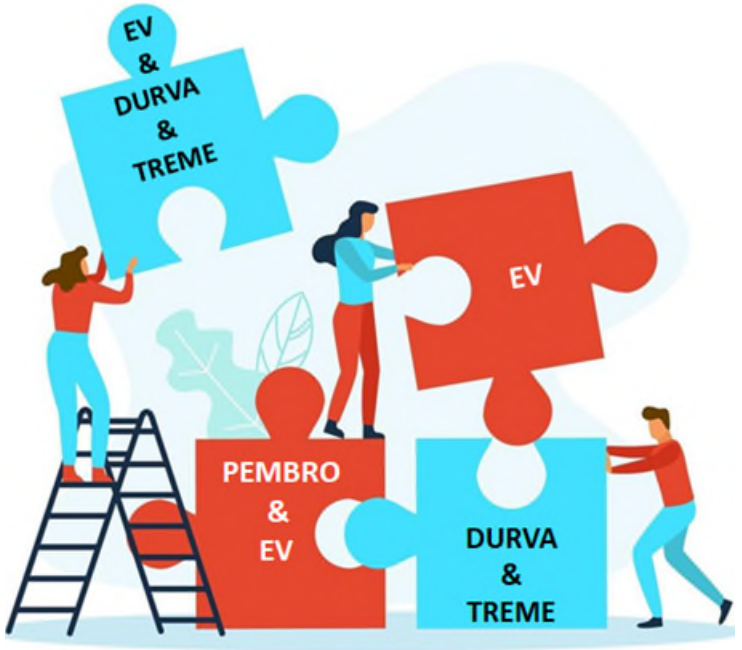
# Response rates for Durvalumab vs Durvalumab/Tremilimumab vs Chemo in front line Urothelial Cancer (DANUBE trial)



# BUILDING UP0N PAST KNOWLEDGE

- ✓ We know Durvalumab-Tremelimumab combo is Safe & Effective in Cisplatin Ineligible
- ✓ EV 103 coh H confirms Enfortumab Vedotin is also safe and effective in this population
- ✓ Durvalumab Adds to Tremelimumab
- ✓ Enfortumab Vedotin adds to PD-1 Therapy



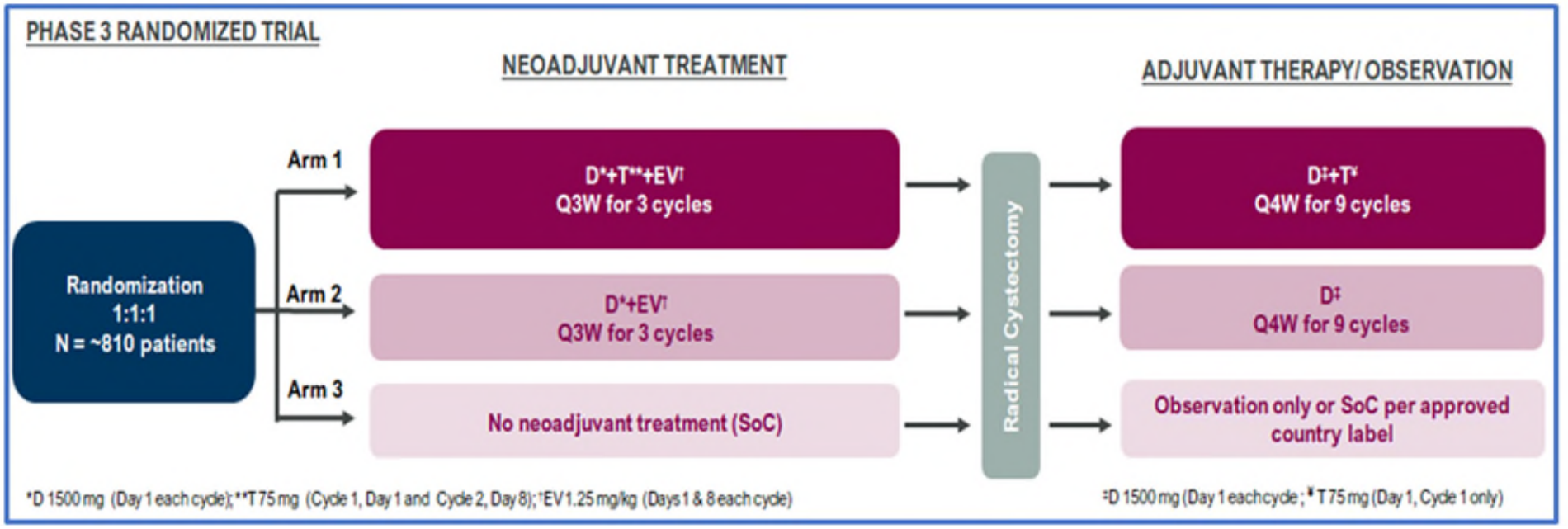

Let's Study a Triple Combination of

<u>Durvalumab/Tremelimumab/Enfortumab Vedotin</u>

in the Neoadjuvant setting

NEOADJUVANT

# Phase 3 Study of Durvalumab (D) + Tremelimumab (T) + Enfortumab Vedotin (EV) or D + EV In Neoadjuvant Cisplatin-Ineligible Muscle-Invasive Bladder Cancer (VOLGA)




## Primary Endpoints

* Pathologic complete response
* Event-free survival (EFS)

## Secondary Endpoints

* OS, DSS, QOL
* Pathologic downstaging to <pT2N0M0
* Safety / Tolerability

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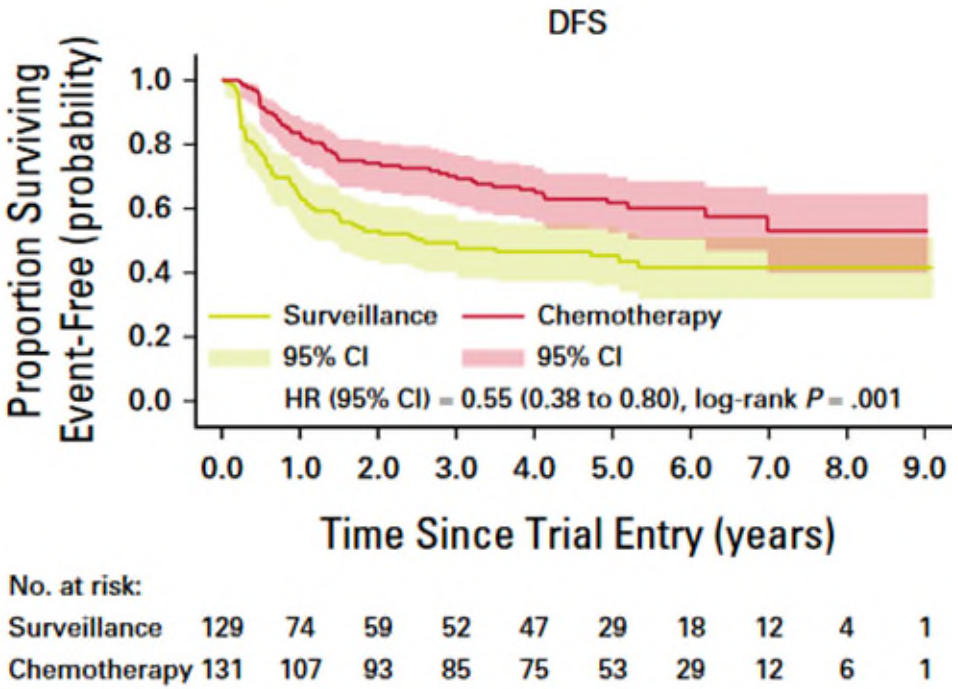
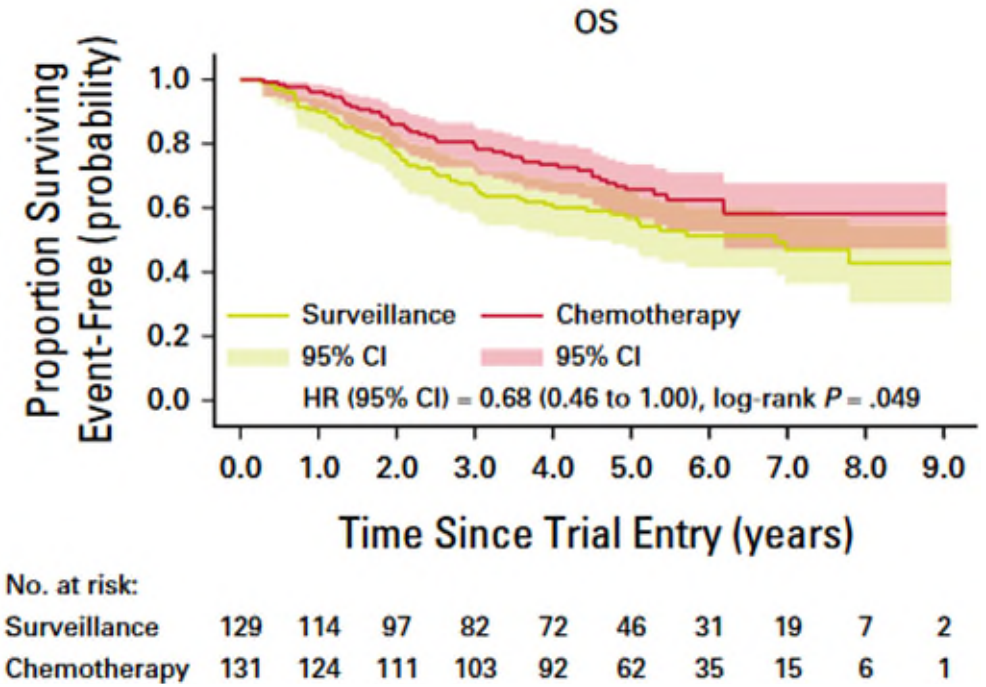
JOURNAL OF CLINICAL ONCOLOGY | Clinical Trial Updates

# Adjuvant Chemotherapy After Nephroureterectomy for Upper Tract Urothelial Cancer: Final Results of the POUT Trial

*Britle et al, JCO 2024*




5-yr DFS **62%** Chemo vs **45%** Surveillance
HR = 0.55 (95% CI, 0.38 to 0.80, P = .001)

