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ARAGÓN · NAVARRA · RIOJA
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Organizador:
Fundación Biomédica Miguel Servet

Cáncer renal y vejiga

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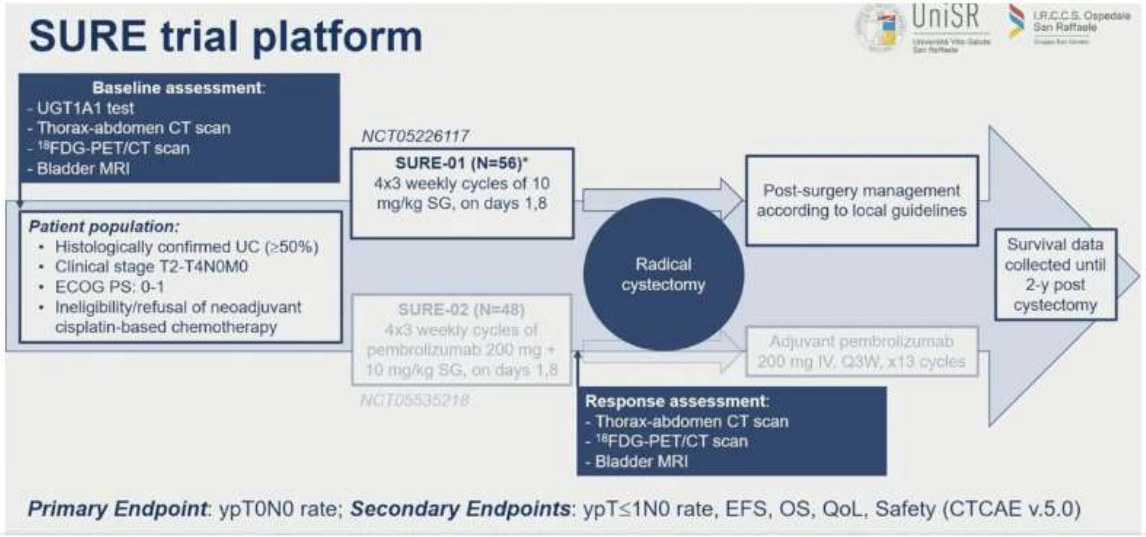
Hospital Clínico Universitario Zaragoza

¿NUEVOS ESQUEMAS EN NEOADYUVANCIA EN CA DE VEJIGA?



The study protocol was amended after the initial eight patients experienced treatment-related adverse events:

- Grade 3–4 neutropenia: 6/8 (75%)
- Timing of grade 3-4 events onset: after C1D8 in 5/6 patients
- Grade 3-4 diarrhea: 4/8 (50%; all after C1D8).
- Dose-reductions of SG: 6/8 (75%), the remaining two patients had treatment discontinuation/death
- One treatment-related grade 5 event (sepsis).
- One treatment-unrelated Grade 5 event.

The dose of SG was reduced to 7.5 mg/kg from cycle 1 day 1. G-CSF use was introduced as a primary prophylactic measure from cycle 1 day 9. Patients who had ≥3 risk factors for febrile neutropenia (per ASCO guidelines) were excluded from trial enrolment.

Three patients died after treatment discontinuation at C1D8:

- One death was due to sepsis following Grade 4 neutropenia + Grade 3 diarrhea.
- Two deaths due to non-treatment-related complications (CNS deterioration for unknown reason and disease-progression, respectively)
- Grade 3-4 treatment-related adverse events were more common in patients with homozygous or heterozygous UGT1A1*28 polymorphisms (5/8; 62.5%) versus wild-type status (2/10; 20%).

¿NUEVOS ESQUEMAS EN NEOADYUVANCIA EN CA DE VEJIGA?

Median follow-up: 7.1 months

Outcome	N (%)
Total N=11 RC-evaluable patients	
• ypT0N0 (95%CI)	4 (36.4; 14.9–64.8)
• ypT≤1N0 (95%CI)	5 (45.4; 21.2–72.0)
Total N=21 ITT patients	
• **ypT0N0-x (95%CI)**	**10 (47.6; 28.3–67.6)**
• ypT≤1N0-x	11 (52.4)
• ypT2Nx[a]	1 (4.7)
• ypT3-4N0[b]	3 (14.3)
• $ypT_{any}N+$[b]	3 (14.3)
Relapse/progression during or post-SG	1 (4.7)

Responses assessed with reTURBT

Our definition of cCR

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Patient ID	VI-RADS post-therapy[1]	Cystoscopy	ctDNA post-therapy	Pathological findings (reTURBT)	Clinical CR	
11	0	Neg	Neg	ypT0Nx	✓	Observation
13	0	Neg	Neg	ypT0Nx	✓	
16	0	Neg	Neg	ypT0Nx	✓	
17	0	Neg	Neg	ypT0Nx	✓	
19	0	Neg	Neg	ypT0Nx	✓	
20	0	Neg	Neg	ypT0Nx	✓	
21	5	Pos	Pos (MTM/mL: 0.32)	ypT2Nx	✗	ChemoRT

¿NUEVOS ESQUEMAS EN NEOADYUVANCIA EN CA DE VEJIGA?

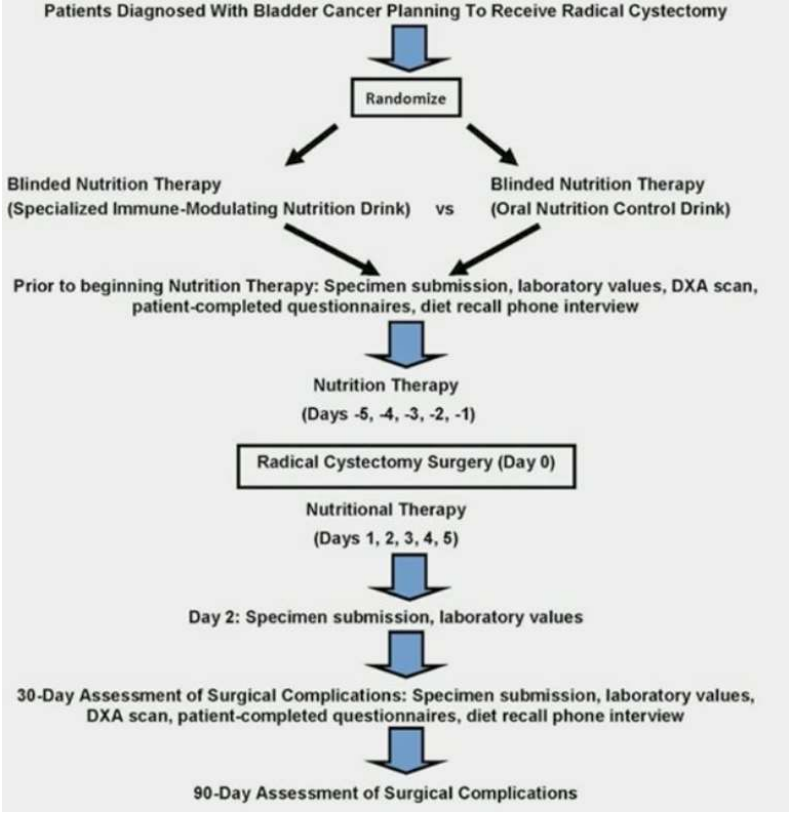
- The interim findings from SURE-01 trial provide several useful information that may be considered for the development of preoperative SG in patients with MIBC:
  - The interim ypT0N0 rate and safety profile post protocol amendment give reassurance for the continuation of the study.
  - A few patients meeting rigorous criteria of clinical complete response, who elected to undergo a bladder-saving approach, revealed a potential for cure (ypT0Nx stage, ctDNA-)
  - Study amendments that included changing the dose from 10 mg/kg to 7.5 mg/kg, requiring primary prophylaxis with PegG-CSF starting at C1D9, and excluding patients at high risk for neutropenia led to an improved safety profile.

¿Es necesaria la cistectomía?

INMUNONUTRICIÓN EN CISTECTOMÍA ¿MENOS COMPLICACIONES?

Effects of immune-enhancing nutrition on radical cystectomy outcomes: Primary results from the randomized phase III double-blind clinical trial (S1600).

Specialized immunonutrition is fortified with nutrients, including L-arginine, omega-3 fatty acids, and dietary nucleotides.



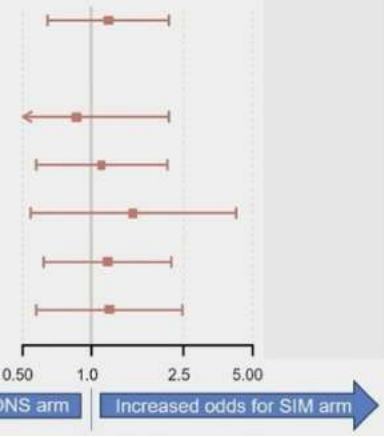
INMUNONUTRICIÓN EN CISTECTOMÍA ¿MENOS COMPLICACIONES? IGUAL

Effects of immune-enhancing nutrition on radical cystectomy outcomes: Primary results from the randomized phase III double-blind clinical trial (S1600).

Figure: Forest Plot of Primary and Secondary Surgical Outcomes

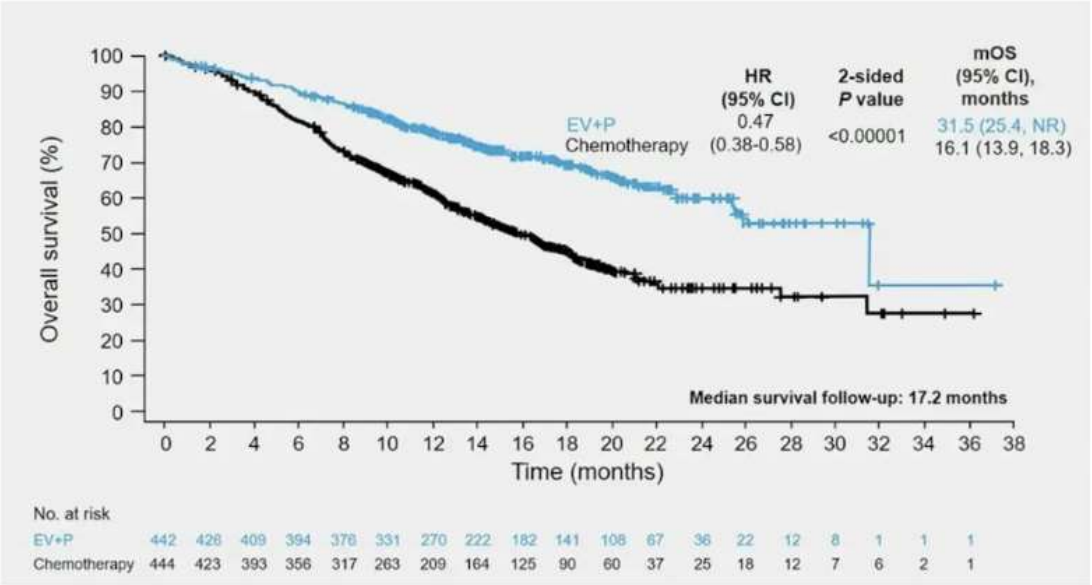
Outcome	Clavien-Dindo Scores (By Grade)*	Percent	Odds Ratio (95% CI)	P-value
Primary Outcome				
30-day Score	Any vs none	62.2 vs 58.0	1.18 (0.64-2.18)	0.71
Secondary Outcomes				
30-day Score	High grade vs 0-II	11.1 vs 12.5	0.86 (0.34-2.17)	0.37
90-day Score	Any vs none	34.9 vs 32.5	1.10 (0.57-2.12)	0.62
90-day Score	High grade vs 0-II	12.1 vs 8.4	1.51 (0.54-4.23)	0.79
30 or 90-day Score	Any vs none	69.2 vs 65.6	1.17 (0.62-2.21)	0.69
30 or 90-day Score	High grade vs 0-II	20.9 vs 18.3	1.19 (0.57-2.49)	0.68

* High grade is Clavien-Dindo scores III-V



CALIDAD DE VIDA (PROS) EN PRIMERA LÍNEA DE CA DE VEJIGA AVANZADO

Patient-reported outcomes (PROs) from a randomized, phase 3 trial of enfortumab vedotin plus pembrolizumab (EV+P) versus platinum-based chemotherapy (PBC) in previously untreated locally advanced or metastatic...



