2nd Annual Southern California Genitourinary Cancer Research Forum

Key Updates in Bladder Cancer

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Disclosures

- Grant/Research Support from Gilead Sciences.
- Consultant for AVEO Oncology, EMD Serono, and Pfizer.
- Speakers Bureau for Eisai, and Merck.

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.

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

STATE LAW:

The California legislature has passed <u>Assembly Bill (AB) 1195</u>, 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 <u>AB 241</u>, 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.

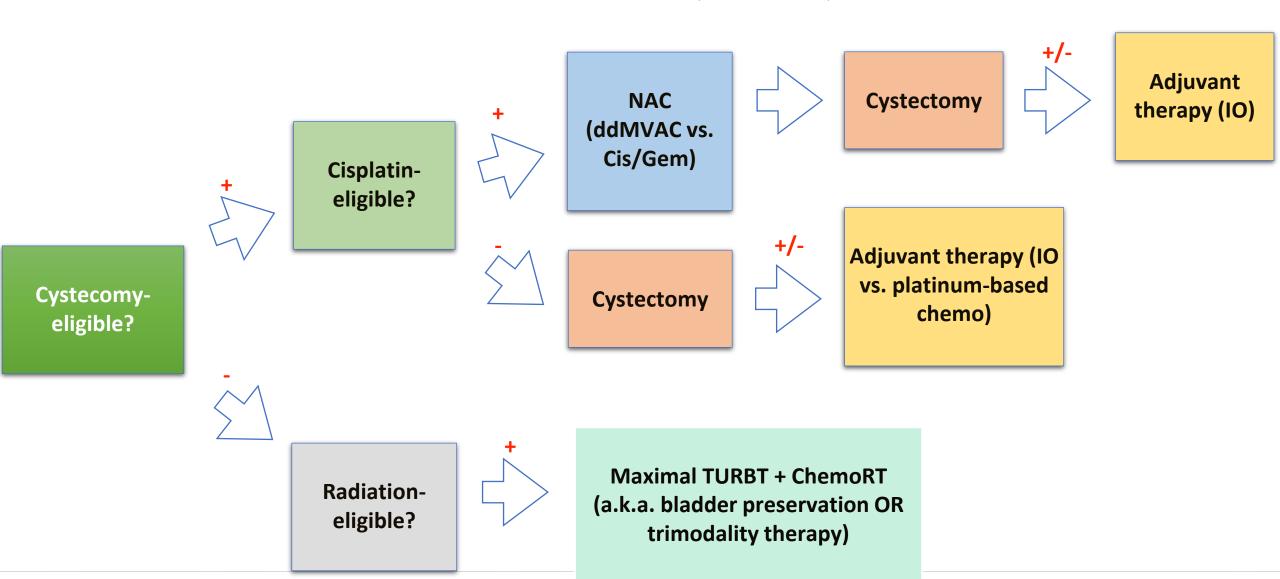
The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

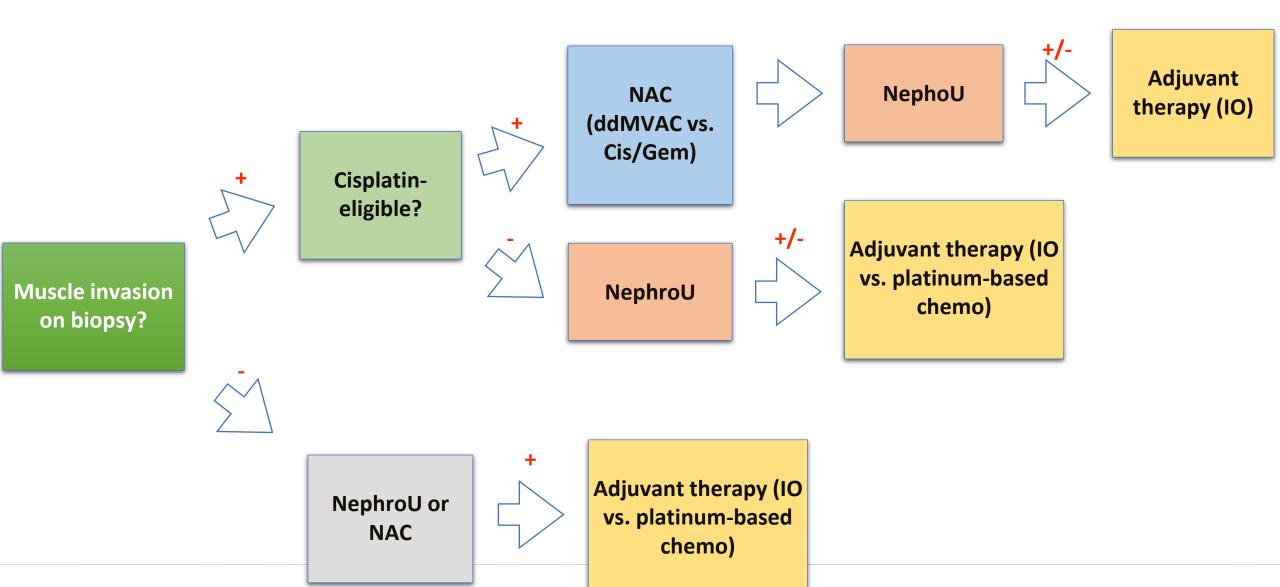
Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