5-yr OS **66%** Chemo vs **57%** Surveillance
HR = 0.68 (95% CI, 0.46 to 1.00, P 5 .049)

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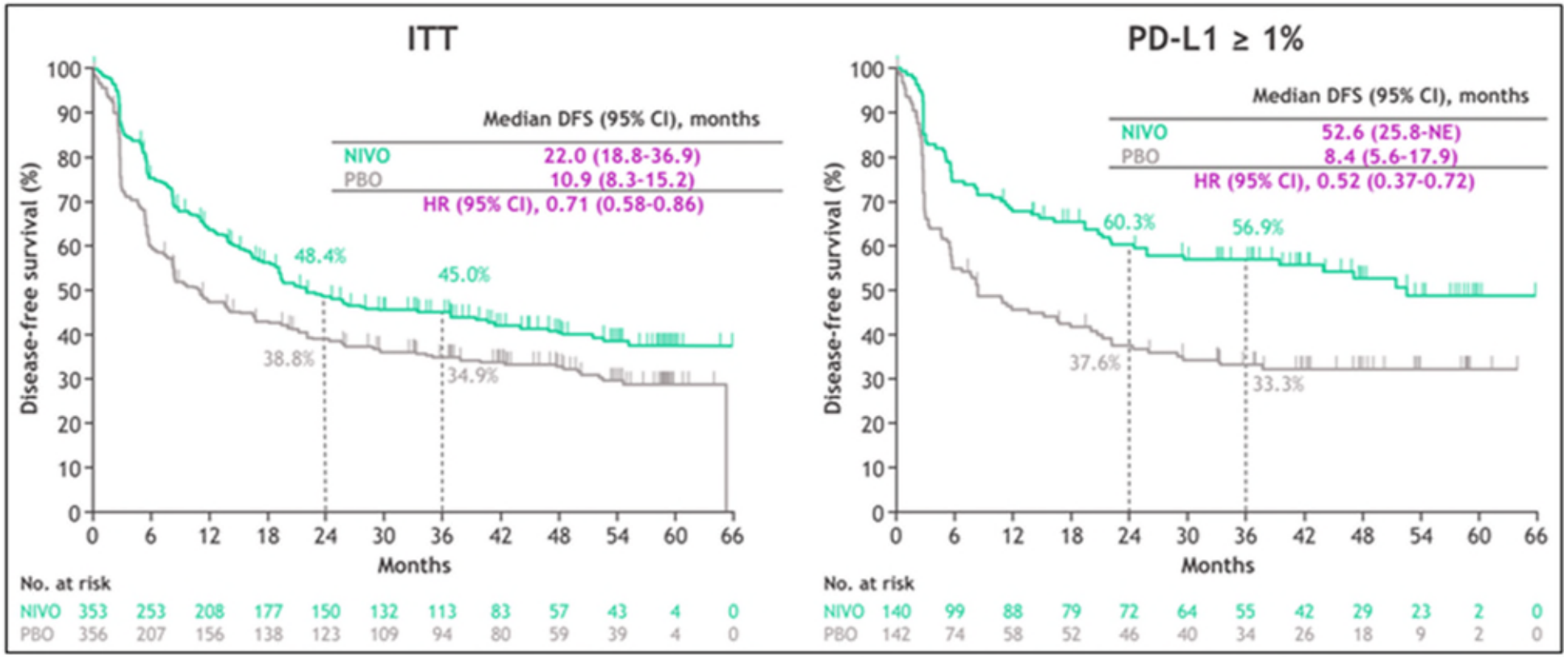
The NEW ENGLAND JOURNAL of MEDICINE

# Adjuvant Nivolumab versus Placebo in Muscle-Invasive Urothelial Carcinoma

Bajorin et al, June 3, 2021




GU ASCO 2023

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*UPDATES*
*GU ASCO 2024*

# AMBASSADOR: Phase 3 Randomized Adjuvant Study of Pembrolizumab in Muscle-Invasive and Locally Advanced Urothelial Carcinoma (MIUC) vs Observation

## Key Eligibility

- Muscle-invasive urothelial carcinoma: bladder, urethra, renal pelvis, ureter
- Post-radical surgery (cystectomy, nephrectomy, nephroureterectomy, or ureterectomy) ≥ 4 but ≤ 16 weeks
- Post-neoadjuvant chemotherapy and ≥ pT2 and/or N+/+margins

OR

- cisplatin-ineligible or refusing and ≥ pT3 and/or pN+/+margins

## Stratify

- PD-L1 status*
- Neoadjuvant chemotherapy yes/no
- Pathologic stage:
  - pT2/3/4aN0
  - pT4aN0
  - pT4bNx/N1-3
  - +surgical margins

**N=739**

**R 1:1**

Pembrolizumab
200 mg q3W
1 year (18 cycles)

Observation

## Dual Primary Endpoints

- **Disease-free survival**
- **Overall survival**

Key Secondary Endpoints
- DFS/OS PD-L1 +/-
- Safety

Correlative Endpoints
- DFS/OS ctDNA +/-
- DFS/OS immune gene signatures
- DFS/OS tumor molecular subtype
- DFS/OS TCR clonality
- QOL

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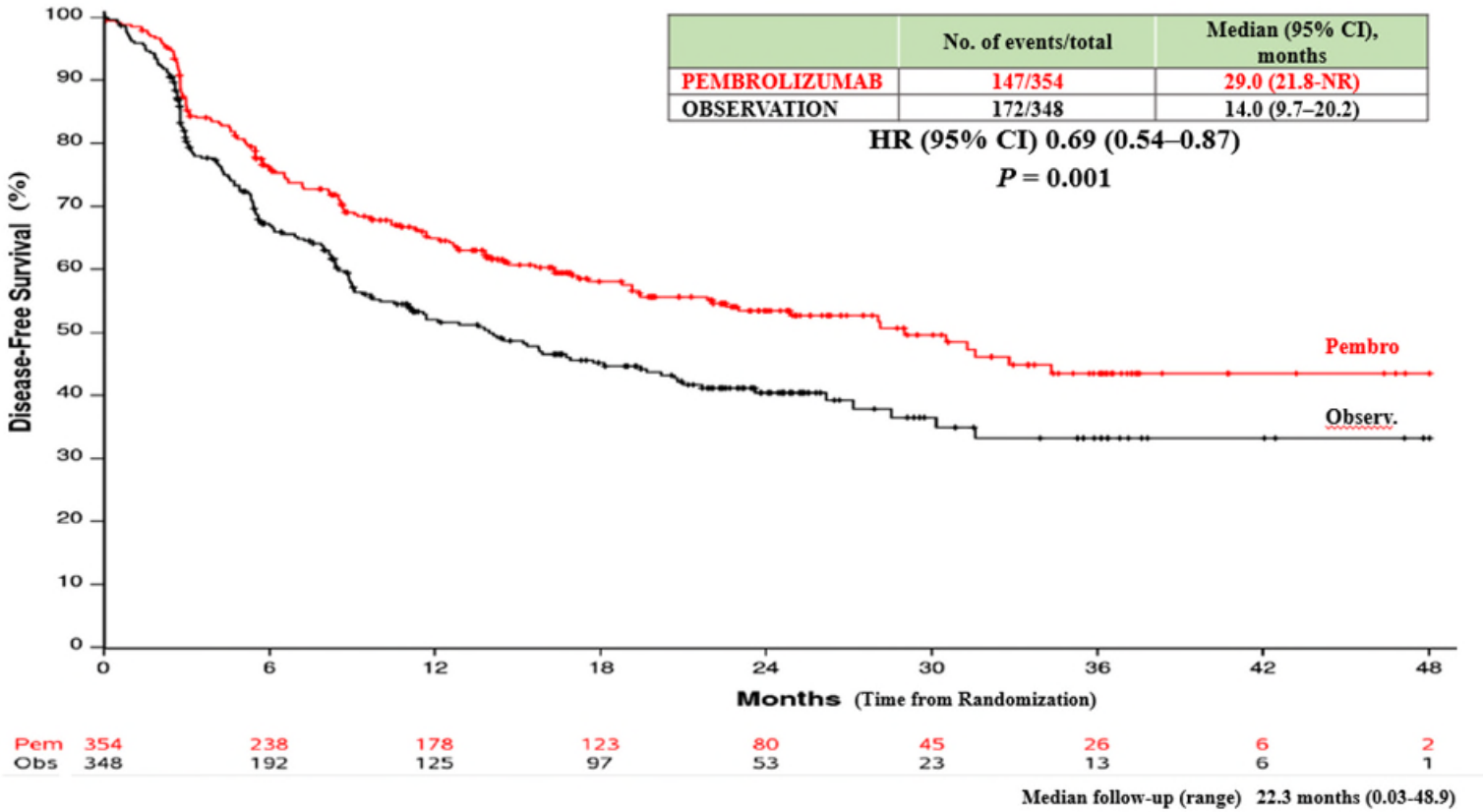
# AMBASSADOR: Adjuvant Pembrolizumab in Muscle-Invasive and Locally Advanced Urothelial Carcinoma (MIUC) vs Observation