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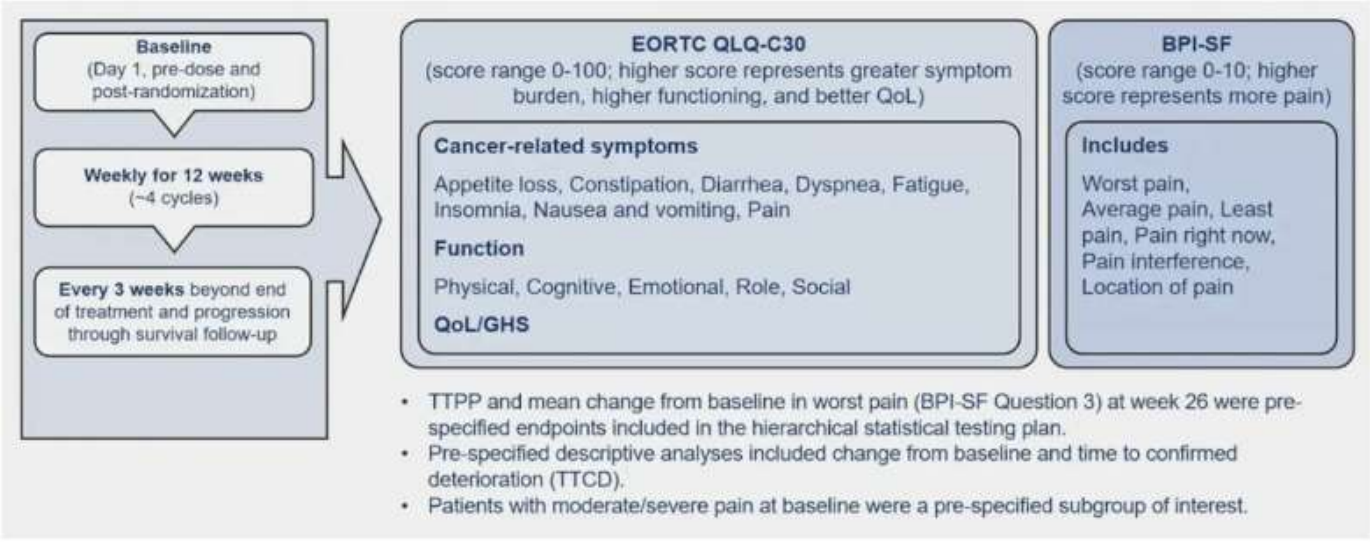

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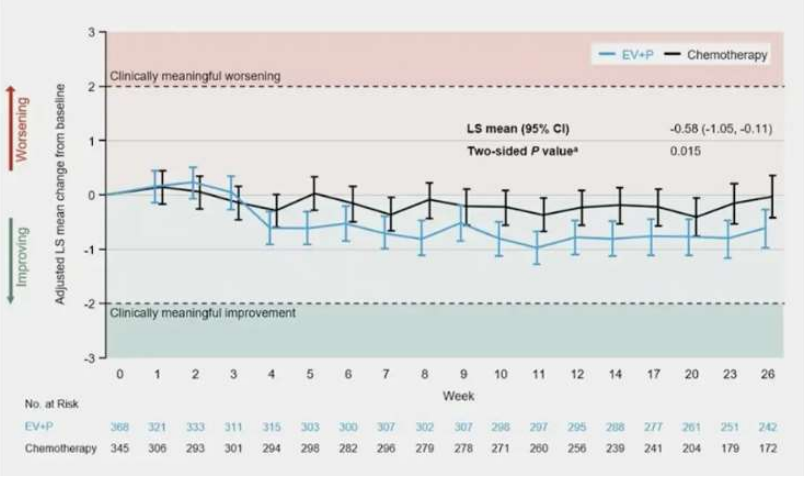
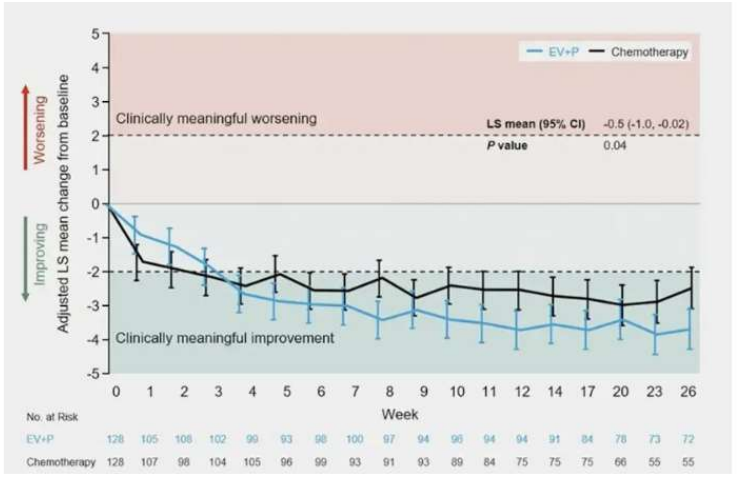


The least squares mean reduction in worst pain at week 26 was numerically greater with enfortumab vedotin + pembrolizumab versus platinum-based chemotherapy (-0.61 vs -0.03, least squares mean difference: -0.58 [95% CI -1.05, -0.11] [nominal 2-sided p-value = 0.015]).

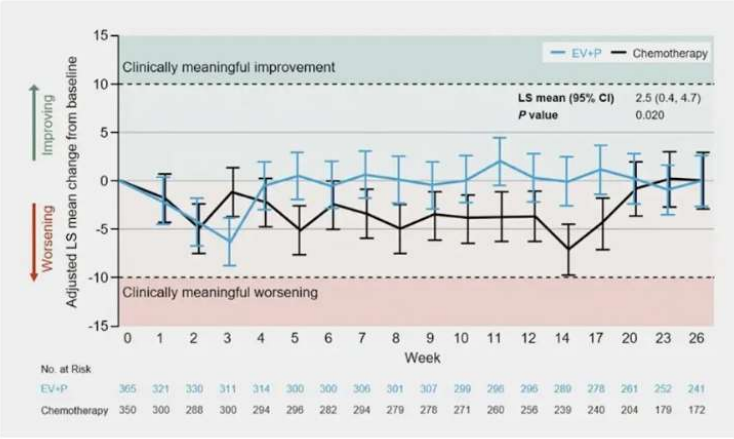


Meaningful (>2 patient) improvement from baseline in BPI worst pain from week 3 through 26:

CALIDAD DE VIDA (PROS) EN PRIMERA LÍNEA DE CA DE VEJIGA AVANZADO

Patient-reported outcomes (PROs) from a randomized, phase 3 trial of enfortumab vedotin plus pembrolizumab (EV+P) versus platinum-based chemotherapy (PBC) in previously untreated locally advanced or metastatic...

In EORTC QLQ-C30 Global Health Status/Quality of Life, enfortumab vedotin + pembrolizumab demonstrated a transient worsening at week 3 (-6.3) that returned to baseline from weeks 4 through 26, while patients treated with platinum-based chemotherapy demonstrated deterioration from week 1 through week 17 (range -1.2 to -7.1) when scores returned to baseline:



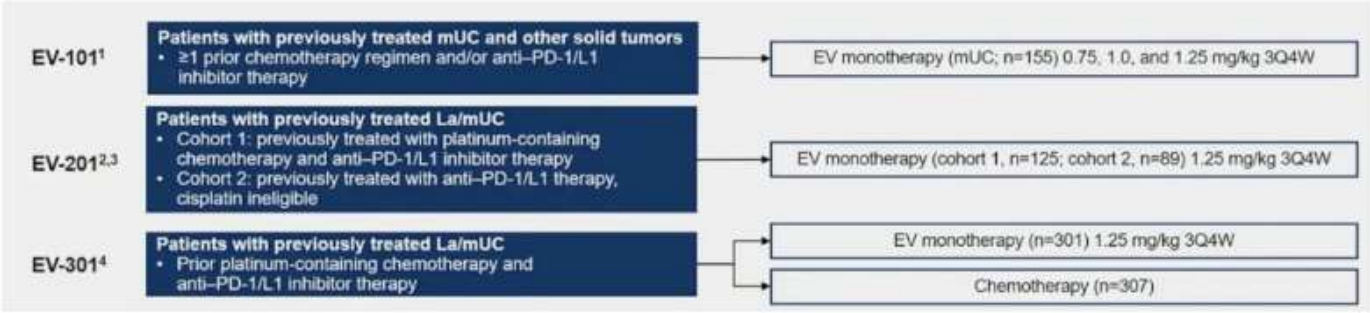
Dr. Gupta concluded her presentation by discussing patient reported outcomes from EV-302 with the following take home messages:

- Patients treated with enfortumab vedotin + pembrolizumab have significantly improved progression free- and overall survival compared with platinum-based chemotherapy without detriment to quality of life and functioning
- Patients with moderate to severe pain treated with enfortumab vedotin + pembrolizumab demonstrated clinically meaningful improvements in worst pain and Global Health Status/Quality of Life
- Data collection across the entire patient journey was a notable approach and was associated with differences in compliance between treatment arms
- Findings from this study may inform the design of future trials
- Patient reported outcome data presented here complement the published clinical efficacy and safety data, add the patient perspective, and support the use of enfortumab vedotin + pembrolizumab for patients with previously untreated locally advanced or metastatic urothelial cancer

¿MÁS ENFORTUMAB ES MEJOR EN CA DE VEJIGA AVANZADO? SÍ

Impact of exposure on outcomes with enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer.

The characterization of dose- and exposure-response for efficacy and exposure-response for safety outcomes included patients in EV-101 (enfortumab vedotin monotherapy 0.75, 1.0, and 1.25 mg/kg on days 1, 8, and 15 of a 28-day cycle [3Q4W]), EV-201, and EV-301 (enfortumab vedotin monotherapy 1.25 mg/kg 3Q4W). Time-averaged exposure up to an event of interest, C_{avg}, was computed using a population pharmacokinetic model. Pharmacokinetic assessment included multiple samples in first 2 cycles and pre-dose samples in subsequent cycles. The characteristics of these three trials are highlighted below:

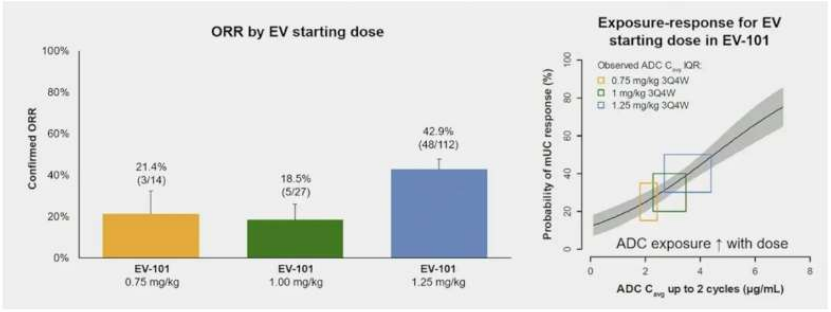


¿MÁS ENFORTUMAB ES MEJOR EN CA DE VEJIGA AVANZADO?: +dosis

Impact of exposure on outcomes with enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer.

+ respuesta

In the phase 1 EV-101 study, EV 1.25 mg/kg 3Q4W achieved a high response rate and was supported by exposure-response analysis:



Furthermore, higher early enfortumab vedotin dose intensity was generally associated with a greater probability of response in pivotal trials:

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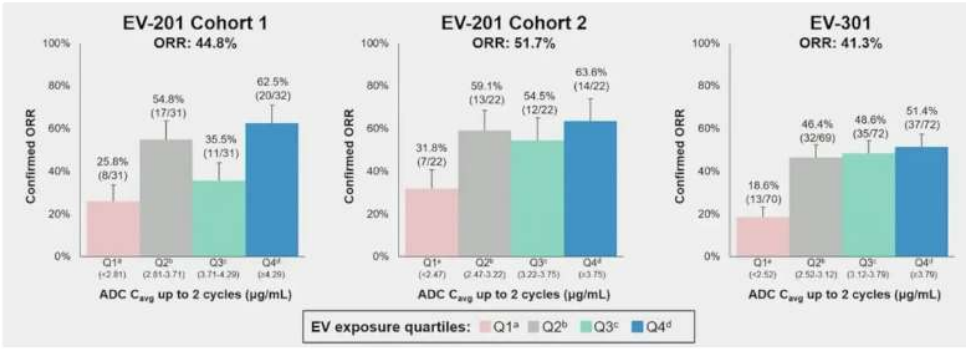

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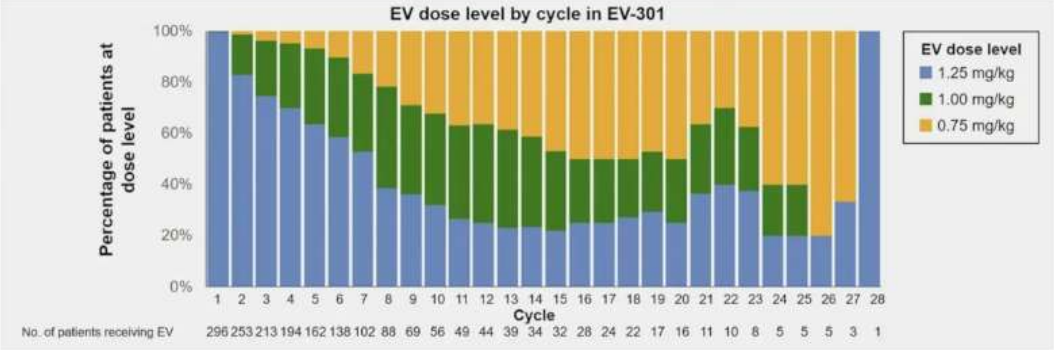
Dose modifications were common, including dose reductions to 1.0 mg/kg (EV-201 42.1%; EV-301 35.1%) and 0.75 mg/kg (EV-201 13.6%; EV-301 11.1%). The majority of patients in EV-301 maintained EV 1.25 mg/kg through cycle 7, though dose reductions were more frequent in later cycles:



¿MÁS ENFORTUMAB ES MEJOR EN CA DE VEJIGA AVANZADO?