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

Muscle-invasive bladder UC (mUC)



Non-metastatic upper tract UC



mUC - neoadjuvant / adjuvant space

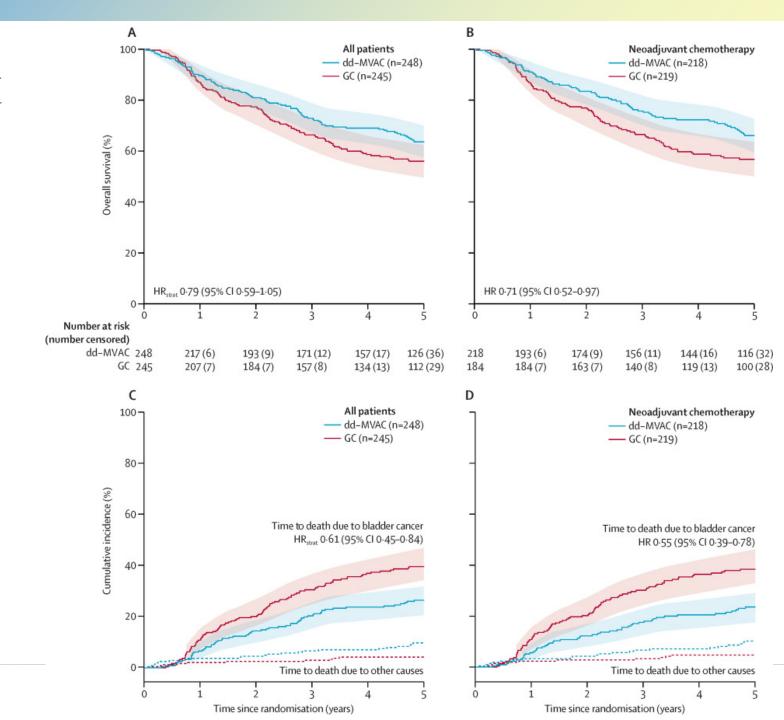
- Galsky criteria for Cisplatin ineligibility.
 - creatinine clearance of ≤60 ml/min
 - Eastern Cooperative Oncology Group (ECOG) status of ≥2
 - peripheral neuropathy ≥2 CTCAE grade
 - hearing loss ≥2 CTCAE grade
 - CHF history

Galsky MD, et al. JCO 2011.

mUC - neoadjuvant

VESPER trial

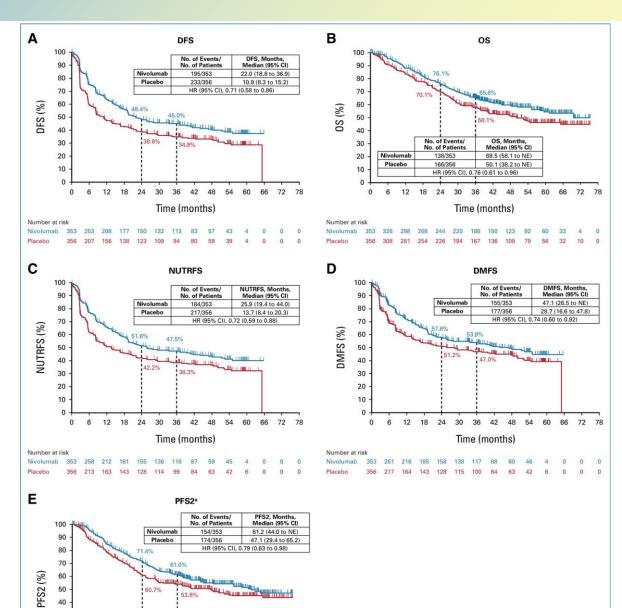
- randomized, phase 3
- Peri-operative ddMVACx6 vs. Cis/Gem (CG) x4.
- NAC given in 89% of CG pts and 88% of ddMVAC pts (rest got AC).