## DISEASE FREE SURVIVAL



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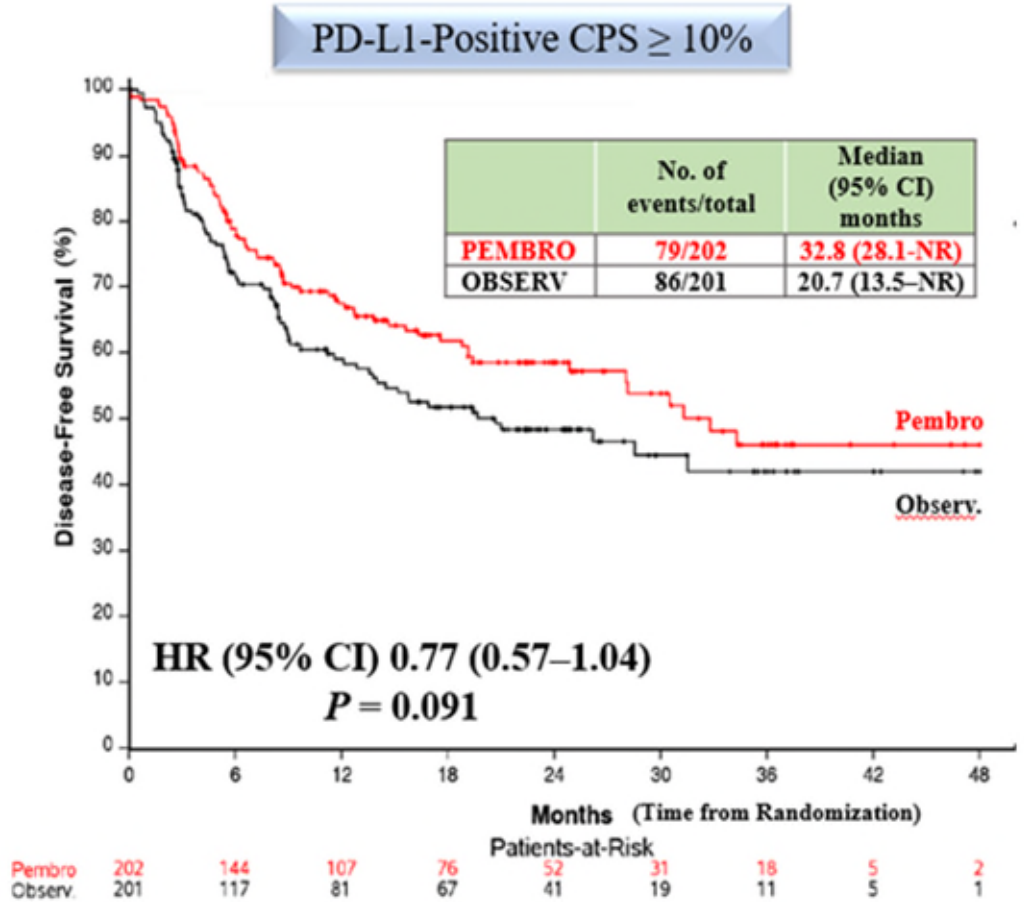
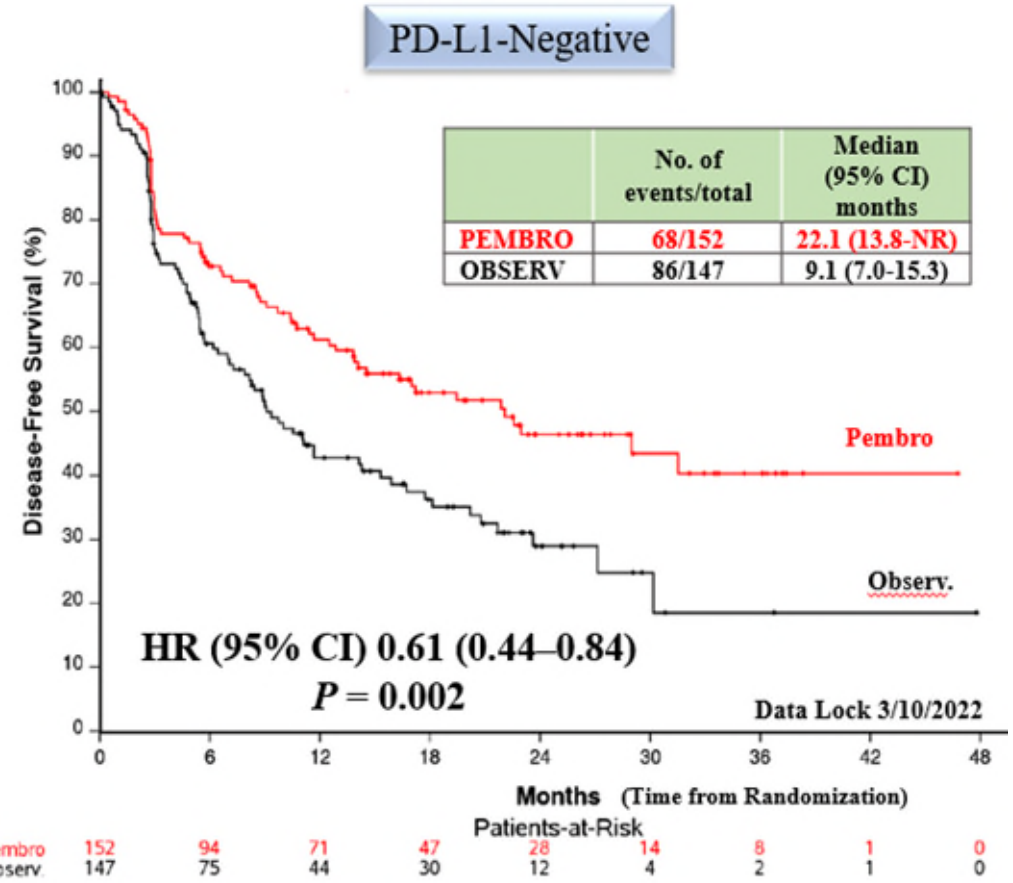
# AMBASSADOR: Adjuvant Pembrolizumab in Muscle-Invasive and Locally Advanced Urothelial Carcinoma (MIUC) vs Observation

## DISEASE FREE SURVIVAL PER PD-L1 STATUS



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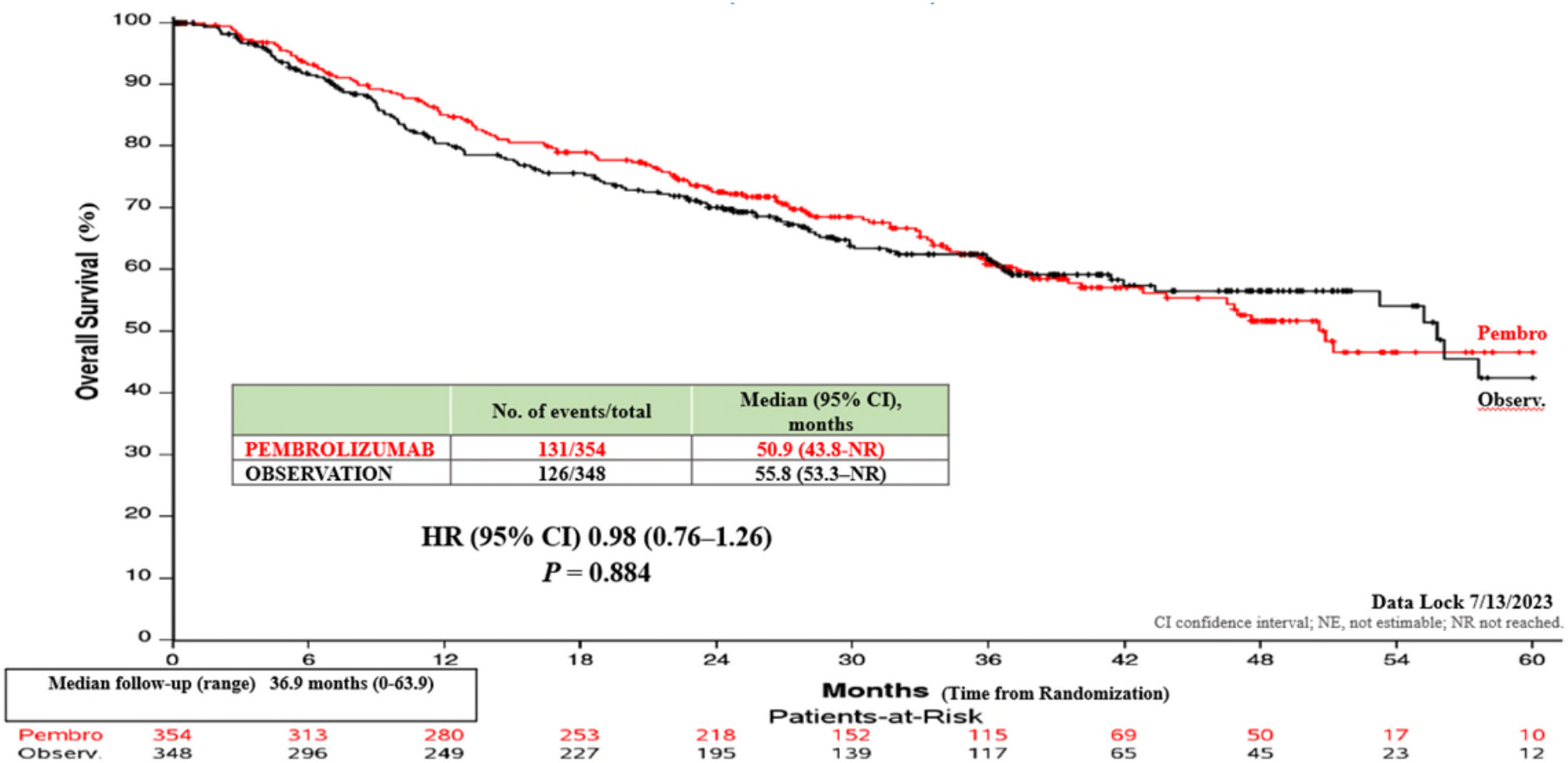
# AMBASSADOR: Adjuvant Pembrolizumab in Muscle-Invasive and Locally Advanced Urothelial Carcinoma (MIUC) vs Observation