Impact of exposure on outcomes with enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer.

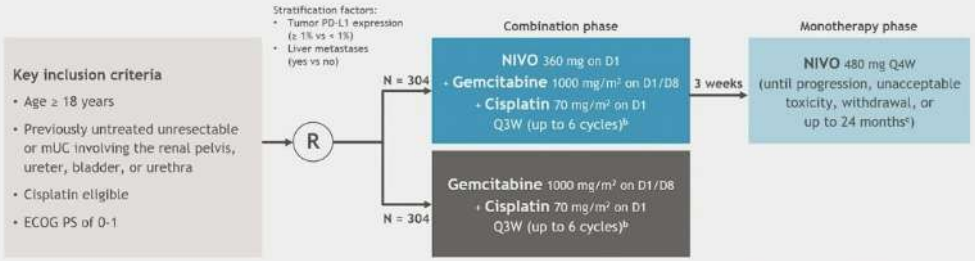
- Enfortumab vedotin monotherapy at the 1.25 mg/kg 3Q4W dose has shown a consistent benefit and manageable safety profile across multiple trials of patients with locally advanced or metastatic urothelial carcinoma in the second and third line setting
- Higher enfortumab vedotin dose intensity was generally associated with a greater probability of response
- Dose modifications, including dose reductions, were common across trials, particularly in later cycles. However, the safety and efficacy outcomes with enfortumab vedotin monotherapy were achieved with the use of dose modifications
- Recommended enfortumab vedotin dose modifications assist in managing adverse events and may allow patients to remain on treatment
- Patients continue to benefit from enfortumab vedotin monotherapy in the setting of dose modifications to manage adverse events
- Enfortumab vedotin monotherapy provided a progression free survival and overall survival benefit versus chemotherapy across exposure quartiles

¿CA DE VEJIGA AVANZADO, CISPLATINO GEMCITABINA NIVOLUMAB ES UN ESTÁNDAR EN AFECTACIÓN ADENOPÁTICA EXCLUSIVA?

Characterization of complete responders to nivolumab + gemcitabine-cisplatin vs gemcitabine-cisplatin alone and patients with lymph node–only metastatic urothelial carcinoma from the CheckMate 901 trial.

Study design

- NIVO+GC vs GC in cisplatin-eligible patients[a]



Median (range) study follow-up: 33.6 (7.4-62.4) months

Primary endpoints: OS, PFS per BICR
Key secondary endpoints: OS and PFS per BICR by PD-L1 ≥ 1%,[d] HRQoL
Key exploratory endpoints: ORR per BICR, safety

Current analysis includes: baseline characteristics, ORR, OS, and PFS in all randomized LN only patients

A total of 102/608 (16.8%) of patients achieved a complete response (CR) in the CheckMate 901 study. Among these, 34 (51.5%) in the Nivolumab+GC arm and 19 (52.8%) in the GC alone arm had lymph node-only mUC, :

Select characteristics for all patients with complete response

	All randomized patients		Patients with CR	
	NIVO+GC (N = 304)	GC (N = 304)	NIVO+GC (N = 66)	GC (N = 36)
Median age (range), years	65.0 (32-86)	65.0 (35-85)	65.0 (33-81)	63.5 (36-80)
Male sex, n (%)	236 (78)	234 (77)	53 (80)	31 (86)
Race				
White	211 (69)	225 (74)	47 (71)	27 (75)
Black or African American	0	2 (< 1)	0	0
American Indian or Alaska Native	1 (< 1)	1 (< 1)	0	1 (3)
Asian	75 (25)	63 (21)	16 (24)	6 (17)
Other	17 (6)	13 (4)	3 (5)	2 (6)
LN only disease,* n (%)	54 (18)	56 (18)	34 (52)	19 (53)
Disease stage at study entry, n (%)				
Stage III	37 (12)	28 (9)	9 (14)	5 (14)
Stage IV	265 (87)	274 (90)	56 (85)	31 (86)
Not reported	2 (< 1)	2 (< 1)	1 (2)	0
PD-L1 status, n (%)				
≥ 1%	112 (37)	109 (36)	28 (42)	11 (31)
< 1%	192 (63)	195 (64)	38 (58)	25 (69)
Subsequent anticancer therapy received	108 (36)	156 (51)	23 (35)	15 (42)

- Of the 608 total patients randomized, 102 (16.8%) achieved a CR
- Approximately 50% of patients with CR had LN only mUC vs approximately 20% of all randomized patients

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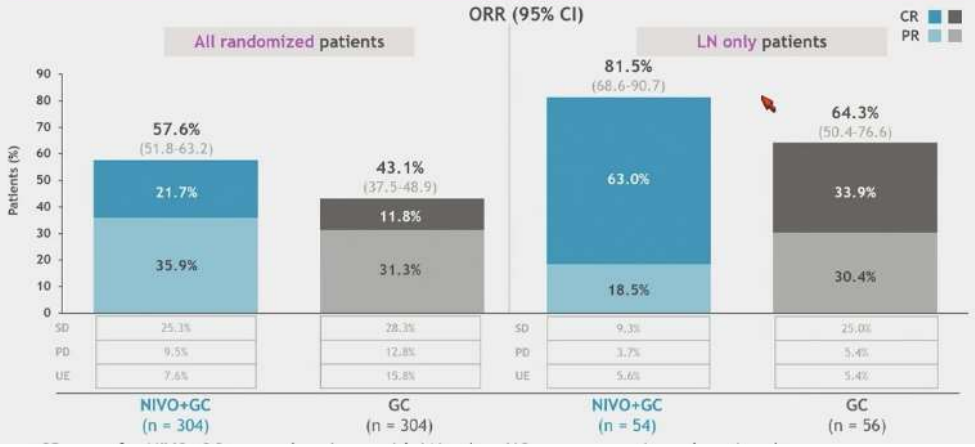
Characterization of complete responders to nivolumab + gemcitabine-cisplatin vs gemcitabine-cisplatin alone and patients with lymph node–only metastatic urothelial carcinoma from the CheckMate 901 trial.

Select baseline characteristics for patients with LN only mUC

	NIVO+GC (N = 54)	GC (N = 56)
Median age (range), years	66 (41-85)	65 (37-80)
Tumor type at study entry, n (%)		
Urinary bladder	40 (74)	36 (64)
Ureter	3 (6)	5 (9)
Urethra	6 (11)	4 (7)
Renal pelvis	5 (9)	11 (20)
ECOG PS, n (%)		
0	37 (69)	38 (68)
1	17 (31)	18 (32)
PD-L1 status, n (%)		
≥ 1%	26 (48)	17 (30)
< 1%	28 (52)	39 (70)

Response per BICR



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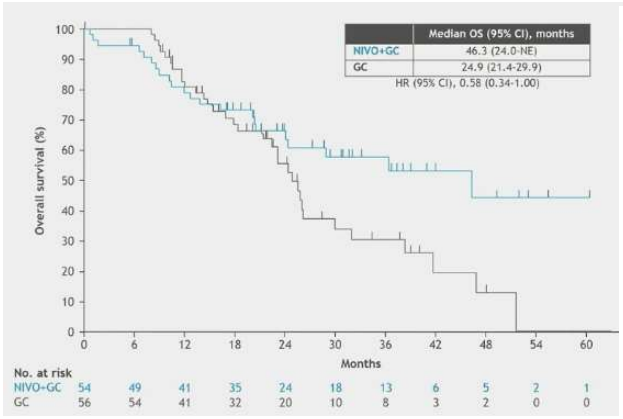
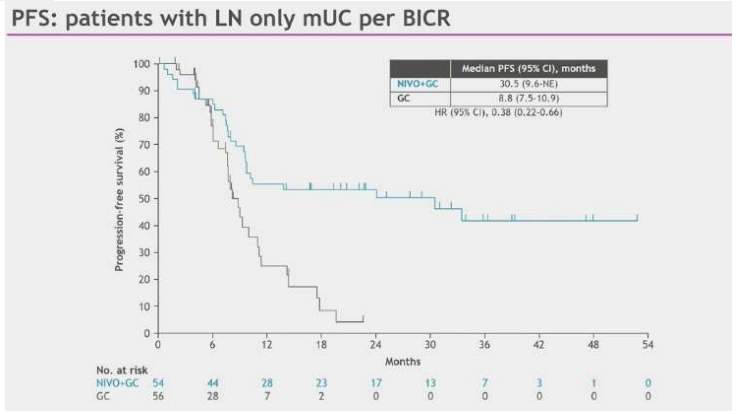
Response characteristics for LN only patients with CR

	NIVO+GC (N = 54)	GC (N = 56)
Patients with CR	n = 34	n = 19
Median time to CR (range), months	2.1 (1.8-2.2)	2.0 (1.6-3.3)
Median duration of CR (95% CI), months	NR (22.0-NE)	8.7 (6.7-15.6)
12-month CR rate (95% CI), %	70 (51-82)	32 (10-57)
24-month CR rate (95% CI), %	65 (45-79)	Not applicable (0)

- The median duration of CR was NR in the NIVO+GC group and was 8.7 months in the GC group
- The 12-month CR rate for patients treated with NIVO+GC was more than twice that of patents treated with GC



PFS: patients with LN only mUC per BICR



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- The post hoc analysis of CheckMate 901 revealed that among patients achieving complete response (CR), more than half had lymph node-only mUC.

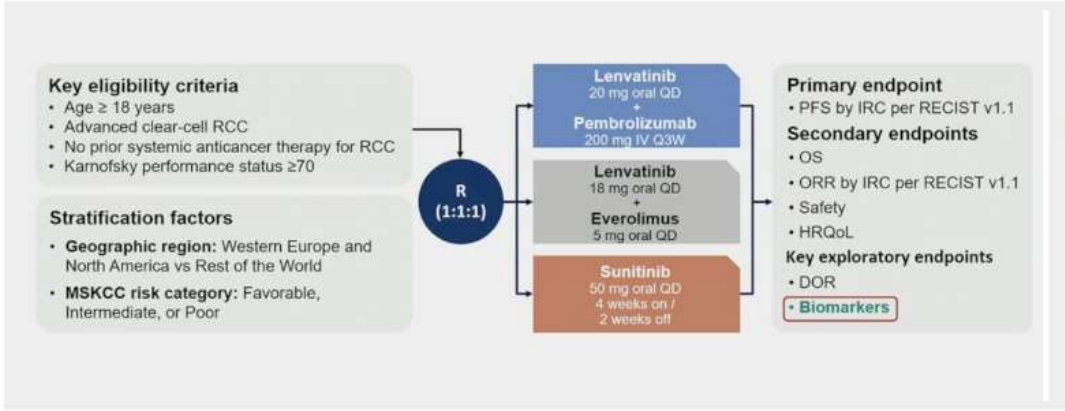
- **In patients with lymph node-only metastatic urothelial carcinoma (mUC), Nivolumab+GC demonstrated durable disease control and clinically meaningful improvements in OS and PFS compared to patients who received GC alone.**

- Lymph node-only mUC represents a distinct clinical entity, and with Nivolumab+GC, we may alter the trajectory of this disease through consolidation therapy, especially for patients with pelvic metastatic lymph nodes.