mUC - adjuvant space

- Definition of high risk
 - If NAC+, ypT2 / ypT3 / ypT4 / ypN+
 - If NAC -, pT3 / pT4 / pN+

- CheckMate 274 study
 - Randomized, phase 3
 - Nivolumab vs. placebo



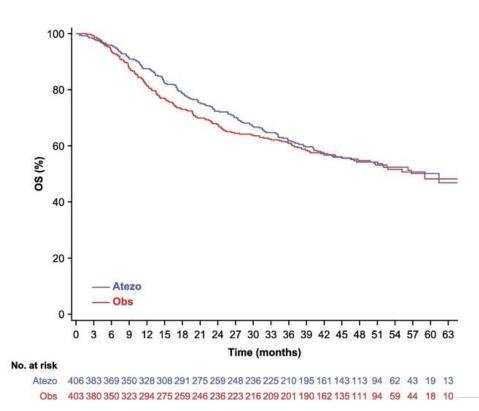
Time (months)

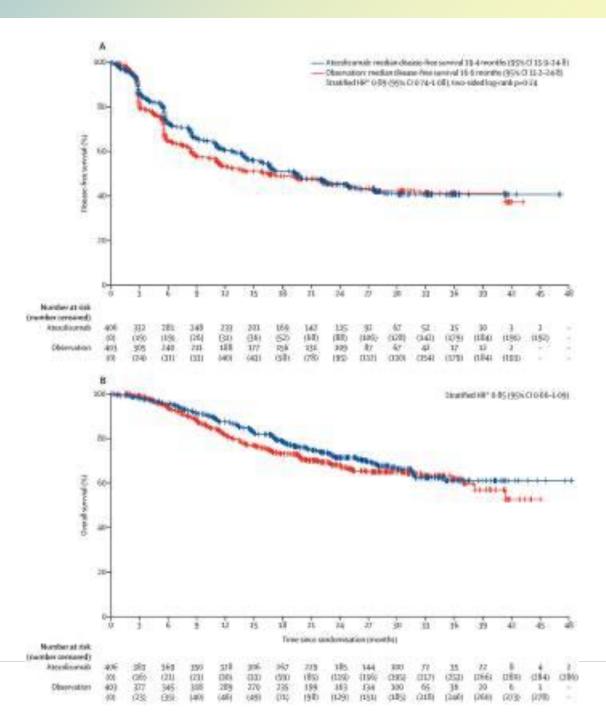
Nivolumab 353 325 286 254 230 203 176 138 111 83