## OVERALL SURVIVAL



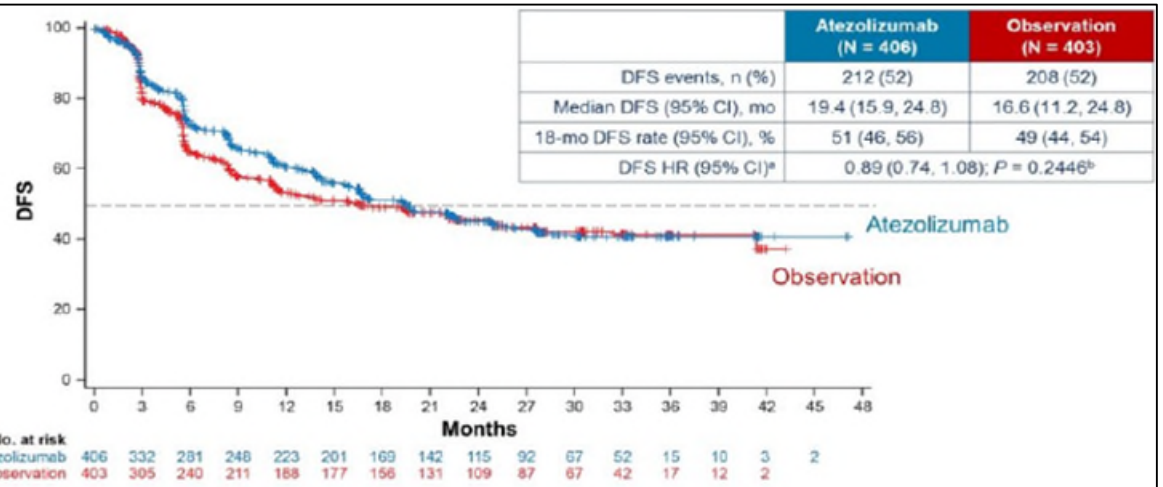
ADJUVANT

# ADJUVANT CLINICAL TRIAL
## Lessons from the past

**Adjuvant atezolizumab versus observation in muscle-invasive urothelial carcinoma (IMvigor010): a multicentre, open-label, randomised, phase 3 trial**

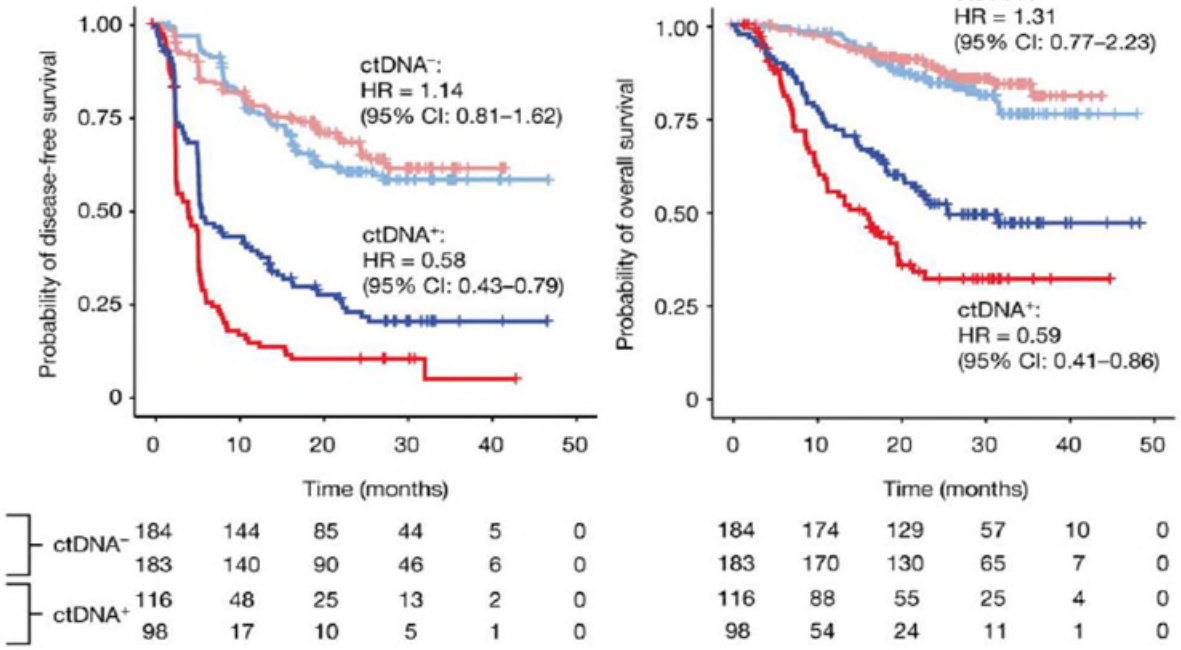
Bellmunt J, Hussain M, Gschwend J, Albers P, Oudard S, Castellano D, Deneschmand S, Grivas P, Drakaki A, O'Donnell P, Rosenberg J, Geynisman D, Petrylak D, Hoffman-Censits J, Zakharia Y, Van der Heijen M, Stendberg C, Davarpanah N, Powles T, IMvigor010 Study group

Lancet Oncol. 2021




| | Atezolizumab (N = 406) | Observation (N = 403) |
|---|---|---|
| DFS events, n (%) | 212 (52) | 208 (52) |
| Median DFS (95% CI), mo | 19.4 (15.9, 24.8) | 16.6 (11.2, 24.8) |
| 18-mo DFS rate (95% CI), % | 51 (46, 56) | 49 (44, 54) |
| DFS HR (95% CI)[a] | 0.89 (0.74, 1.08); P = 0.2446[b] | |

**Atezolizumab was NOT associated with DFS**




| | DFS (mo) | OS(mo) |
|---|---|---|
| ct DNA+ | | |
| Atezolizumab | 5.9 | 25.8 |
| Observation | 4.4 | 15.8 |

*Powles T. et al, Nature 2021*

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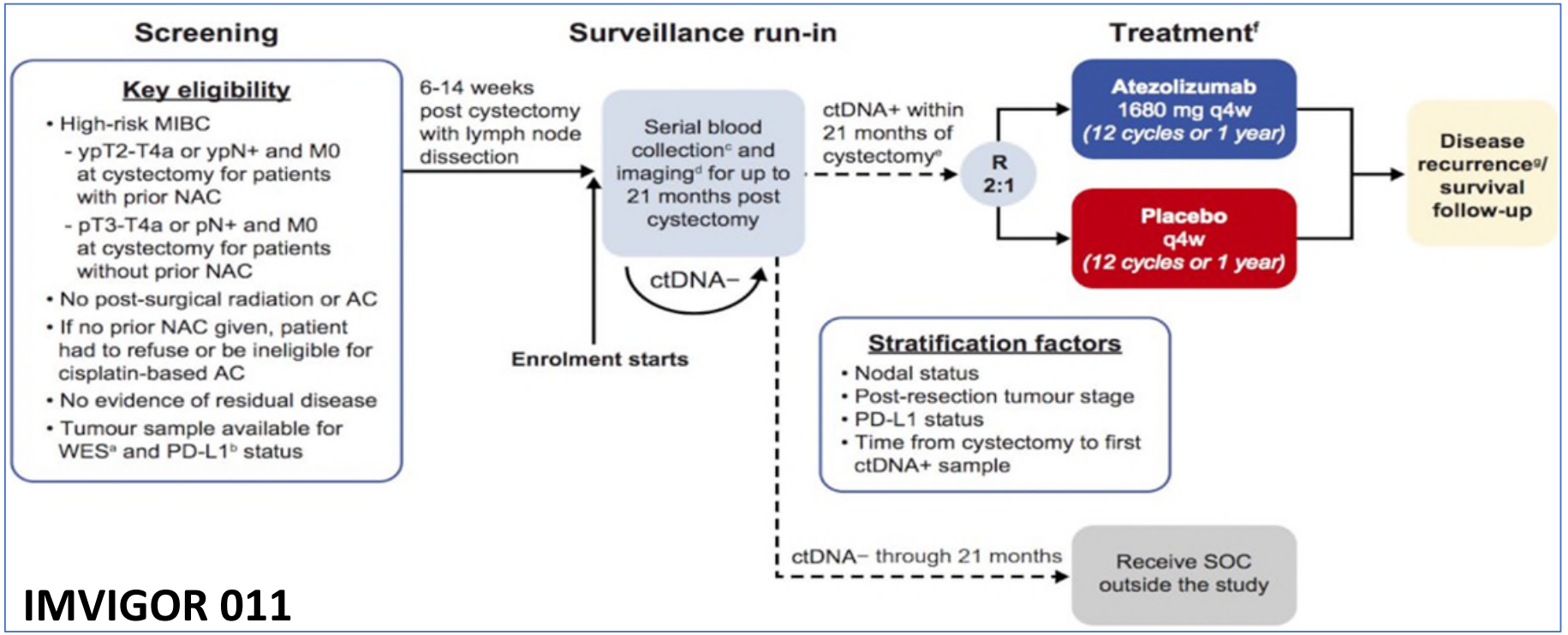
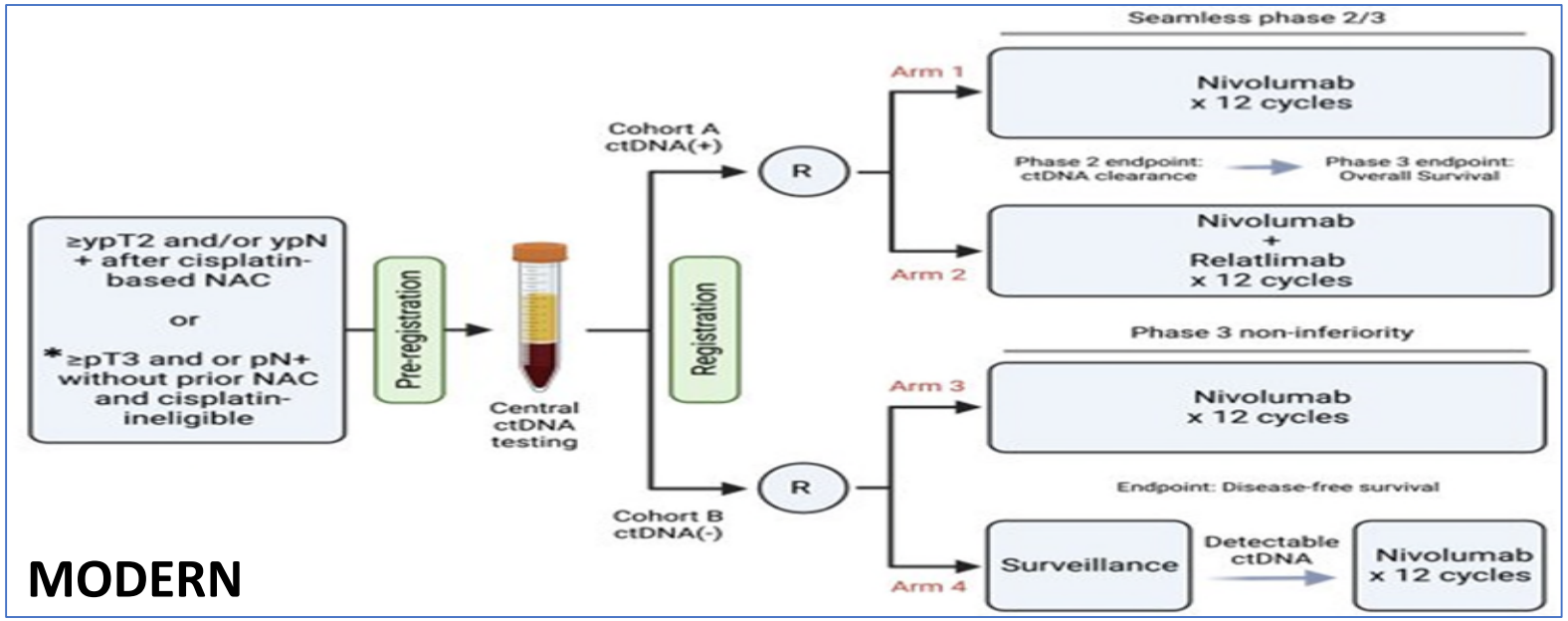
*MAKING HISTORY*




