III JORNADA DE ACTUALIZACIÓN EN
URO-ONCOLOGÍA:
UPDATE 2026

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Ensayo EV-303

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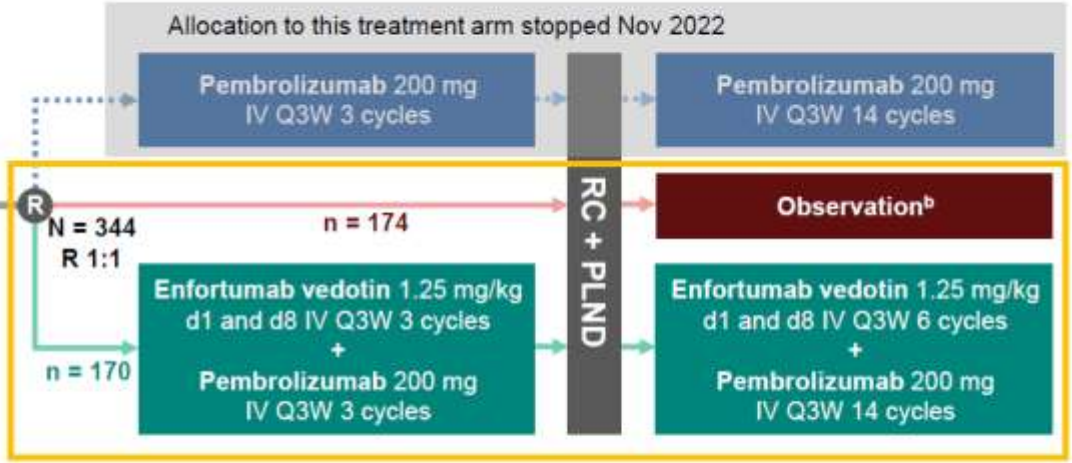
KEYNOTE-905/EV-303 Study (NCT03924895)

Key Eligibility Criteria

- Adults with MIBC
- Clinical stage T2-T4aN0M0 or T1-T4aN1M0 by central assessment
- ≥50% Urothelial histology
- Cisplatin-ineligible per Galsky criteria[a] or cisplatin-declining
- ECOG PS 0-2

Stratification Factors

- Cisplatin ineligibility (ineligible vs. eligible but declining)
- Clinical stage (T2N0 vs. T3/T4aN0 vs. T1-4aN1)
- Region (US vs. EU vs. Most of World)

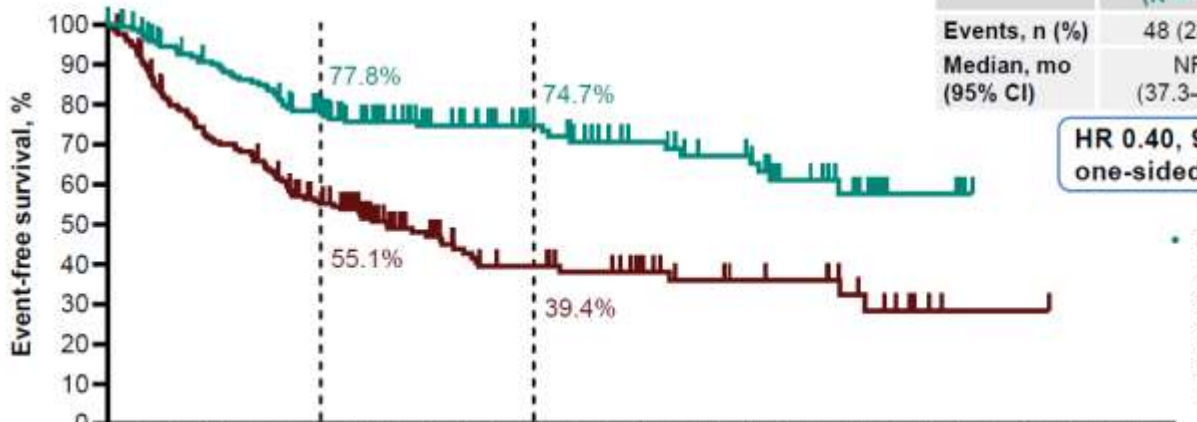


Primary endpoint: Event-free survival (EFS) by BICR
Key secondary endpoints: OS and pathological complete response (pCR; pT0N0, i.e. absence of viable tumor in examined tissue from surgery) by central pathologist review
Other secondary endpoints include: Safety
Exploratory endpoints include: EFS by pCR status

BICR, blinded independent central review; IV, intravenous; Q3W, every 3 weeks. [a]Protocol-defined as having ≥1 of the following: impaired renal function (creatinine clearance 30–59 ml/min), ECOG PS 2, gr ≥2 audiometric hearing loss, or NYHA class III heart failure; [b]As of Nov 2022, adjuvant nivolumab was permitted when clinically indicated and regionally available.