mUC - adjuvant space

IMvigor 010 study

- Randomized, phase 3
- Atezolizumab vs. observation

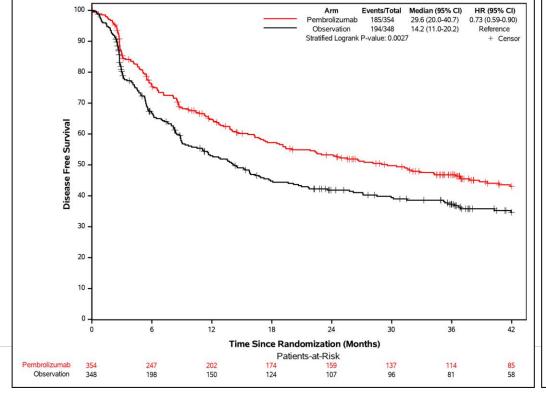


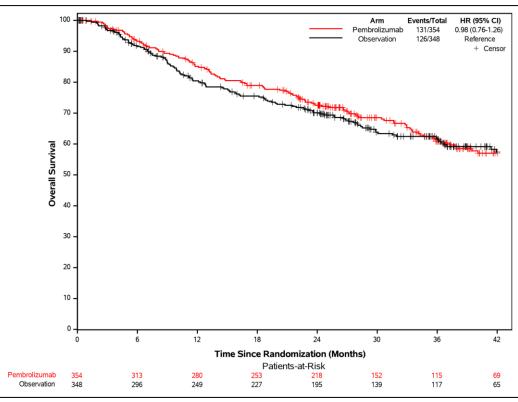


mUC - adjuvant space

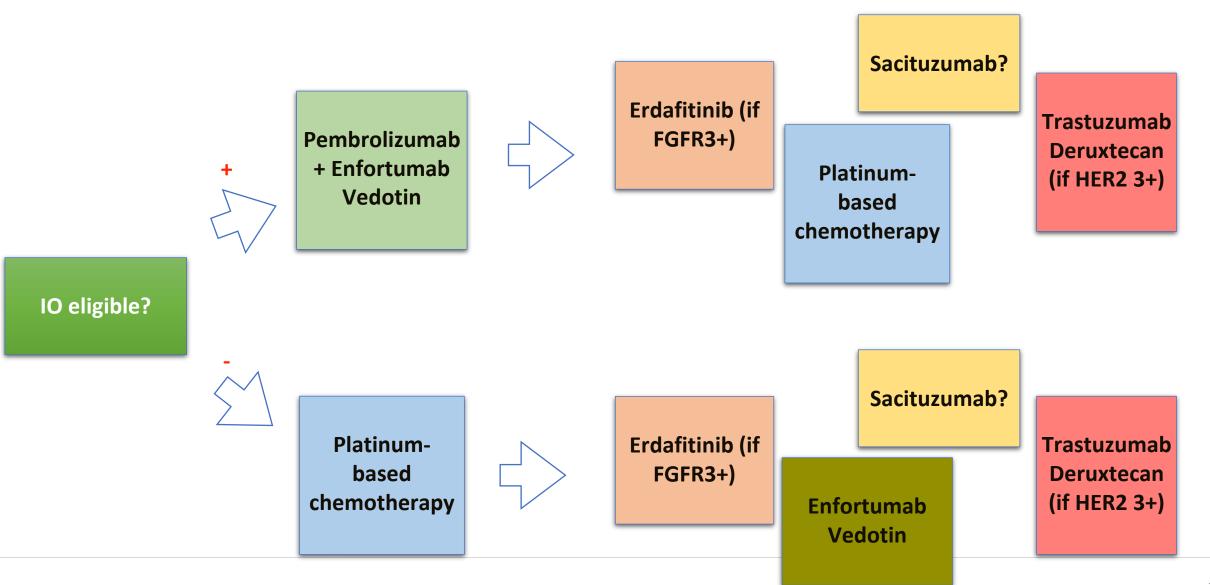
AMBASSADOR study

- Randomized, phase 3
- Pembrolizumab vs. observation

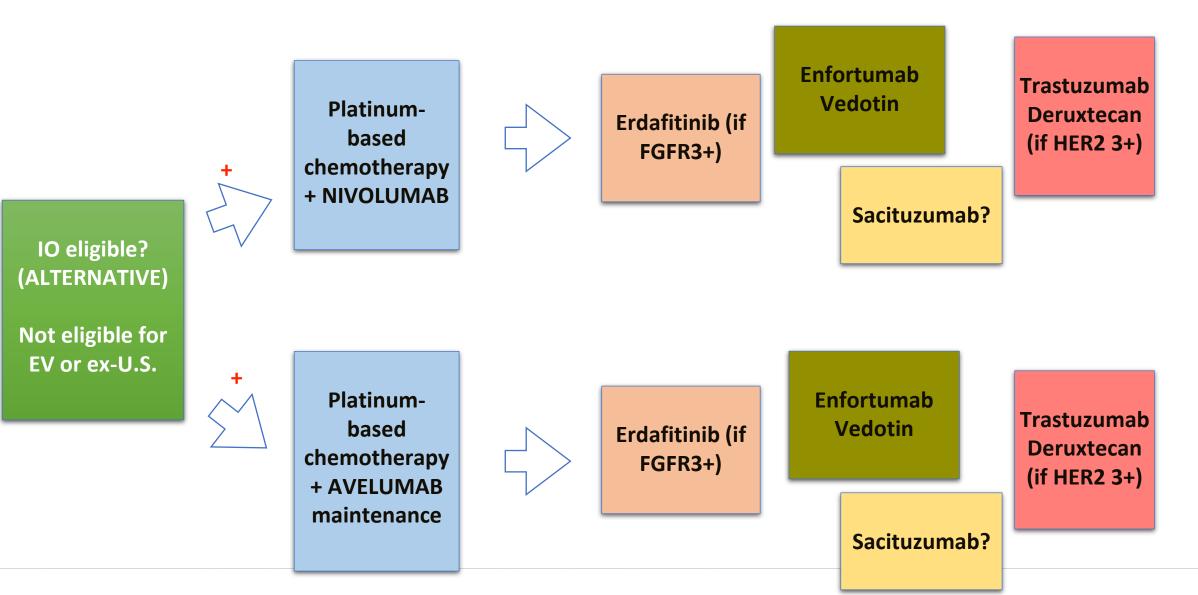




Locally advanced/metastatic UC (la/mUC)



Locally advanced/metastatic UC (la/mUC)

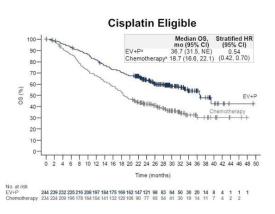


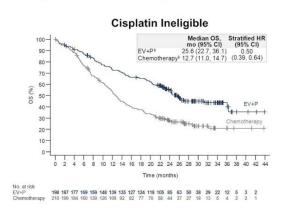
la/mUC - 1st line