- These findings strengthen the rationale for Nivolumab plus cisplatin-based chemotherapy as a standard first-line treatment option for patients with mUC.

Biomarcadores en primera línea de cáncer renal avanzado: CLEAR

Biomarker analyses in patients with advanced renal cell carcinoma (aRCC) from the phase 3 CLEAR trial.



Biomarker analyses focused on the lenvatinib + pembrolizumab and sunitinib arms

Analysis (Baseline)	Assay
PD-L1 expression n=441	**IHC:** 22C3 pharmDx
Gene alteration n=380	**Whole-exome sequencing:** ImmunoID NeXT Platform
Gene expression n=388	**RNA-seq:** ImmunoID NeXT Platform

Biomarcadores en primera línea de cáncer renal avanzado: CLEAR

Biomarker analyses in patients with advanced renal cell carcinoma (aRCC) from the phase 3 CLEAR trial.

There were no notable differences in baseline characteristics and tumor responses in biomarker analysis sets versus the intention to treat population:

	Full analysis set		PD-L1 analysis set		RNA-seq analysis set		WES analysis set	
Category	**L+P (N=355)**	**S (N=357)**	**L+P (n=219)**	**S (n=222)**	**L+P (n=192)**	**S (n=196)**	**L+P (n=186)**	**S (n=194)**
MSKCC Risk, %								
Fav / Int / Poor	27 / 64 / 9	27 / 64 / 9	28 / 64 / 8	27 / 64 / 8	26 / 67 / 7	27 / 66 / 8	26 / 66 / 8	27 / 65 / 8
IMDC Risk, %								
Fav / Int / Poor	31 / 59 / 9	35 / 54 / 10	31 / 59 / 10	34 / 54 / 12	28 / 65 / 8	36 / 54 / 10	29 / 62 / 9	35 / 54 / 11
PD-L1, %								
CPS <1 / ≥1 / NA	32 / 30 / 38	29 / 33 / 38	51 / 49 / 0	46 / 54 / 0	46 / 48 / 6	41 / 52 / 7	47 / 47 / 5	41 / 54 / 6
CLINICAL OUTCOMES								
Median PFS, mo (95% CI)	23.9 (20.8–27.7)	9.2 (6.0–11.0)	25.3 (21.4–29.0)	9.2 (6.0–11.0)	24.3 (18.6–28.6)	9.4 (6.0–11.1)	25.3 (20.3–31.1)	9.2 (5.9–11.0)
PFS HR of L+P vs S (95% CI)	0.48 (0.39–0.58)*		0.47 (0.37–0.60)		0.52 (0.41–0.68)		0.49 (0.38–0.63)	
ORR, %	71	37	76	40	76	41	75	38

In the lenvatinib + pembrolizumab arm, the continuous gene-expression profile signature score was not associated with best overall response:

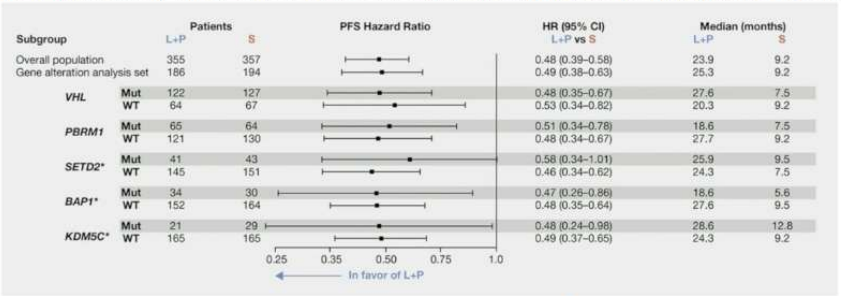
Biomarcadores en primera línea de cáncer renal avanzado: CLEAR

Biomarker analyses in patients with advanced renal cell carcinoma (aRCC) from the phase 3 CLEAR trial.

PD-L1 IHC (CPS)	Association with PFS (*p*-value)	
	Lenvatinib + pembrolizumab n=219	Sunitinib n=222
	0.2301	0.0670

Statistical testing for L+P arm: one-sided test; for S arm: two-sided test. Analysis with KPS score group-adjusted PFS was performed using the Cox regression model.

Progression-free survival was higher with lenvatinib + pembrolizumab vs sunitinib, regardless of the deleterious mutation status of *BAP1*, *VHL*, *PBRM1*, *SETD2*, and *KDM5C*, which are frequently mutated genes in RCC:

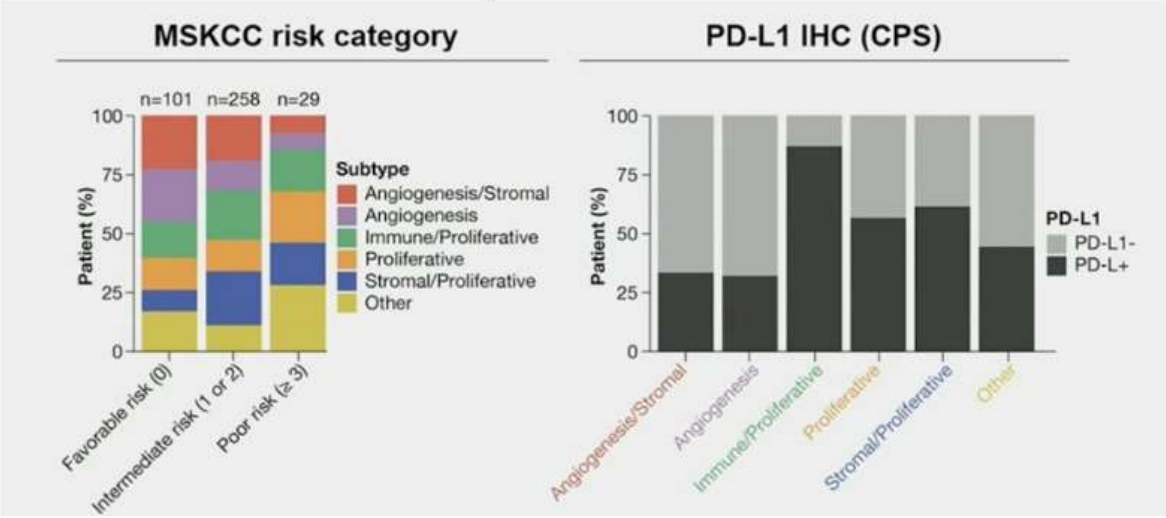


Gene signature scores were not associated with PFS outcomes for the lenvatinib + pembrolizumab arm:

Biomarcadores en primera línea de cáncer renal avanzado: CLEAR

Biomarker analyses in patients with advanced renal cell carcinoma (aRCC) from the phase 3 CLEAR trial.

Tumors of patients with favorable and intermediate risk were enriched in the angiogenesis and angiogenesis/stromal clusters, and tumors of patients with poor risk were enriched in the proliferative cluster. Tumors of patients that were PD-L1+ were enriched in the immune/proliferative cluster:



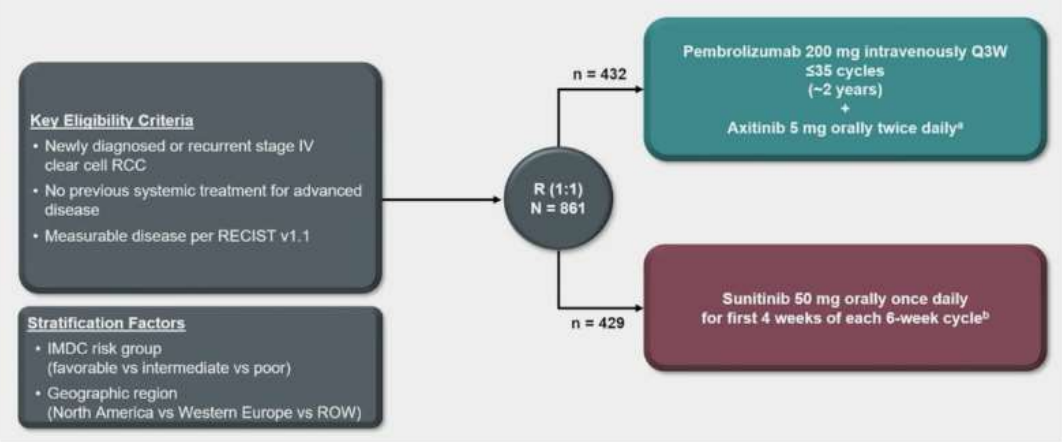
Biomarcadores en primera línea de cáncer renal avanzado: CLEAR

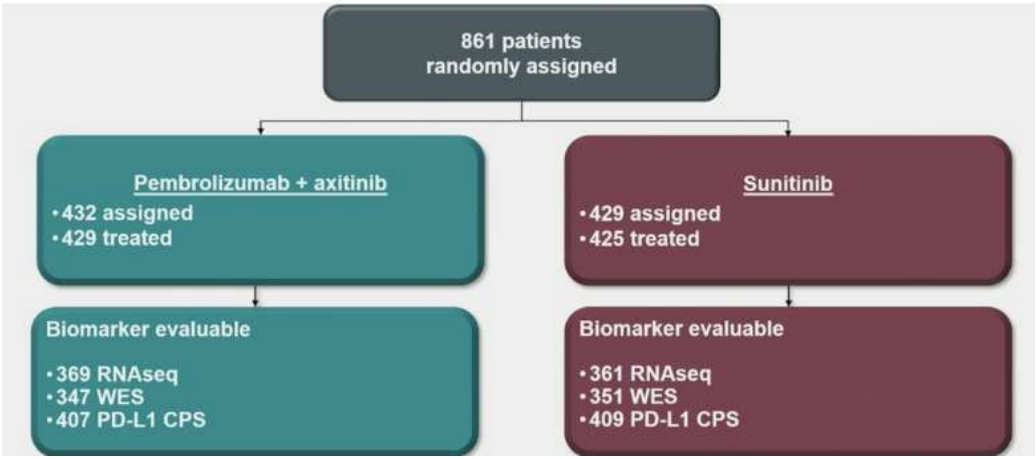
Biomarker analyses in patients with advanced renal cell carcinoma (aRCC) from the phase 3 CLEAR trial.

- Lenvatinib + pembrolizumab showed clinical benefit over sunitinib in patients with advanced renal cell carcinoma regardless of biomarker subtypes
- The progression-free survival analysis of lenvatinib + pembrolizumab confirms the high level efficacy of the combination irrespective of PD-L1 CPS
- Lenvatinib + pembrolizumab showed longer progression-free survival and improved objective response rate versus sunitinib regardless of RCC driver gene mutation status or gene signature
- Lenvatinib + pembrolizumab demonstrated numerically higher tumor response and longer progression-free survival than sunitinib across all molecular subtypes

Biomarcadores en primera línea de cáncer renal avanzado: Keynote-426

Biomarker analysis of the phase 3 KEYNOTE-426 study of pembrolizumab (P) plus axitinib (A) versus sunitinib (S) for advanced renal cell carcinoma (RCC).





Biomarcadores en primera línea de cáncer renal avanzado: Keynote-426

Biomarker analysis of the phase 3 KEYNOTE-426 study of pembrolizumab (P) plus axitinib (A) versus sunitinib (S) for advanced renal cell carcinoma (RCC).