**IMVIGOR 011**

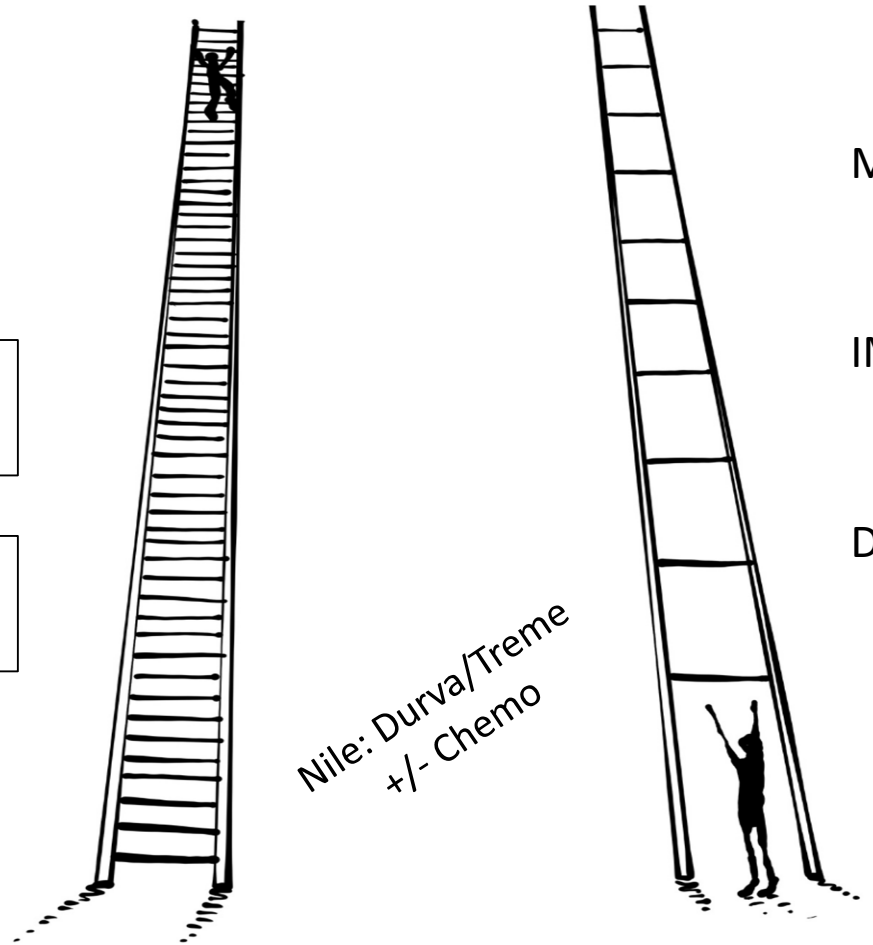



**MODERN**

# Treating Metastatic Bladder Cancer
# a 10 year journey


EV 302 : Enfortumab Vedotin & Pembro vs cis/carbo & gem

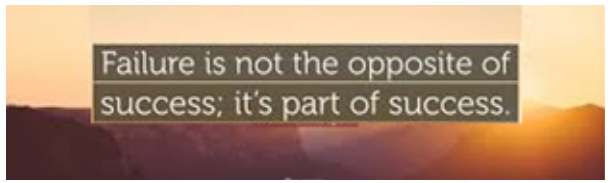
Checkmate 901 : Cis/Gem vs Nivolumab & Cis/Gem




Merck 361 : Pembrolizumab & Chemo vs Pembro vs Chemo

IMVIGOR 130: Atezolizumab & Chemo vs Chemo vs Atezo

DANUBE: Durvalumab & Tremelimumab vs Durvalumab vs Chemo



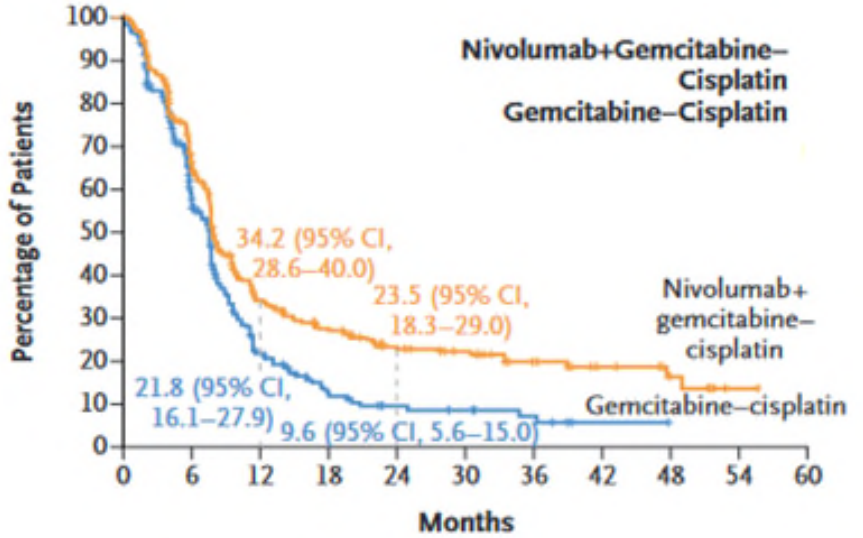
FIRST LINE

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

# Nivolumab plus Gemcitabine–Cisplatin in Advanced Urothelial Carcinoma

**Progression-free Survival**

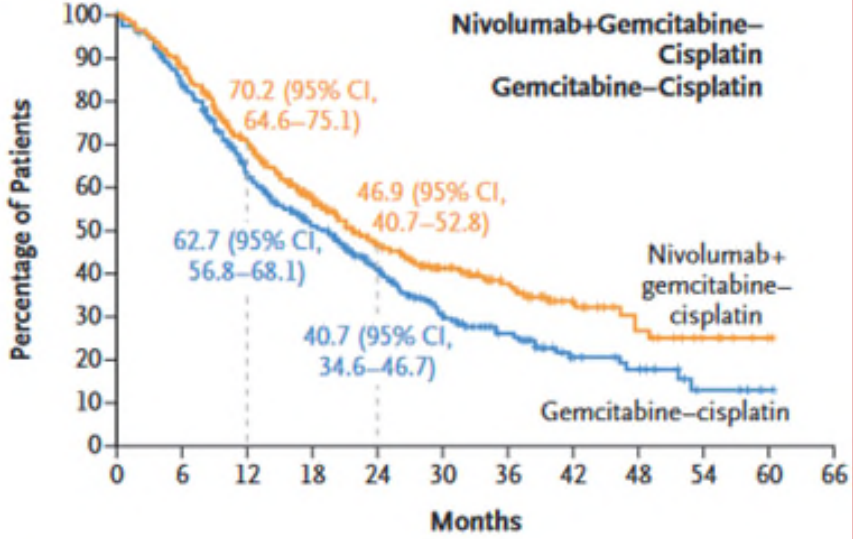



| No. at Risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab+gemcitabine–cisplatin | 304 | 179 | 82 | 57 | 41 | 31 | 19 | 11 | 6 | 1 | 0 |
| Gemcitabine–cisplatin | 304 | 119 | 35 | 17 | 10 | 8 | 5 | 1 | 0 | 0 | 0 |

| No. of Events/ No. of Patients | Median Progression-free Survival (95% CI) |
|---|---|
| | *mo* |
| 211/304 | 7.9 (7.6–9.5) |
| 191/304 | 7.6 (6.1–7.8) |

Hazard ratio for disease progression or death, 0.72 (95% CI, 0.59–0.88)
P=0.001

**Overall Survival**



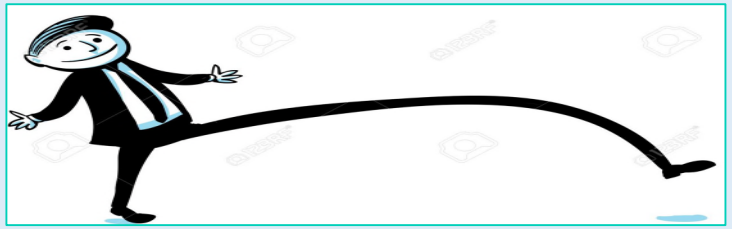

| No. at Risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab+gemcitabine–cisplatin | 304 | 264 | 196 | 142 | 97 | 69 | 48 | 25 | 15 | 7 | 2 | 0 |
| Gemcitabine–cisplatin | 304 | 242 | 166 | 122 | 82 | 49 | 33 | 17 | 13 | 4 | 1 | 0 |

| No. of Events/ No. of Patients | Median Overall Survival (95% CI) |
|---|---|
| | *mo* |
| 172/304 | 21.7 (18.6–26.4) |
| 193/304 | 18.9 (14.7–22.4) |