- EV-302 trial
 - randomized, phase 3
 - EV/P vs. Cis/Gem or Carbo/Gem

OS Subgroup Analysis: Cisplatin Eligibility

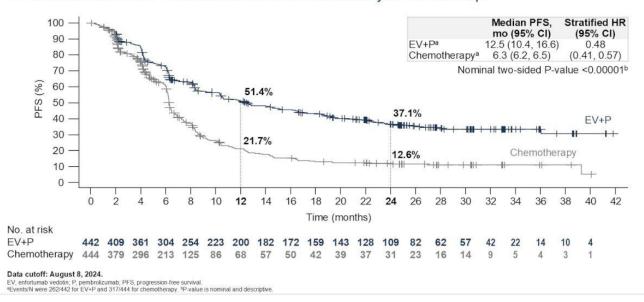
OS benefit was consistent with the overall population regardless of cisplatin eligibility





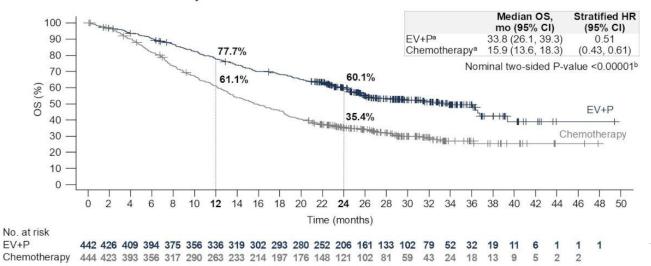
PFS by BICR in the Overall Population

PFS benefit with EV+P was maintained with 1 additional year of follow-up



OS in the Overall Population

Risk of death was reduced by almost 50%

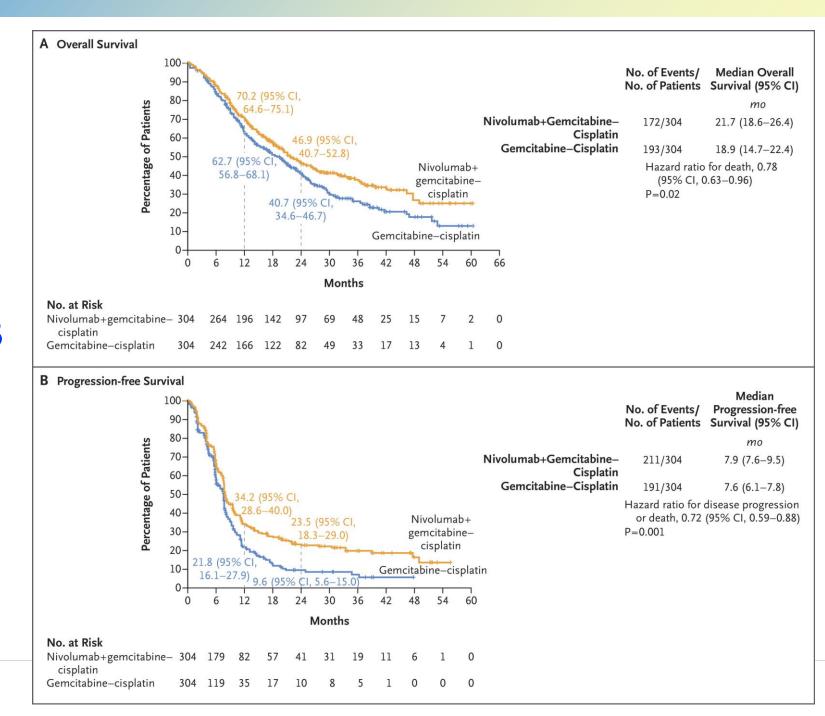


Data cutoff: August 8, 2024.