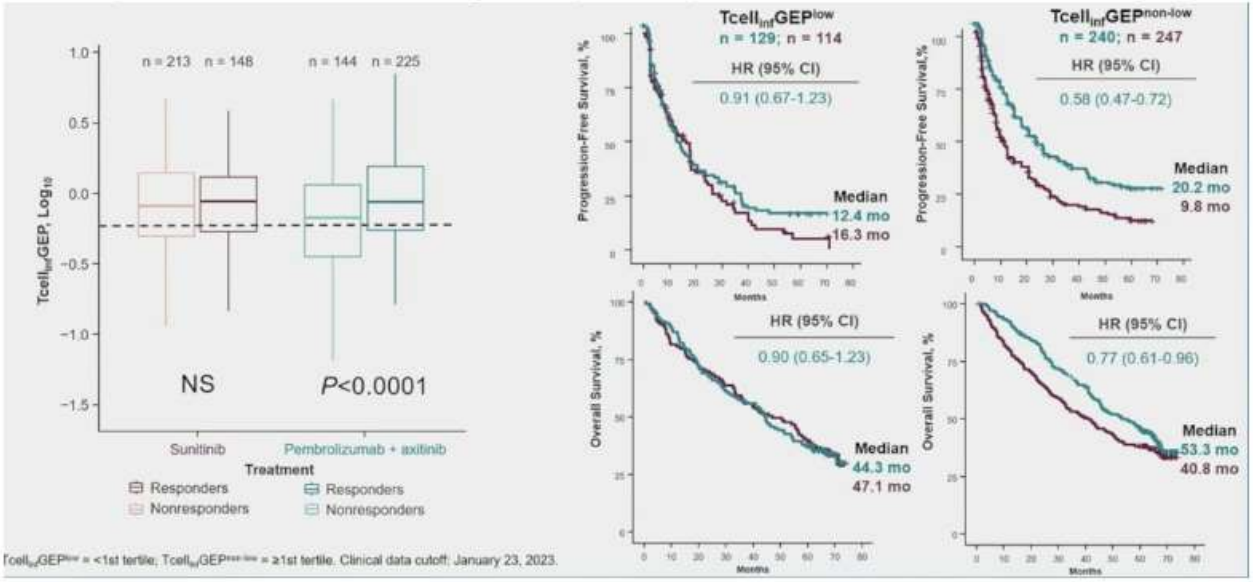
	Pembrolizumab + axitinib			Sunitinib		
Biomarker	**ORR**	**PFS**	**OS**	**ORR**	**PFS**	**OS**
$Tcell_{inf}GEP$	**<0.0001(+)**	**<0.0001(+)**	**0.002(+)**	NS	NS	NS
Angiogenesis	NS	NS	**0.004(+)**	**0.002(+)**	**<0.001(+)**	**<0.0001(+)**
PD-L1 CPS	NS	NS	NS	NS	NS	**0.025(-)**

- PD-L1 CPS was negatively associated with overall survival (p = 0.013) for sunitinib.
- There was a strong positive association of T-cell–inflamed gene signature with overall survival (p = 0.003), progression-free survival (p < 0.0001), and objective response rate (p < 0.0001) for pembrolizumab + axitinib.
- Angiogenesis was positively associated with overall survival (p = 0.013) for pembrolizumab + axitinib, and there was a strong positive association with overall survival (p < 0.0001), progression-free survival (p < 0.001), and objective response rate (p = 0.002) for sunitinib:

Biomarcadores en primera línea de cáncer renal avanzado: Keynote-426

Biomarker analysis of the phase 3 KEYNOTE-426 study of pembrolizumab (P) plus axitinib (A) versus sunitinib (S) for advanced renal cell carcinoma (RCC).

Comparison of T-cell inflamed gene expression profile and clinical outcomes



Biomarcadores en primera línea de cáncer renal avanzado: Keynote-426

Biomarker analysis of the phase 3 KEYNOTE-426 study of pembrolizumab (P) plus axitinib (A) versus sunitinib (S) for advanced renal cell carcinoma (RCC).

Other RNA signatures:

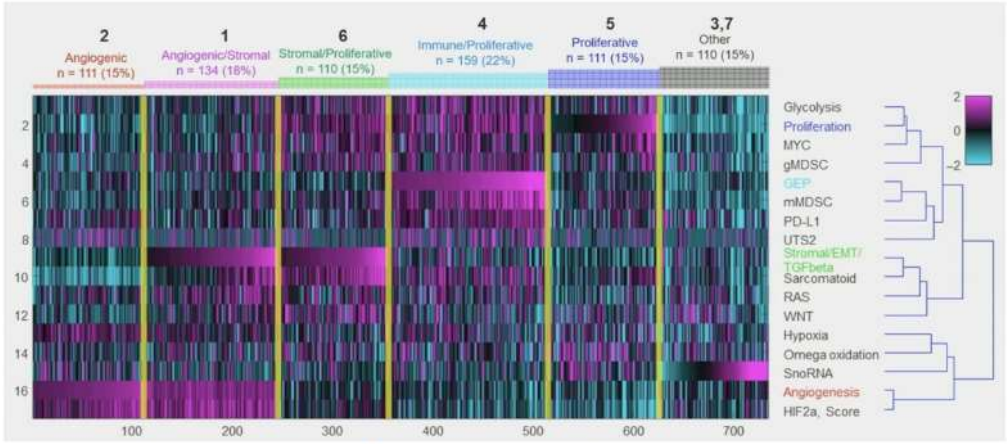
- Pembrolizumab + axitinib positive association with monocytic myeloid-derived suppressor cells was found for progression-free survival (p = 0.018) and objective response rate (p = 0.093).
- Sunitinib, positive association was found with hypoxia (overall survival, p = 0.034; objective response rate, p = 0.071) and negative associations with MYC (overall survival, p < 0.001; progression-free survival, p = 0.012) and proliferation (overall survival, p = 0.002)

	Pembrolizumab + axitinib n = 369			Sunitinib n = 361		
Signature	**ORR**	**PFS**	**OS**	**ORR**	**PFS**	**OS**
mMDSC	**0.058(+)**	**0.039(+)**	**0.057(+)**	NS	NS	NS
Hypoxia	NS	NS	NS	**0.071(+)**	NS	**0.094(+)**
MYC	NS	NS	NS	NS	**0.017(-)**	**<0.001(-)**
Proliferation	NS	NS	NS	NS	NS	**<0.001(-)**
Molecular subtype[a]	NS	NS	NS	NS	NS	**0.010**

Biomarcadores en primera línea de cáncer renal avanzado: Keynote-426

Biomarker analysis of the phase 3 KEYNOTE-426 study of pembrolizumab (P) plus axitinib (A) versus sunitinib (S) for advanced renal cell carcinoma (RCC).

Across all molecular clusters, objective response rate favored pembrolizumab + axitinib over sunitinib, with the highest pembrolizumab + axitinib objective response rate in the immune/proliferative cluster:



By WES, *PBRM1* mutation had positive association with objective response rate (p = 0.004) and progression-free survival (p = 0.079) for pembrolizumab + axitinib. For sunitinib, positive associations were observed with overall survival for *VHL* (p = 0.073) and *PBRM1* (p = 0.001) mutations, and a negative one observed for *BAP1* mutation (p = 0.046). Pembrolizumab + axitinib improved objective response rate over sunitinib regardless of mutational status.

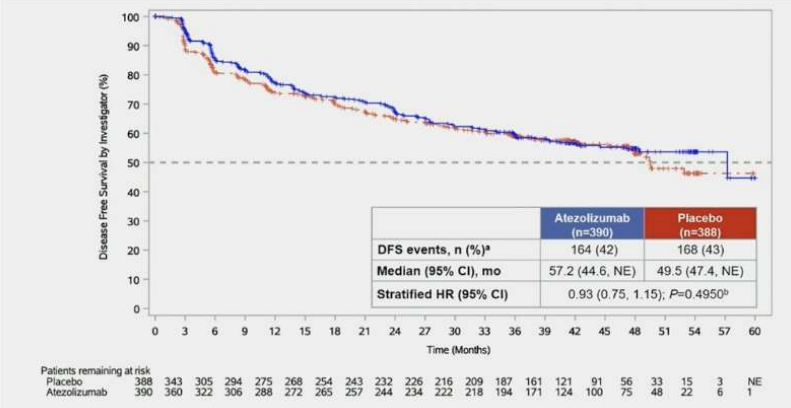
Biomarcadores en primera línea de cáncer renal avanzado: Keynote-426

Biomarker analysis of the phase 3 KEYNOTE-426 study of pembrolizumab (P) plus axitinib (A) versus sunitinib (S) for advanced renal cell carcinoma (RCC).

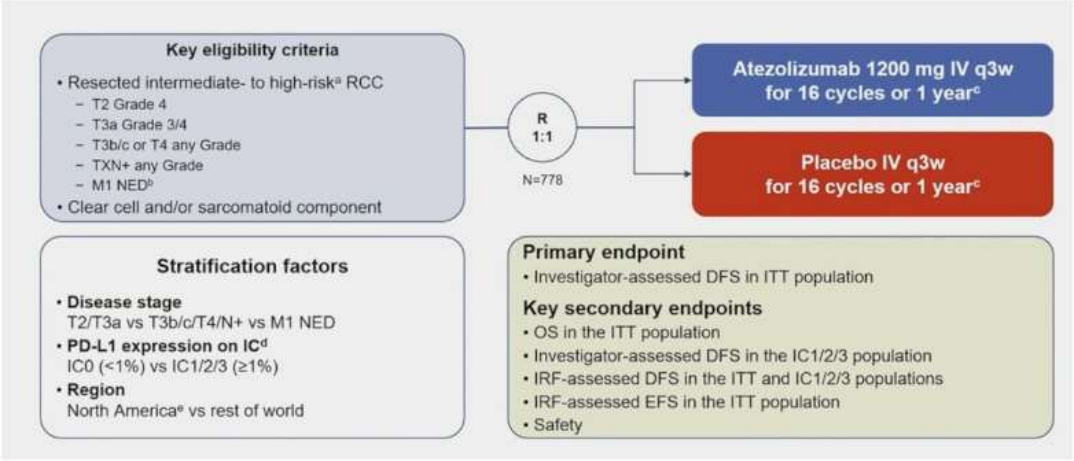
- In this exploratory analysis of KEYNOTE-426, higher T-cell inflamed gene expression profile values were positively associated with clinical outcomes for pembrolizumab + axitinib, and angiogenesis had a positive association with clinical outcomes for sunitinib
- PD-L1 CPS was not associated with clinical outcomes for pembrolizumab + axitinib
- Pembrolizumab + axitinib showed improved objective response rate versus sunitinib across molecular subtypes
  - Within the pembrolizumab + axitinib arm, the objective response rate was highest in the immune/proliferative subtype, and within the sunitinib arm, the objective response rate was highest in the angiogenic subtype
- Additional correlative data and further prospective clinical investigation are needed for biomarker-directed treatment

BIOMARCADORES EN CANCER RENAL ADYUVANCIA: KIM-1

Circulating kidney injury molecule-1 (KIM-1) biomarker analysis in IMmotion010: A randomized phase 3 study of adjuvant (adj) atezolizumab (atezo) vs placebo (pbo) in patients (pts) with renal cell carcinoma (RCC) a

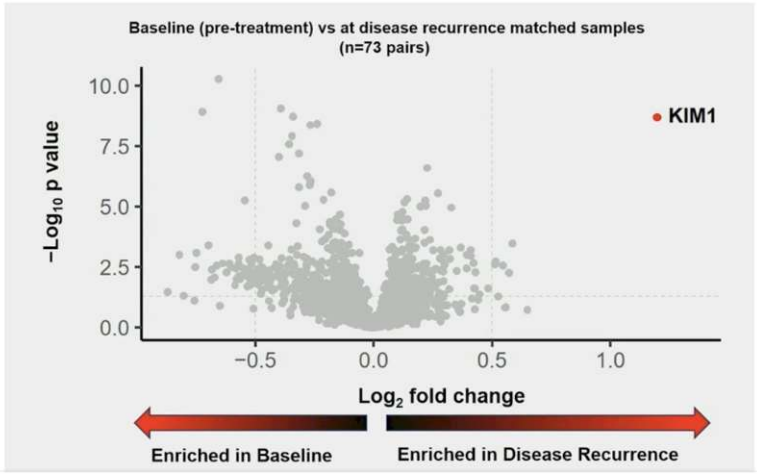


	Atezolizumab (n=390)	Placebo (n=388)
DFS events, n (%)[a]	164 (42)	168 (43)
Median (95% CI), mo	57.2 (44.6, NE)	49.5 (47.4, NE)
Stratified HR (95% CI)	0.93 (0.75, 1.15); *P*=0.4950[b]	



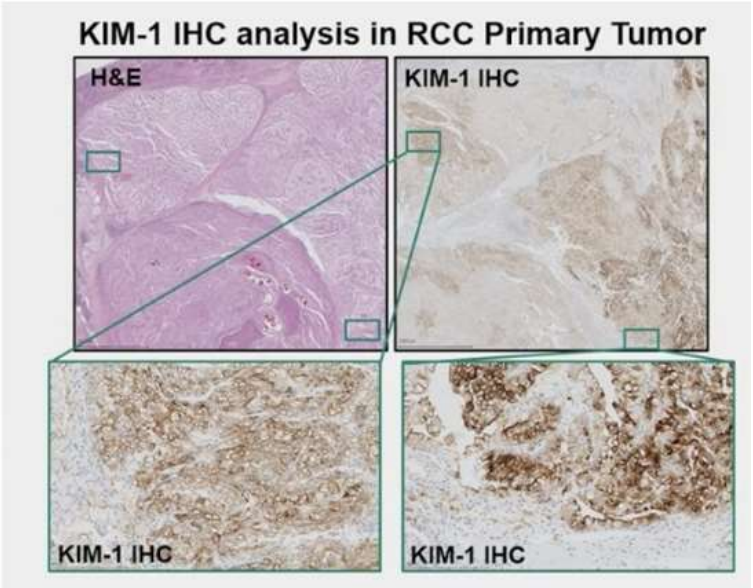
BIOMARCADORES EN CANCER RENAL ADYUVANCIA: KIM-1