Primary Endpoint: EFS[a] by BICR

ITT Population



	EV + pembro (N = 170)	Control (N = 174)
Events, n (%)	48 (28.2)	95 (54.6)
Median, mo (95% CI)	NR (37.3–NR)	15.7 (10.3–20.5)

HR 0.40, 95% CI 0.28–0.57, one-sided *P* <.0001*

- 29/174 pts (16.7%) in the control arm received adjuvant nivolumab as of data cutoff per local guidelines/prescribing information

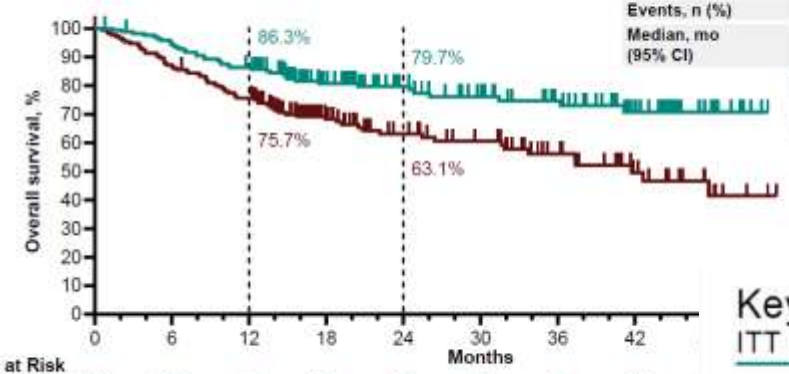
No. at Risk

EV + pembro	170	140	116	73	56	42	35	16	3	0	0
Control	174	116	84	48	33	22	14	9	1	0	0

NR, not reached. * denotes statistical significance (one-sided boundary 0.0097). [a]Time from randomization to first occurrence of: radiographic PD precluding surgery; biopsy-proven residual MIBC (pts who did not undergo surgery); gross residual disease post-surgery or newly detected metastatic disease at surgery; local/distant recurrence post-surgery (imaging or biopsy); or death (any cause). Any new high-risk NMIUC was also considered an event. Pts who did not undergo surgery were considered as having an EFS event if they met criteria for EFS events at any point in time or were censored within ≤16 wks from last dose of neoadjuvant therapy or surgery.

Data cutoff date: 6 June 2025

Key Secondary Endpoint: OS
ITT Population



No. at Risk							
EV + pembro 170	159	144	94	68	56	45	28
Control 174	150	130	75	54	45	30	18

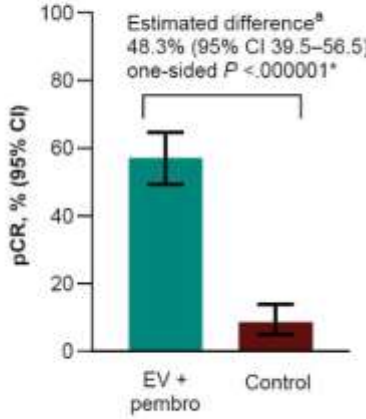
	EV + pembro (N = 170)	Control (N = 174)
Events, n (%)	38 (22.4)	68 (39.1)
Median, mo (95% CI)	NR (NR–NR)	41.7 (31.8–NR)

HR 0.50, 95% CI 0.33–0.74, one-sided *P* =.0002*

- 8/170 pts (4.7%) in the EV + pembro arm and 46/174 (26.4%) in the control arm received subsequent therapy for recurrent/metastatic

NR, not reached. * denotes statistical significance (one-sided boundary 0.00488).

Key Secondary Endpoint: pCR by Central Pathology Review
ITT Population



	EV + pembro (N = 170)	Control (N = 174)
pCR, n	97	15
pCR rate, % (95% CI)	57.1 (49.3–64.6)	8.6 (4.9–13.8)