Hazard ratio for death, 0.78 (95% CI, 0.63–0.96)
P=0.02

FIRST LINE

# Big Step Forward!



## EV-302 A Phase III study of Enfortumab Vedotin & Pembrolizumab vs Gemcitabine + Cisplatin / Carboplatin

Treatment Naïve
**Metastatic Urothelial Cancer**

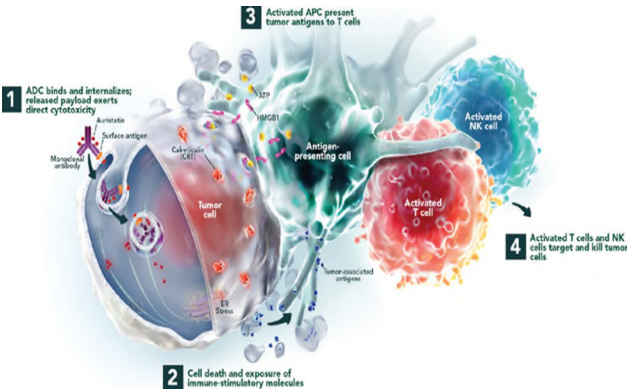
- Cisplatin Eligible/Ineligible
- PDL1 +/-

Randomization 1:1
**1095 patients**

**Arm A**
Enfortumab vedotin (Days 1 and 8)
+ Pembro (Day 1)

**Arm B**
Gemcitabine (Days 1 and 8)
+ Cisplatin/Carboplatin (Day 1)

**Practice Changing**

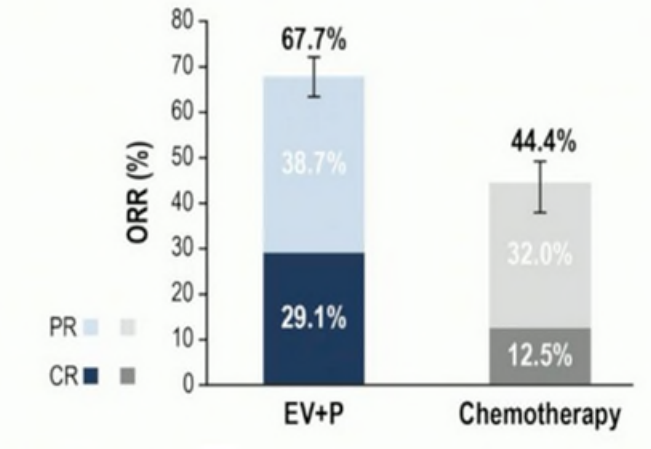


FIRST LINE

# EV-302 A Phase III study of Enfortumab Vedotin & Pembrolizumab vs Gemcitabine + Cisplatin / Carboplatin

## Confirmed Overall Response per BICR

Significant improvement in objective response rate was observed with EV+P




| | EV+P (N=437) | Chemotherapy (N=441) |
|---|---|---|
| **Confirmed ORR, n (%) (95% CI)** | **296 (67.7) (63.1-72.1)** | **196 (44.4) (39.7-49.2)** |
| **2-sided P value** | <0.00001 | |
| **Best overall response[a], n (%)** | | |
| Complete response | 127 (29.1) | 55 (12.5) |
| Partial response | 169 (38.7) | 141 (32.0) |
| Stable disease | 82 (18.8) | 149 (33.8) |
| Progressive disease | 38 (8.7) | 60 (13.6) |
| Not evaluable/No assessment[b] | 21 (4.8) | 36 (8.2) |
| **Median DOR (95% CI)** | NR (20.2, NR) | 7.0 (6.2, 10.2) |

FIRST LINE

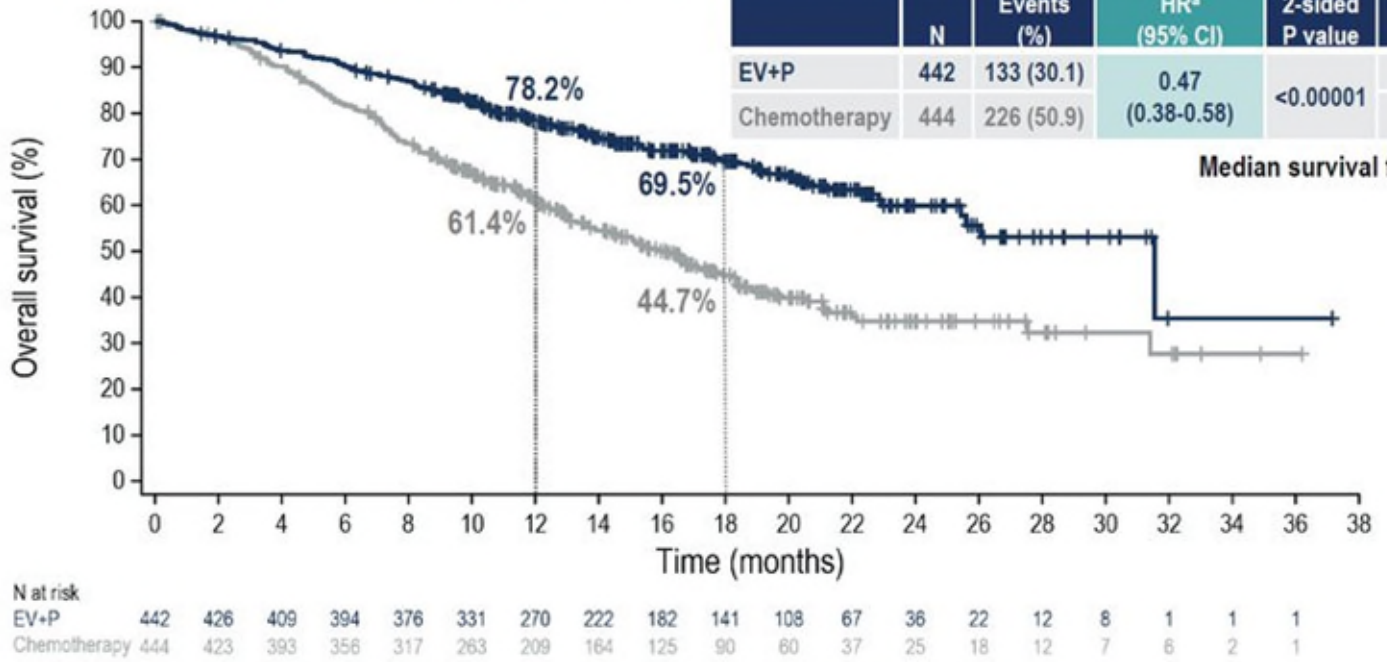
# EV-302 A Phase III study of Enfortumab Vedotin & Pembrolizumab vs Gemcitabine + Cisplatin / Carboplatin

## Overall Survival

Risk of death was reduced by 53% in patients who received EV+P

| | N | Events (%) | HR[a] (95% CI) | 2-sided P value | mOS (95% CI), months |
|---|---|---|---|---|---|
| EV+P | 442 | 133 (30.1) | 0.47 (0.38-0.58) | <0.00001 | 31.5 (25.4-NR) |
| Chemotherapy | 444 | 226 (50.9) | | | 16.1 (13.9-18.3) |

Median survival follow-up: 17.2 months



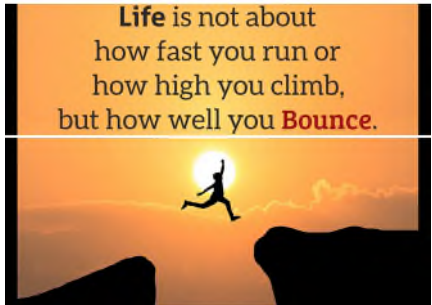

Data cutoff: 08 Aug 2023

OS at 12 and 18 months was estimated using Kaplan-Meier method
mOS, median overall survival; NR, not reached
[a]Calculated using stratified Cox proportional hazards model. A hazard ratio <1 favors the EV+P arm

MADRID 2023 ESMO congress

Powles et al.



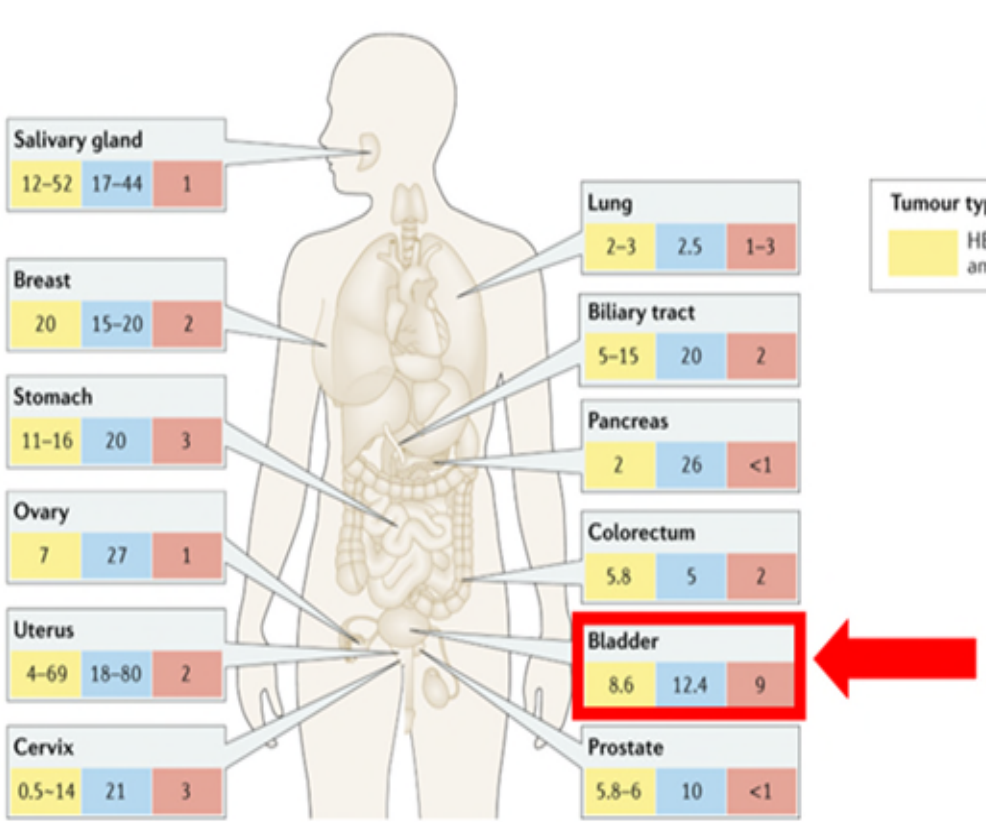


UCLA Health

October 18, 2023

# 25 years of Herceptin: A groundbreaking advancement in breast cancer treatment

This year marks the 25th anniversary of the FDA approval of the first gene-based drug for cancer, developed by UCLA's Dr. Dennis Slamon