Part one of the circulating biomarker analysis scheme included a retrospective proteomics analysis was done with an affinity-based proximity extension assay panel of approximately 3,000 analytes to identify circulating proteins with differential abundance patterns in matched serum samples (baseline versus at recurrence). Circulating proteins with differential abundance patterns in matched baseline versus disease recurrence samples (n=73) were identified. Among these 73 patients with matched proximity extension assay, circulating kidney injury molecule-1 was identified as the most significantly enriched protein at recurrence versus baseline:



Circulating kidney injury molecule-1 (KIM-1) biomarker analysis in IMmotion010: A randomized phase 3 study of adjuvant (adj) atezolizumab (atezo) vs placebo (pbo) in patients (pts) with renal cell carcinoma (RCC) a

In the ASSURE trial of adjuvant sunitinib, sorafenib, or placebo, higher levels of kidney injury molecule-1 in post-nephrectomy, pre-treatment plasma samples were associated with worse disease free and overall survival



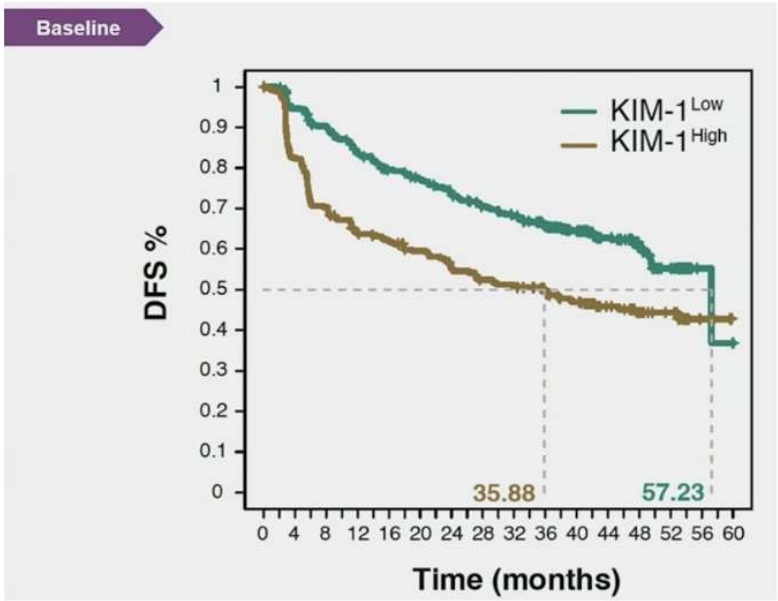
BIOMARCADORES EN CANCER RENAL ADYUVANCIA: KIM-1

Circulating kidney injury molecule-1 (KIM-1) biomarker analysis in IMmotion010: A randomized phase 3 study of adjuvant (adj) atezolizumab (atezo) vs placebo (pbo) in patients (pts) with renal cell carcinoma (RCC) a

Among 778 patients enrolled in IMmotion010, 752 (97%) had baseline kidney injury molecule-1 data (high: 300 [40%]; low: 452 [60%]):

Characteristic	KIM-1^{High} (n=300)	KIM-1^{Low} (n=452)
Age, median (range), y	64 (56-70)	58 (50-67)
Male, n (%)	232 (77)	314 (69)
Region, n (%)[a]		
Europe and Middle East	128 (43)	207 (46)
North America	102 (34)	172 (38)
Asia-Pacific	53 (18)	23 (5)
Central or South America	12 (4)	41 (9)
Australia	5 (2)	9 (2)
Pathologic disease stage, n (%)		
T2/T3a	171 (57)	313 (69)
T3b/c/T4/N+	81 (27)	82 (18)
M1 NED	48 (16)	57 (13)
Disease stage, n (%)		
I	16 (5)	14 (3)
II	21 (7)	26 (6)
III	249 (83)	388 (86)
IV	14 (5)	24 (5)
PD-L1 Status[a]		
PD-L1 positive	188 (63)	266 (59)
PD-L1 negative	112 (37)	186 (41)
Sarcomatoid component	48 (16)	51 (11)

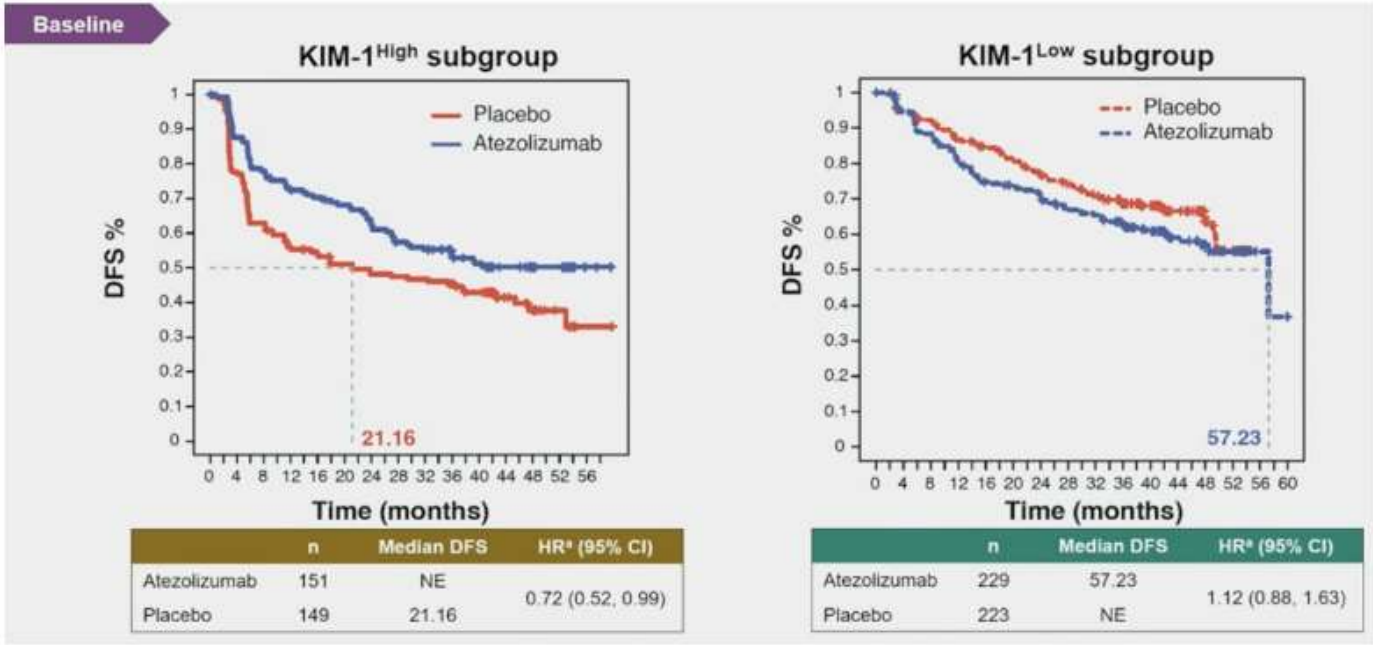
Kidney injury molecule-1–high status was associated with reduced disease-free survival, and patients with kidney injury molecule-1 high had better disease-free survival with atezolizumab versus placebo (HR 1.75, 95% CI 1.40-2.17)



BIOMARCADORES EN CANCER RENAL ADYUVANCIA: KIM-1

Circulating kidney injury molecule-1 (KIM-1) biomarker analysis in IMmotion010: A randomized phase 3 study of adjuvant (adj) atezolizumab (atezo) vs placebo (pbo) in patients (pts) with renal cell carcinoma (RCC) a

Atezolizumab improved disease free survival versus placebo in the baseline kidney injury molecule-1 high subgroup (HR 0.72, 95% CI 0.52-0.99), but not in the kidney injury molecule-1 low group:



	n	Median DFS	HR[a] (95% CI)
Atezolizumab	151	NE	0.72 (0.52, 0.99)
Placebo	149	21.16	

	n	Median DFS	HR[a] (95% CI)
Atezolizumab	229	57.23	1.12 (0.88, 1.63)
Placebo	223	NE	

BIOMARCADORES EN CANCER RENAL ADYUVANCIA: KIM-1

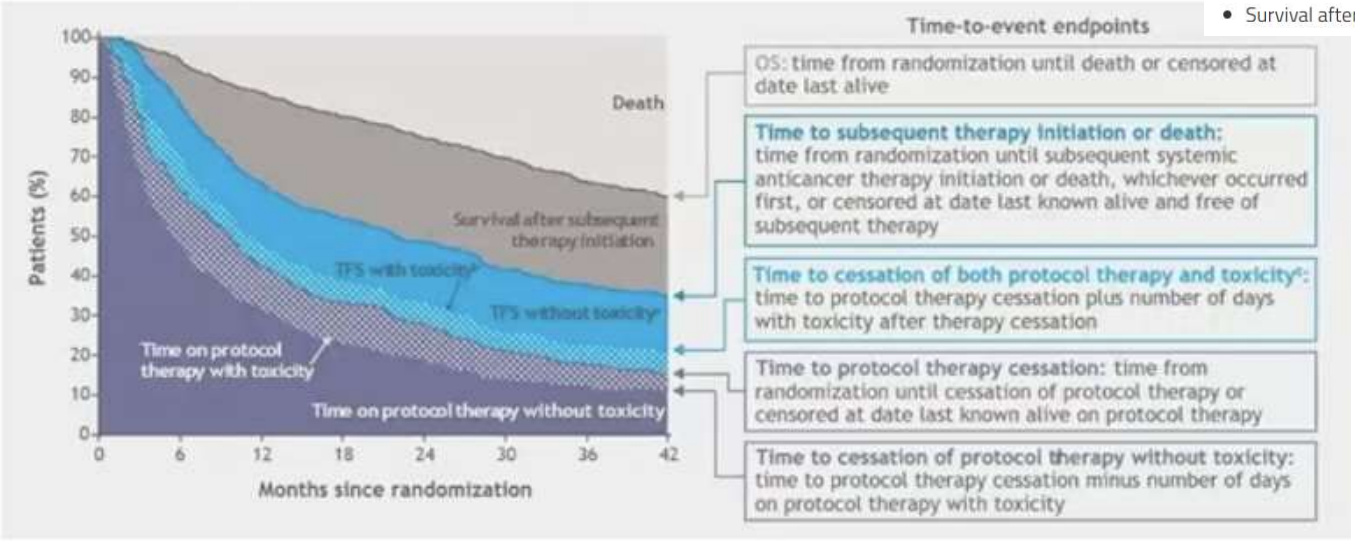
Circulating kidney injury molecule-1 (KIM-1) biomarker analysis in IMmotion010: A randomized phase 3 study of adjuvant (adj) atezolizumab (atezo) vs placebo (pbo) in patients (pts) with renal cell carcinoma (RCC) a

- In IMmotion010, high baseline serum kidney injury molecule-1 levels were associated with poorer prognosis but improved clinical outcomes with atezolizumab versus placebo
- Increased post-treatment kidney injury molecule-1 was associated with worse disease-free survival
- Additional validation studies are warranted to confirm the utility of circulating serum kidney injury molecule-1 in adjuvant RCC as a non-invasive biomarker for:
  - Identification of minimal residual disease
  - Predicting outcomes to checkpoint inhibitor treatment
  - Longitudinal monitoring for disease recurrence

Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

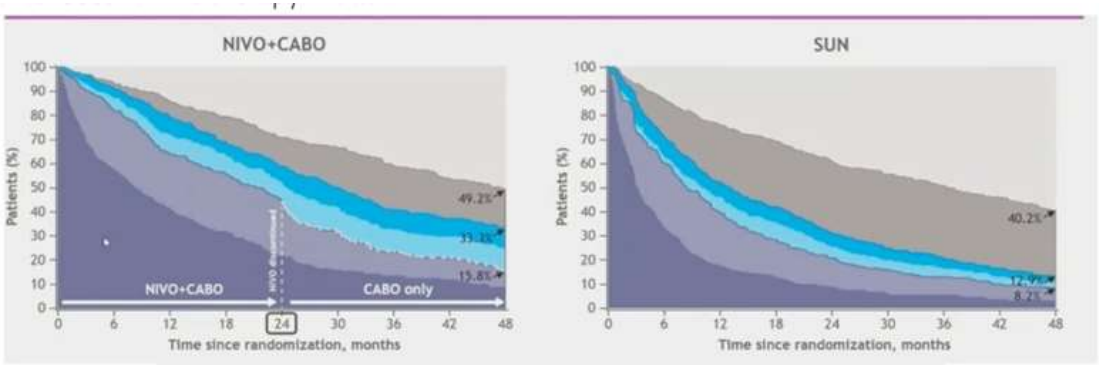
Partitioned overall survival: Comprehensive analysis of survival states over 4 years in CheckMate 9ER comparing first-line nivolumab plus cabozantinib versus sunitinib in advanced renal cell carcinoma (aRCC).