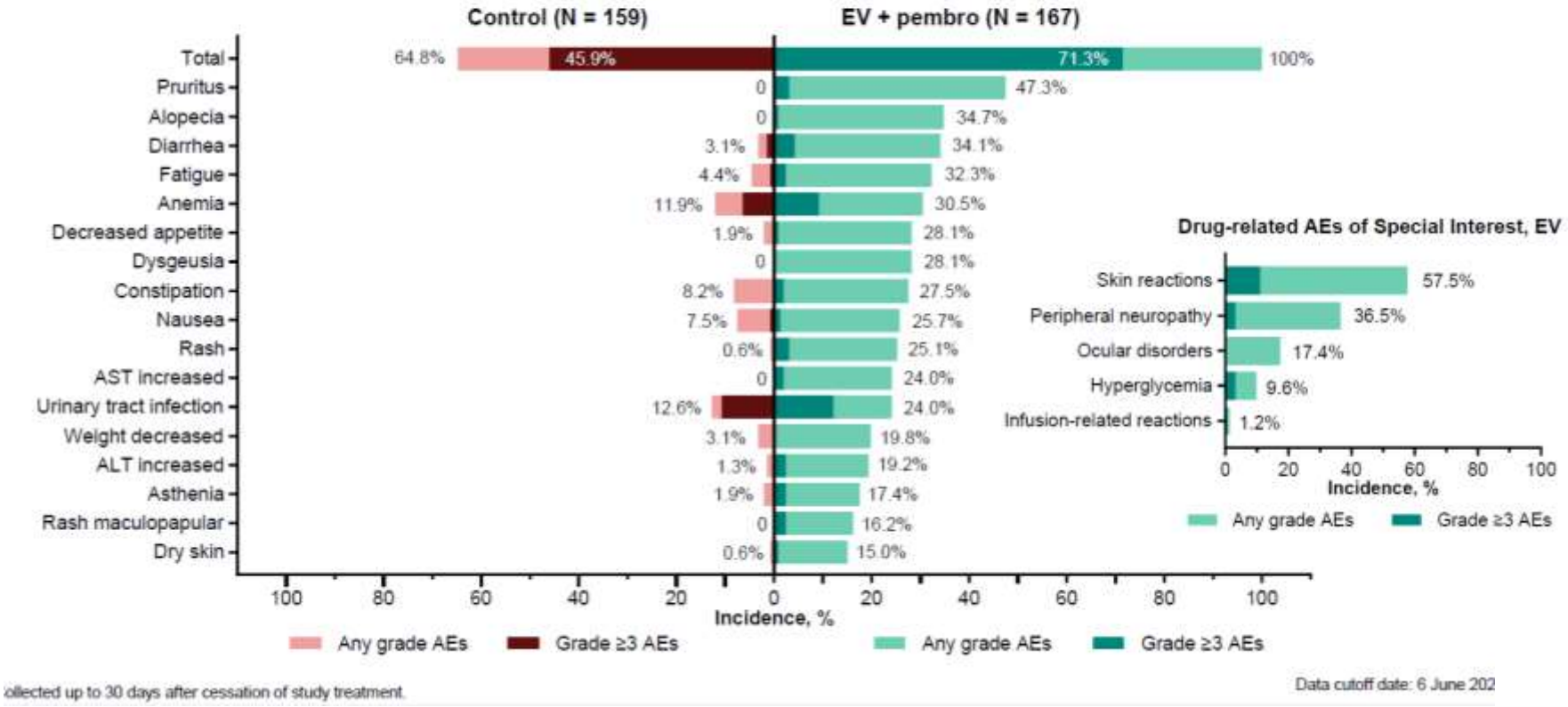
- **pCR:** absence of viable tumor (pT0N0) in examined tissue from RC + PLND
- Pts who did not undergo surgery, including those with clinical complete response after neoadjuvant therapy, were considered non-responders

* denotes statistical significance (one-sided boundary 0.00025).
[a]Based on stratified Miettinen and Nurminen method.

Data cutoff date: 6 June 2025

Common TEAEs[a] (Incidence ≥15%), All Phases of Treatment

Safety Analysis Population



ollected up to 30 days after cessation of study treatment.

Data cutoff date: 6 June 202

Retraso en la cirugía: 1/156 (0.6%) en control vs 6/149 (4%) EV+pembro

CONCLUSIONES:

- El tratamiento **neoadyuvante con EV + pembrolizumab**, seguido de **cistectomía radical + linfadenectomía pélvica** y **EV + pembrolizumab adyuvantes**, mejoró de forma significativa y clínicamente relevante la **supervivencia libre de eventos,** la **supervivencia global,** y la **tasa de respuesta patológica completa** en pacientes con **MIBC** no elegibles para cisplatino o que lo rechazaron.
- **No afectó la posibilidad** de que los pacientes se sometieran a una la **cirugía.**
- El **perfil de seguridad** fue **manejable** y **coherente con lo conocido** en el escenario avanzado o metastásico
- **Podría representar un nuevo estándar de tratamiento** en esta población con **alta necesidad clínica no cubierta**.
- **COMING SOON EV-304:** Pacientes elegibles para cisplatino.