# Phase 2 Study Evaluating the Efficacy & Safety of Disitamab Vedotin in HER-2 expressing Urothelial Ca

Koshkin V, Powles T, Iyer G, Loriot Y, Drakaki A, Duran I,De Santis M, Retz M, Jain R, Chan S, Ichimaru M, Galsky M

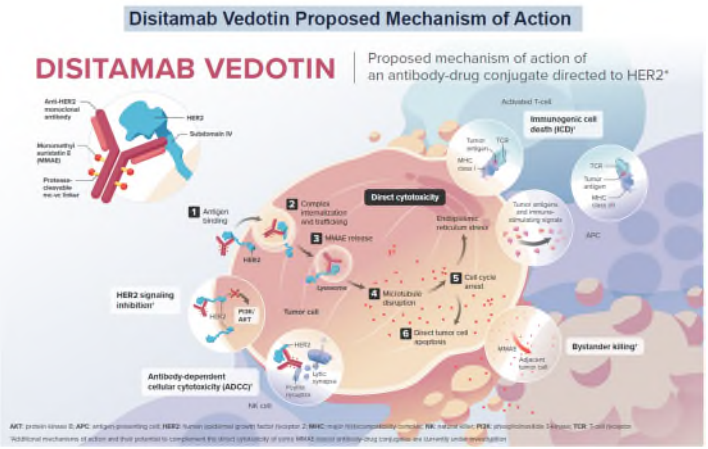
ESMO congress

# Phase 2 Study Evaluating efficacy and safety of Disitimab Vedotin with or without Pembrolizumab in patients with Her2 Urothelial Cancer

Matsubara N, Powles T, Rosenberg J, Koshkin V, Brown J, Aragon-Ching J,Drakaki A, O'Donnell P, Yu E, Campbella M, Krieger L, Chan S, Sokolowski K, Galsky M.

Japan Society of Clinical Oncology

- ✓ HER-2 overexpression correlates with poor outcome in UC
- ✓ No HER-2 directed tx approved for UC in USA
- ✓ Phase1B/II DV in HER2 expressing UC : ORR of 51 %
- ✓ DV has breakthrough designation in China for gastric and UC
- ✓ DV & Pembro in HER2 untreated UC




## Study Design

PHASE 2 • OPEN-LABEL • MULTICENTER

**Eligibility**
- LA/mUC*
- Prior anti-PD(L)1 allowed
- No prior anti-HER2 agents or MMAE ADC
- Cohorts A, B:
  - 1–2 lines of prior therapy
  - Prior platinum-containing chemotherapy
- Cohort C:
  - No prior systemic therapy for LA/mUC

**Cohort A** HER2+ (n=75)

**Cohort B** HER2-low (n=75)

**Cohort C** HER2+/HER2-low (n=120)

Single arm DV + pembrolizumab (n=20)

DV

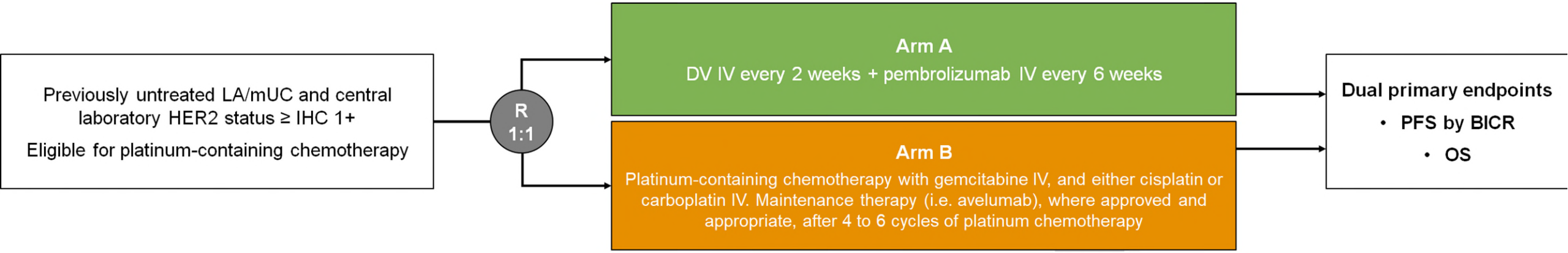
DV + pembrolizumab (n=50)

DV (n=50)

**Primary Endpoint**
- cORR by BICR

**What's Next**

# Phase 3 open-label, randomized, controlled study of disitamab vedotin with pembrolizumab versus chemotherapy in untreated locally advanced or metastatic urothelial carcinoma that expresses HER2 (DV-001; Trial in Progress).

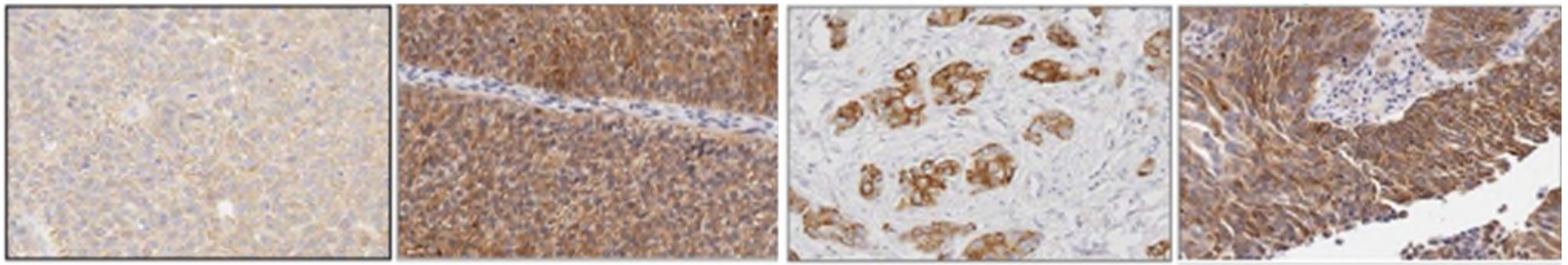


What's Next

# Enfortumab Vedotin Antibody–Drug Conjugate Targeting Nectin-4 Is a Highly Potent Therapeutic Agent in Multiple Preclinical Cancer Models

Challita-Eid et al, Cancer Res 2016

| | | H-Score * | | | |
|---|---|---|---|---|---|
| Cancer type | Overall positive (%) | Strong | Moderate | Low | Negative |
| Bladder (*N* = 524) | 83 | 162 (31) | 154 (29) | 118 (23) | 90 (17) |
| Breast (*N* = 654) | 78 | 174 (27) | 168 (26) | 170 (26) | 142 (22) |
| Pancreatic (*N* = 164) | 71 | 21 (13) | 39 (24) | 56 (34) | 48 (29) |
| Lung (*N* = 618) | 55 | 46 (7) | 121 (20) | 173 (28) | 278 (45) |
| Ovarian (*N* = 118) | 57 | 0 | 21 (18) | 46 (39) | 51 (43) |
| Head & Neck (*N* = 135) | 59 | 3 (2) | 22 (16) | 54 (40) | 56 (41) |
| Esophageal (*N* = 181) | 55 | 7 (4) | 37 (20) | 55 (30) | 82 (45) |
| **Total (*N* = 2,394)** | **69** | **413 (17)** | **562 (24)** | **672 (28)** | **747 (31)** |
| ** H-Score based on intensity of staining:* | | *200-300* | *100-199* | *15-99* | *0-14* |



Breast, H-score =110 | Bladder, H-score= 250 | Pancreatic, H-score=300 | Lung, H-score= 250

ONGOING

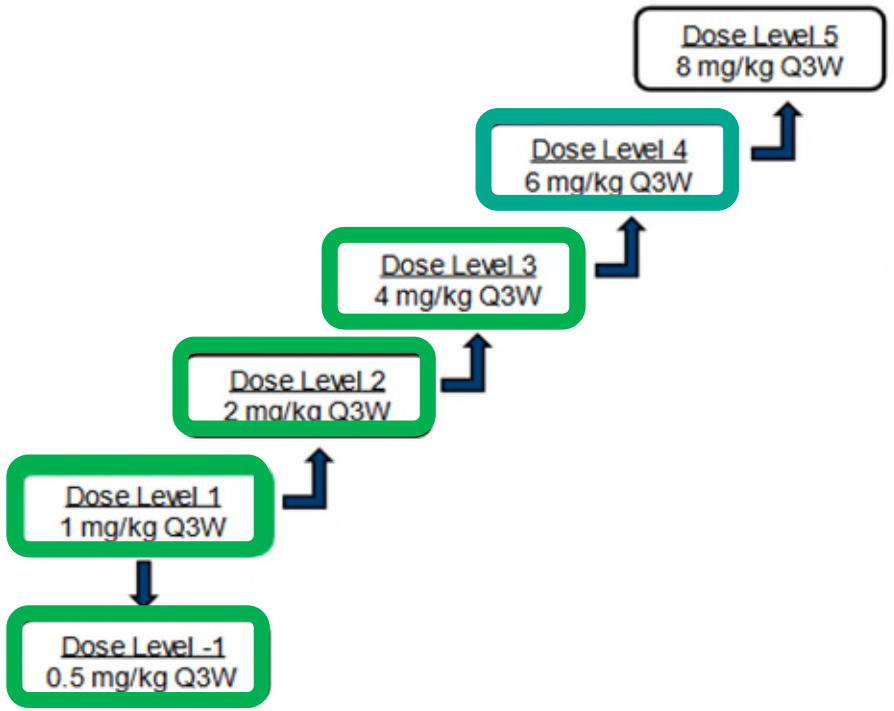
# A Study of ADRX-0706 in Select Advanced Solid Tumors