- Time on first-line protocol therapy
  - Meantime with/without reported grade 2+ treatment-related adverse events (TRAEs)
- TFS: Time between firs-line protocol therapy cessation and second-line therapy initiation or death (difference between the two endpoints)
  - Meantime with/without reported grade 2+ TRAEs
- Survival after subsequent systemic therapy (second line) initiation.



Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Partitioned overall survival: Comprehensive analysis of survival states over 4 years in CheckMate 9ER comparing first-line nivolumab plus cabozantinib versus sunitinib in advanced renal cell carcinoma (aRCC).



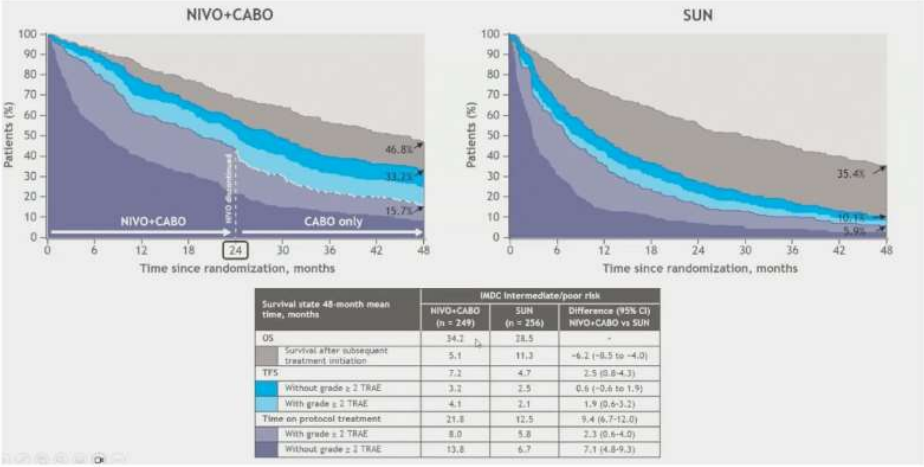
Survival state 48-month mean time, months	Intent-to-treat		
	NIVO+CABO (N = 323)	SUN (N = 328)	Difference (95% CI) NIVO+CABO vs SUN
OS	35.1	30.7	-
Survival after subsequent treatment initiation	5.5	12.0	−6.5 (−8.6 to −4.4)
TFS	7.0	4.6	2.4 (0.8-3.9)
Without grade ≥ 2 TRAE	3.0	2.3	0.7 (−0.4 to 1.8)
With grade ≥ 2 TRAE	3.9	2.3	1.6 (0.5-2.8)
Time on protocol treatment	22.6	14.1	8.5 (6.2-10.8)
With grade ≥ 2 TRAE	8.3	6.7	1.7 (0.1-3.2)
Without grade ≥ 2 TRAE	14.3	7.4	6.8 (4.8-8.8)

Nivolumab+Cabozantinib group spent a mean of 8.5 (95% CI 6.2–10.8) months more survival time on first-line protocol therapy, whereas the control group spent a mean of 6.5 (95% CI 4.4–8.6) months more survival time after second-line therapy initiation.

Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Partitioned overall survival: Comprehensive analysis of survival states over 4 years in CheckMate 9ER comparing first-line nivolumab plus cabozantinib versus sunitinib in advanced renal cell carcinoma (aRCC).

In patients with IMDC intermediate/poor risk, Nivolumab + Cabozantinib was associated with improved OS compared to sunitinib (46.8% vs. 35.4%). At 48 months, 15.7% of patients in the Nivolumab + Cabozantinib group were continuing first-line protocol therapy, compared to 5.9% in the Sunitinib group. The mean TFS (95% CI) was 2.5 (0.8–4.3) months longer after treatment with Nivolumab + Cabozantinib, and the difference in mean TFS without toxicity was 0.6 (95% CI –0.4 to 1.8) months.



Survival state 48-month mean time, months	IMDC Intermediate/poor risk		
	NIVO+CABO (n = 249)	SUN (n = 256)	Difference (95% CI) NIVO+CABO vs SUN
OS	34.2	28.5	-
Survival after subsequent treatment initiation	5.1	11.3	−6.2 (−8.5 to −4.0)
TFS	7.2	4.7	2.5 (0.8-4.3)
Without grade ≥ 2 TRAE	3.2	2.5	0.6 (−0.6 to 1.9)
With grade ≥ 2 TRAE	4.1	2.1	1.9 (0.6-3.2)
Time on protocol treatment	21.8	12.5	9.4 (6.7-12.0)
With grade ≥ 2 TRAE	8.0	5.8	2.3 (0.6-4.0)
Without grade ≥ 2 TRAE	13.8	6.7	7.1 (4.8-9.3)

Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

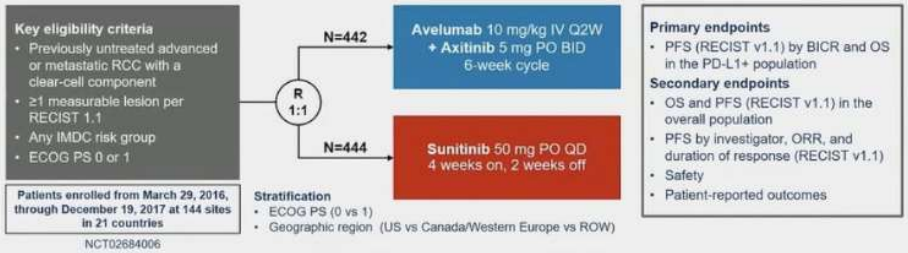
Partitioned overall survival: Comprehensive analysis of survival states over 4 years in CheckMate 9ER comparing first-line nivolumab plus cabozantinib versus sunitinib in advanced renal cell carcinoma (aRCC).

- At four years post-randomization in the CheckMate 9ER study, there was a longer OS in patients assigned to Nivolumab + Cabozantinib compared to Sunitinib (49.2% vs. 40.2%).
- The longer OS achieved with Nivolumab + Cabozantinib was accompanied by 1.5 times longer mean time surviving treatment-free before second-line therapy compared to Sunitinib (difference of 2.4 months).
- The mean TFS difference was similarly longer for Nivolumab + Cabozantinib versus Sunitinib across most subgroups analyzed.
- TFS was more frequently observed after patients discontinued therapy for TRAEs, toxicity, or other reasons such as completion of therapy per protocol.
- This research highlights the importance of monitoring patient status after treatment discontinuation to understand the patient survival experience.

Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.

JAVELIN Renal 101: a multicenter, randomized, phase 3 trial



- The primary (final) OS analysis was planned when 368 deaths had occurred in the PD-L1+ population, which would provide 90% power to detect an HR of 0.70 using a 1-sided log-rank test at a significance level of 0.021

Prior results from JAVELIN Renal 101 in the overall population

	Primary analysis of PFS 1st interim analysis of OS ≥6 months of follow-up[1]		3rd interim analysis of OS ≥28 months of follow up[2]	
	Avelumab + Axitinib (N=442)	Sunitinib (N=444)	Avelumab + Axitinib (N=442)	Sunitinib (N=444)
PFS				
Median PFS (95% CI), months	13.8 (11.1-NE)*	8.4 (6.9-11.1)*	13.9 (11.1-16.6)†	8.5 (8.2-9.7)†
HR (95% CI)	0.69 (0.563-0.838)		0.67 (0.568-0.785)	
p-value	1-sided p<0.001		1-sided p<0.0001	
OS				
Median OS (95% CI), months	Not reached (NE)	Not reached (NE)	Not reached (42.2-NE)	37.8 (31.4-NE)
HR (95% CI)	0.78 (0.554-1.084)		0.79 (0.643-0.969)	
Confirmed ORR (95% CI), %	51.4 (46.6-56.1)*	25.7 (21.7-30.0)*	59.3 (54.5-63.9)†	31.8 (27.4-36.3)†

- The analysis of OS remained immature in 3 prespecified interim analyses

HR, hazard ratio; NE, not estimable; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.
*By blinded independent central review. †By investigator assessment.
1. Motzer RJ, et al. N Engl J Med. 2019;380:1103-15. 2. Haanen J, et al. ESMO Open 2023;8:101210.

2024 ASCO ANNUAL MEETING #ASCO24 PRESENTED BY: Robert J. Motzer, MD

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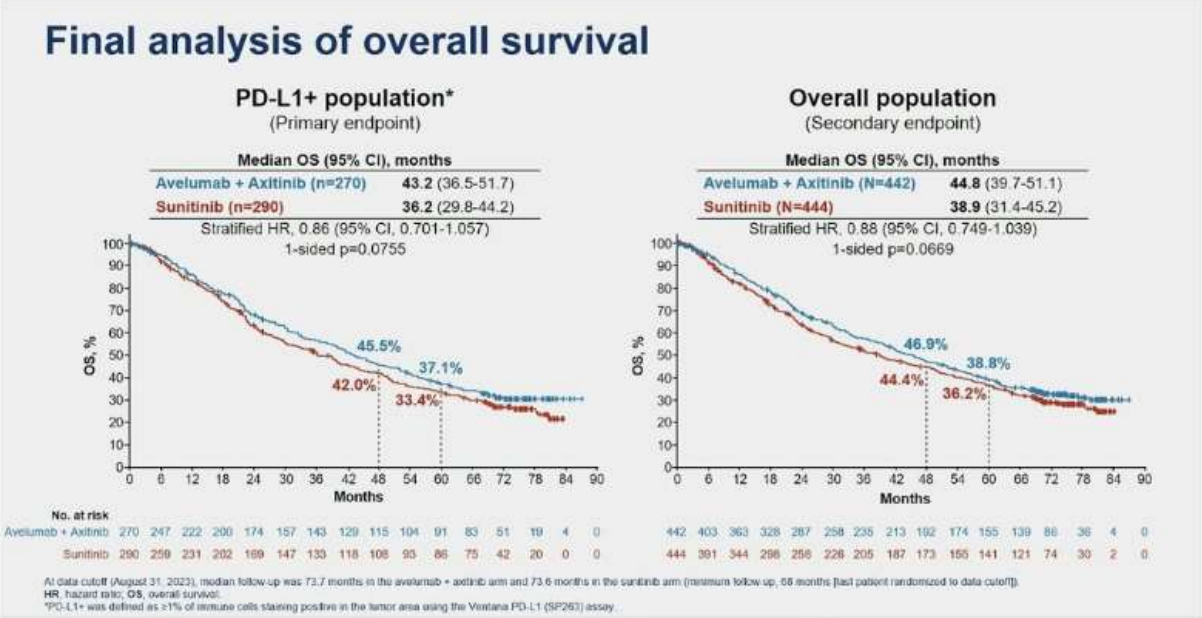
Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.



Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.