EV, enfortumab vedotin; P, pembrolizumab; OS, overall survival. *Events/N were 203/442 for EV+P and 297/444 for chemotherapy. *P-value is nominal and descriptive

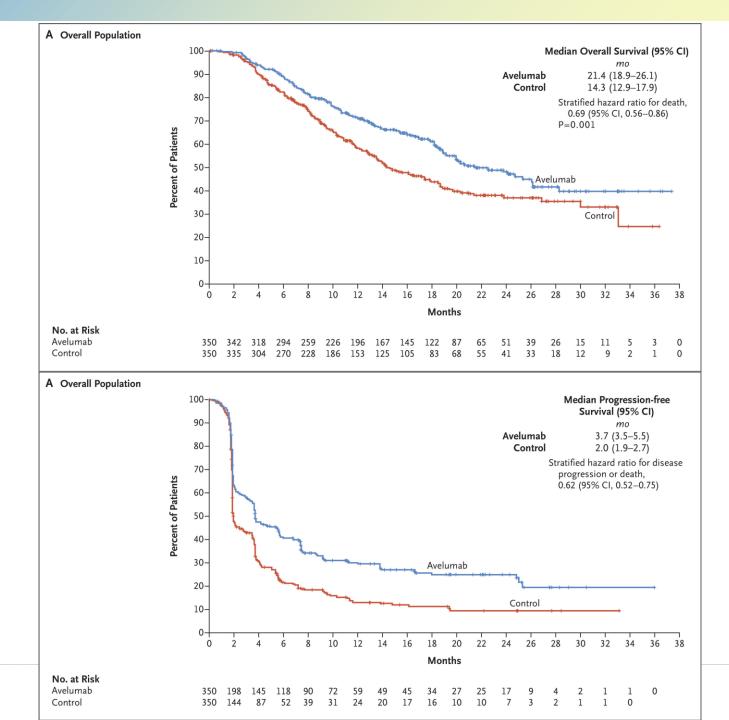
la/mUC - 1st line

- CheckMate 901 trial
 - randomized, phase 3
 - Cis/Gem/Nivo vs.
 Cis/Gem



la/mUC - 1st line

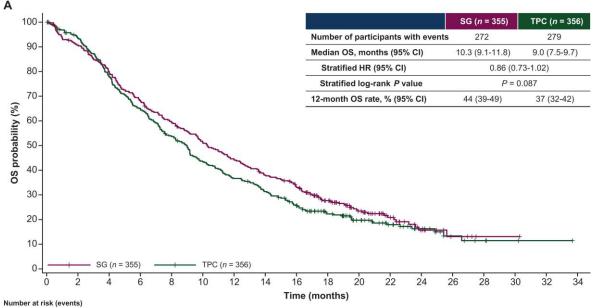
- JAVELIN Bladder 100 trial
 - randomized, phase 3
 - Avelumab maintenance
 - + BSC vs. BSC