*ClinicalTrials.gov* NCT06036121

- Part A – **Dose Escalation** in patients with histologically confirmed select solid tumors
  - UC, HNSCC, breast, cervical, ovarian, NSCLC, pancreatic
- Part B - **Dose Expansion** in three disease-specific cohorts

## Phase 1a: BOIN Dose Escalation (N= 30 to 42)

*Select advanced solid tumors (urothelial, head and neck, breast, cervical, ovarian, non small cell lung, and pancreatic cancers)*




## Phase 1b: Dose Expansion (N = 72)

Cohort 1: 2L+ **HNSCC** (N=24)
N=12 at dose A
↓
N=12 at dose A or B

Cohort 2: 2L+ **Cervical Cancer** (N=24)
N=12 at dose A
↓
N=12 at dose A or B

Cohort 3: 2L+ **UC** (N=24)

3a: 2L+ UC (intolerant/refractory to prior Nectin-4 ADC)
N=6 at dose A → N=6 at dose A or B

3b: 2L+ UC (Nectin-4 ADC treatment naïve)
N=6 at dose A → N=6 at dose A or B

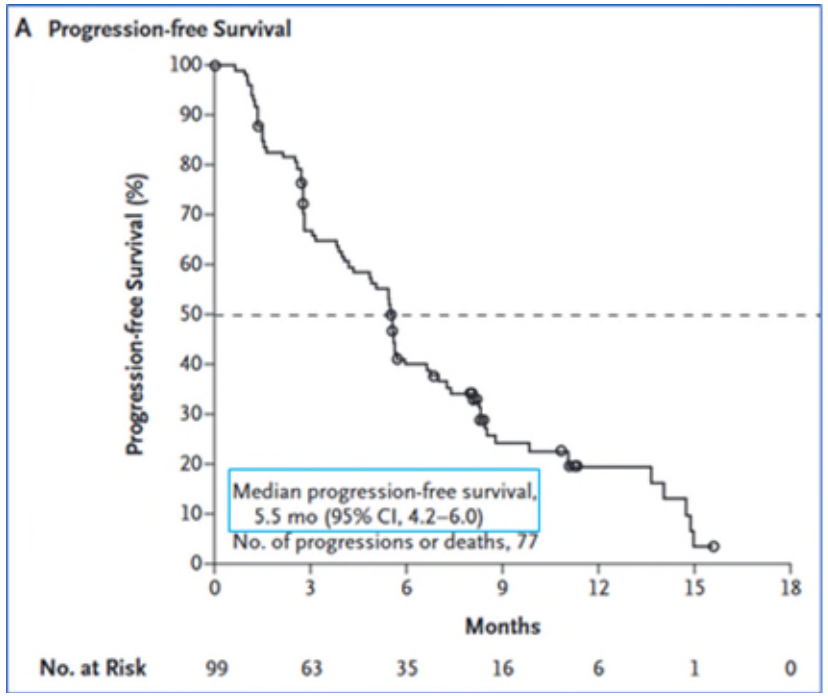
**Targeted *SOC***

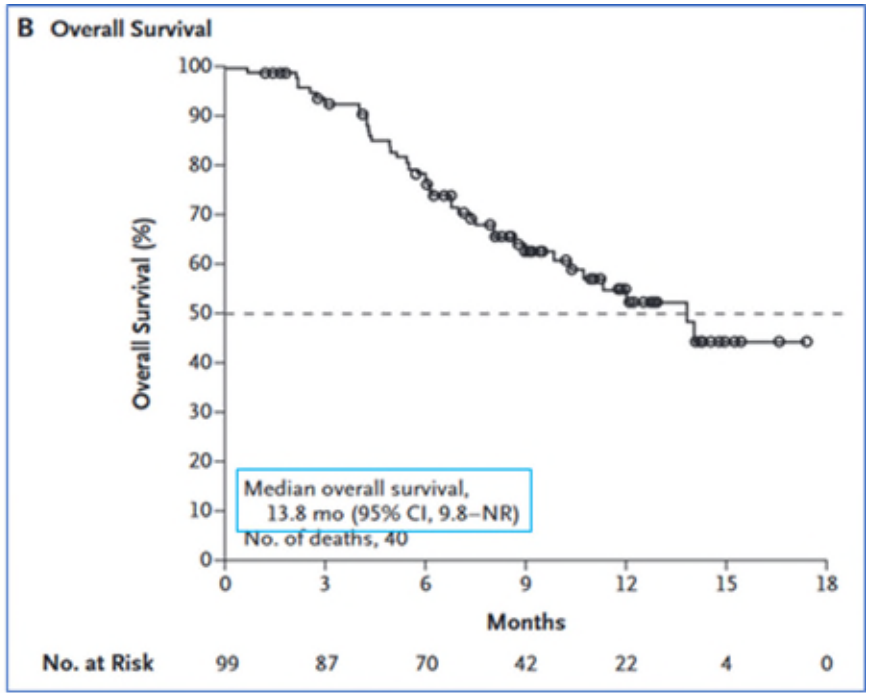
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

# Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma

*Activating mutations common (~86%) in low grade, early stage bladder tumors
*TCGA: ~12% with mutations in MIBC
*FGFR 3 mutations/fusions(~21%) in advanced UC, UTUC - high-grade, invasive
*ERDAFITINIB: oral, potent pan FGFR inhibitor
- 99 pts / 40% RR



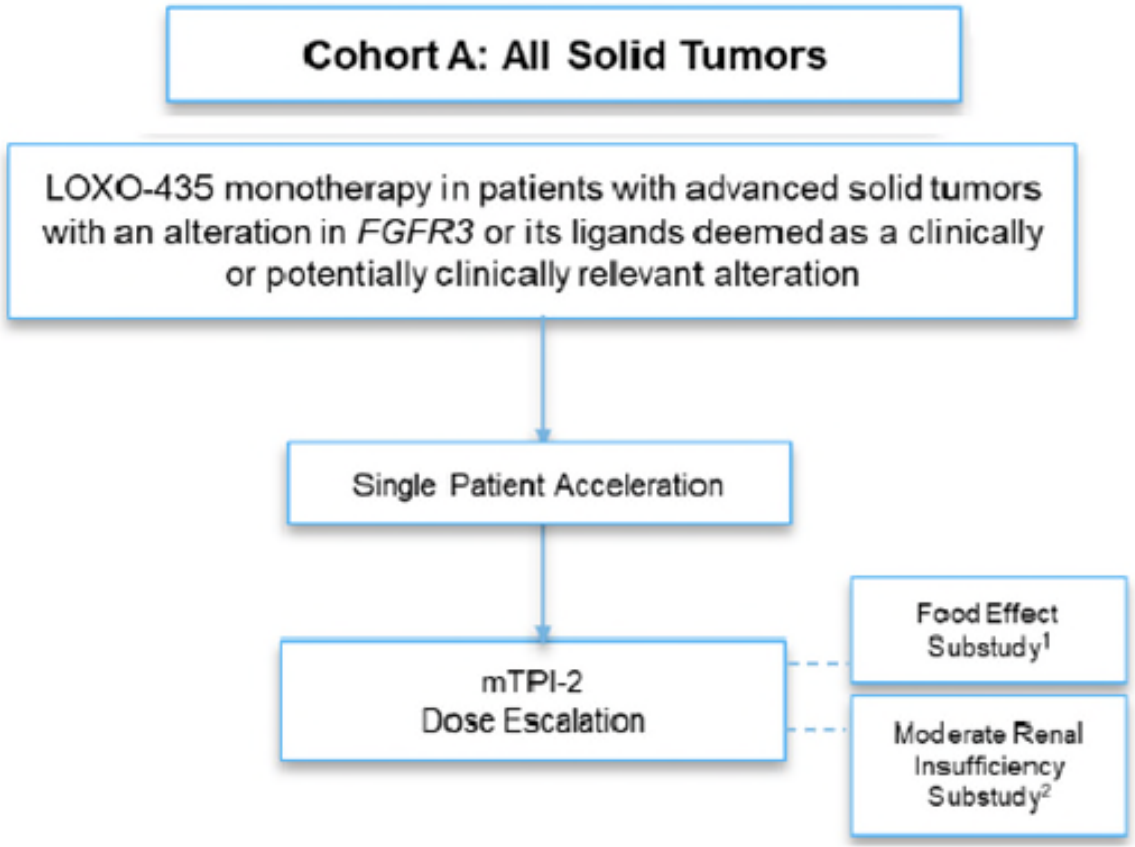



ONGOING

# LOXO-FG3-22001 : AN OPEN-LABEL, MULTICENTER STUDY OF LOXO-435 (LY3866288) IN ADVANCED SOLID TUMOR MALIGNANCIES WITH FGFR3 ALTERATIONS

## STUDY DESIGN

### PHASE 1A: DOSE ESCALATION



# GU ONCOLOGY PROGRAM: Meet the Team

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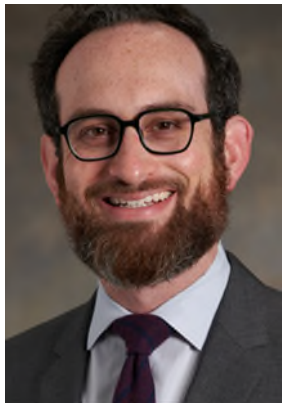
Alexandra Drakaki, MD, PhD



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Yuritzi Palma

**Research Assistants**
Parker Sundeen

**Data Managers**
Jaelyn Abad
Sam Xiong
Lucia Verdugo

Sometimes there is only one chance for

<u>CURE</u>

Let’s Make a Change Together

**Thank you**