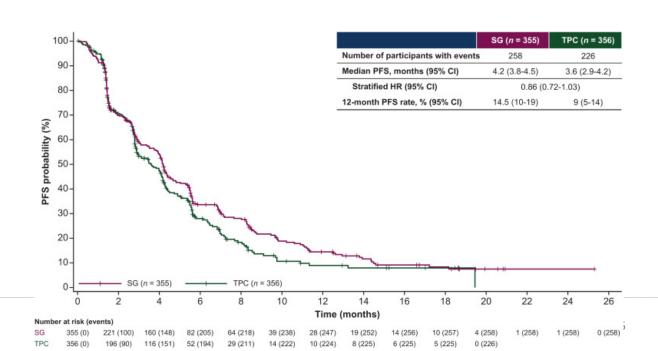
la/mUC - pretreated

TROPiCS-04 trial

- randomized, phase 3
- Sacituzumab govitecan vs. taxane chemotherapy

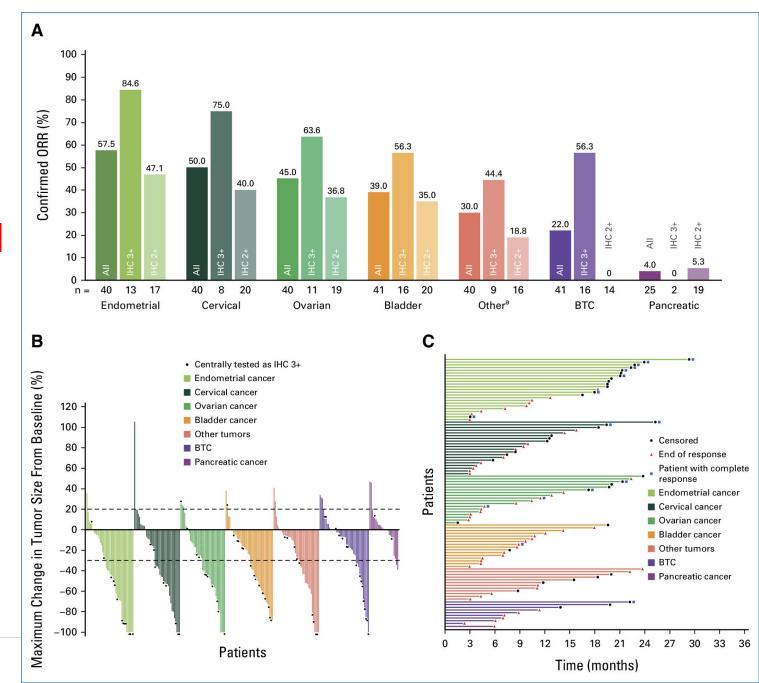


SG 355 (0) 320 (33) 282 (71) 241 (112) 209 (143) 179 (172) 155 (196) 132 (218) 112 (235) 78 (252) 49 (262) 26 (266) 12 (271) 4 (272) 1 (272) 1 (272) 0 (272) TPC 356 (0) 323 (22) 269 (76) 224 (121) 184 (160) 148 (195) 125 (218) 106 (236) 84 (255) 59 (265) 41 (271) 26 (274) 16 (276) 7 (278) 4 (279) 2 (279) 1 (279) 0 (279)



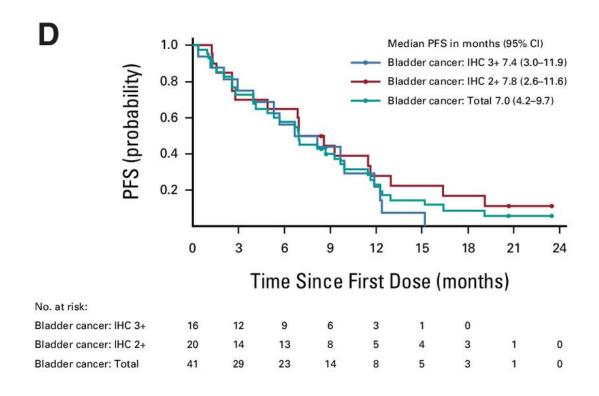
la/mUC - pretreated

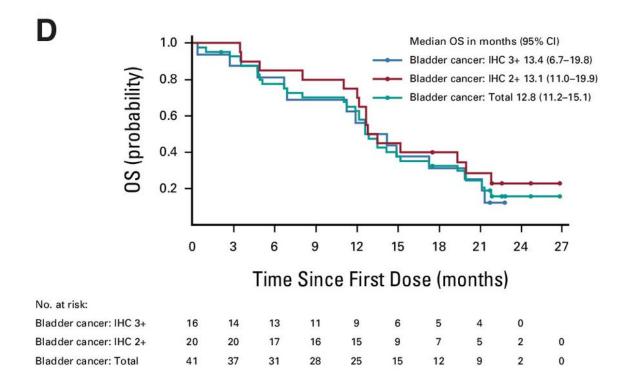
- DESTINY-PanTumor02 trial
 - single-arm, phase 2
 - Trastuzumab deruxtican (T-DXd) monotherapy



la/mUC - pretreated

DESTINY-PanTumor02 trial





THANK YOU!!