OS in prespecified subgroups in the overall population

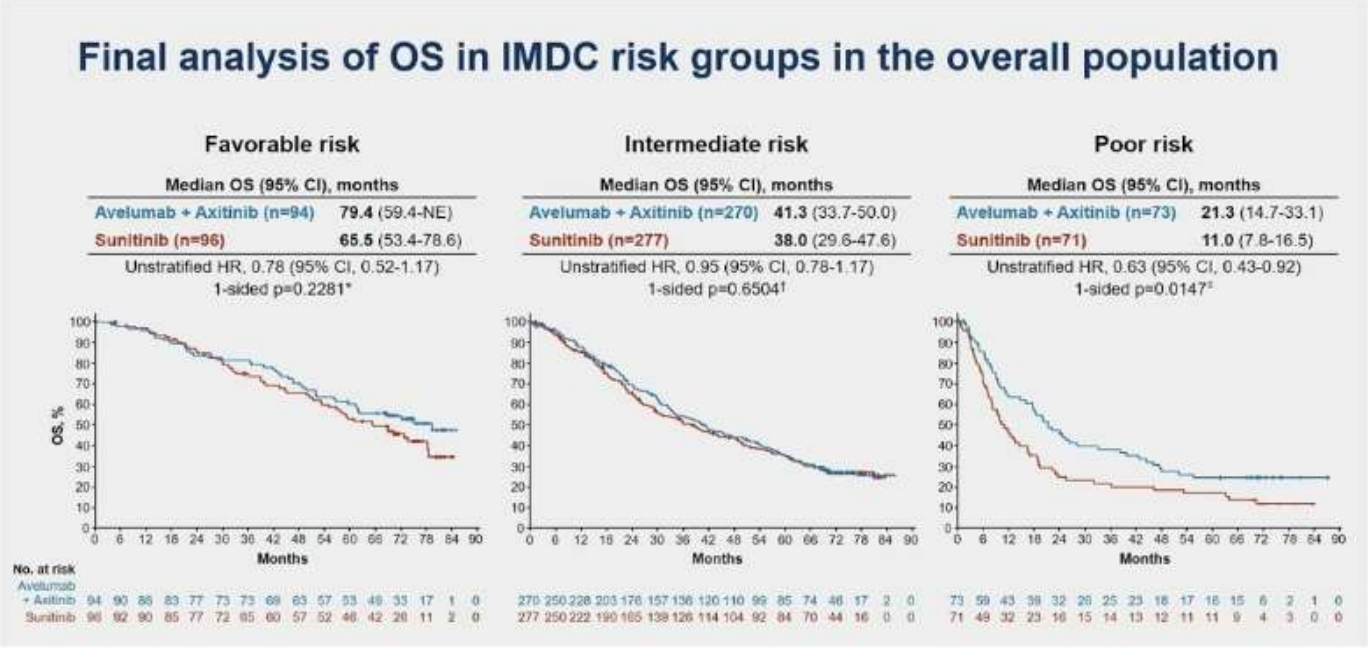
	Subgroup	Events/patients Avelumab + Axitinib	Events/patients Sunitinib	HR (95% CI)
Overall	All participants (stratified)	283/442	295/444	0.882 (0.749-1.039)
	All participants (unstratified)	283/442	295/444	0.877 (0.745-1.033)
ECOG PS (per IRT)	0	164/279	175/281	0.837 (0.677-1.036)
	1	119/163	120/163	0.939 (0.728-1.210)
Geographic region (per IRT)	United States	81/128	92/130	0.800 (0.593-1.078)
	Canada/Western Europe	88/128	91/128	0.863 (0.644-1.158)
	Rest of the world	114/186	112/186	0.951 (0.733-1.235)
Age	<65 years	171/271	182/275	0.835 (0.678-1.029)
	≥65 years	112/171	113/169	0.955 (0.735-1.240)
Sex	Male	195/316	228/344	0.813 (0.671-0.984)
	Female	88/126	67/100	1.076 (0.782-1.479)
IMDC risk status	Favorable	44/94	52/96	0.781 (0.523-1.168)
	Intermediate	185/270	184/277	0.954 (0.778-1.170)
	Poor	51/73	59/71	0.628 (0.431-0.916)
PD-L1 status*	Positive	176/270	199/290	0.863 (0.704-1.057)
	Negative	81/132	77/120	0.889 (0.650-1.214)
	Unknown	26/40	19/34	0.992 (0.548-1.795)

ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; IMDC, International Metastatic RCC Database Consortium; IRT, interactive response technology; OS, overall survival; RCC, renal cell carcinoma.
*PD-L1+ was defined as ≥1% of immune cells staining positive within the tumor area using the Ventana PD-L1 (SP263) assay

When stratifying by IMDC risk groups, OS was still not significantly better in the favorable or intermediate risk groups. However, in the poor risk group, the median OS was 21.3 months in the avelumab + axitinib group compared to 11.0 months for sunitinib (HR 0.63, 95% CI 0.43-0.92, p=0.015).

Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.



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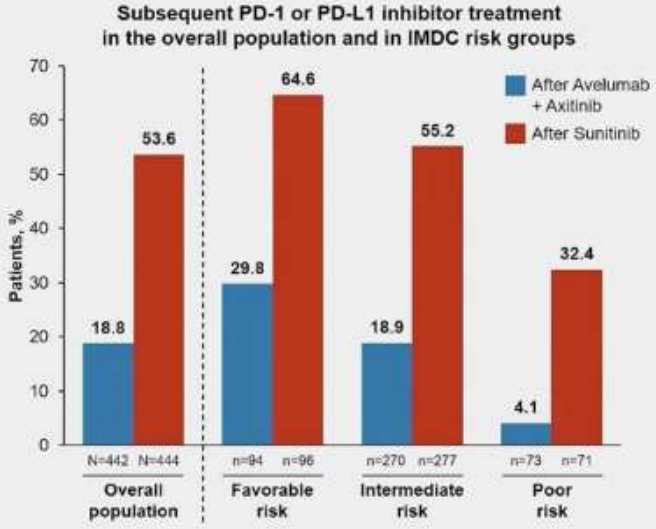
Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.

Subsequent treatment in the overall population

	Avelumab + Axitinib (N=442)	Sunitinib (N=444)
Received ≥1 subsequent anticancer drug treatment, n (%)	257 (58.1)	308 (69.4)
Category of drug received, n (%)*		
PD-1 or PD-L1 inhibitor	83 (18.8)	238 (53.6)
VEGF or VEGFR inhibitor	226 (51.1)	205 (46.2)
Other drug therapy	102 (23.1)	120 (27.0)
No. of subsequent drug regimens, n (%)		
0	88 (19.9)	66 (14.9)
1	147 (33.3)	155 (34.9)
≥2	110 (24.9)	153 (34.5)
Not reported	97 (21.9)	70 (15.8)



Second-line therapy was received by 58.1% of patients in the avelumab + axitinib arm and 69.4% in the sunitinib arm.

This included a PD-L1 inhibitor in 18.8% of the avelumab + axitinib arm and 53.6% of the sunitinib arm.

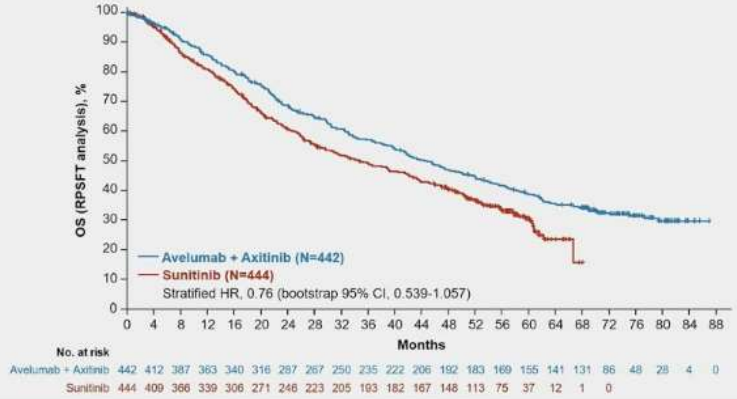
Additionally, more than double (65% vs. 30%) the number of patients in the favorable risk group and more than triple (55.2% vs. 19%) in the intermediate risk group received subsequent treatment in the sunitinib arm compared to the avelumab + axitinib arm.

Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.

In an exploratory analysis, after adjusting for subsequent PD1 or PD-L1 treatment in the overall population, there was still no significant benefit associated with avelumab + axitinib for OS (sHR 0.76, 95% CI 0.539-1.057).

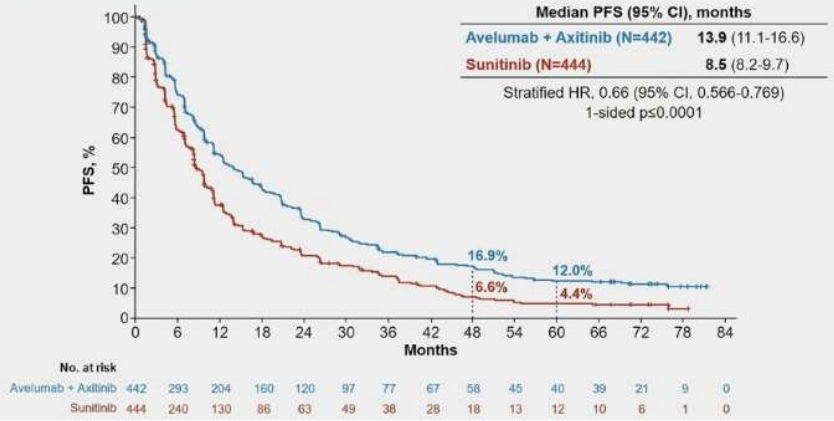
OS analyses adjusted for subsequent PD-1 or PD-L1 inhibitor treatment in the overall population



Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

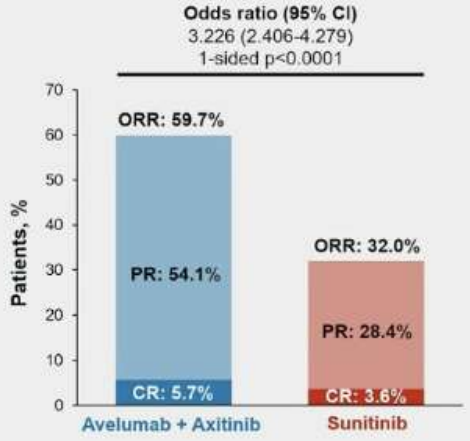
Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.

Long-term analysis of PFS by investigator assessment in the overall population



Responses by investigator assessment in the overall population

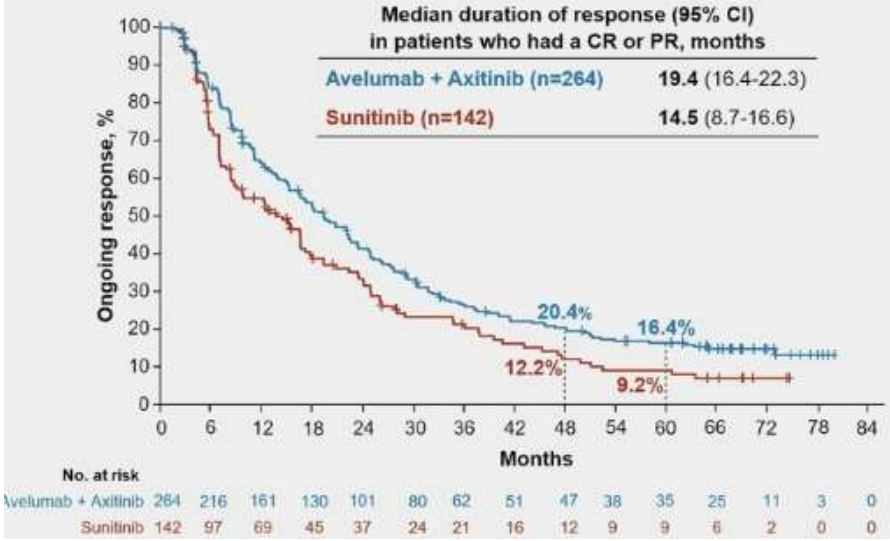
	Avelumab + Axitinib (N=442)	Sunitinib (N=444)
Confirmed BOR, n (%)		
CR	25 (5.7)	16 (3.6)
PR	239 (54.1)	126 (28.4)
SD	111 (25.1)	196 (44.1)
PD	40 (9.0)	68 (15.3)
NE	26 (5.9)	37 (8.3)
Non-CR/non-PD*	1 (0.2)	1 (0.2)



Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.

Duration of response by investigator assessment in the overall population



Proportion of patients in the TOTAL arm by duration of response, n (%)

Duration of response	Avelumab + Axitinib (N=442)	Sunitinib (N=444)
Any	264/442 (59.7)	142/444 (32.0)
≥6 months	216 (48.9)	97 (21.8)
≥1 years	161 (36.4)	69 (15.5)
≥2 years	101 (22.9)	37 (8.3)
≥3 years	62 (14.0)	21 (4.7)
≥4 years	47 (10.6)	12 (2.7)
≥5 years	35 (7.9)	9 (2.0)
≥6 years	11 (2.5)	2 (0.5)

Supervivencia global en cáncer renal avanzado: ¿Alguna novedad?

Avelumab + axitinib vs sunitinib in patients (pts) with advanced renal cell carcinoma (aRCC): Final overall survival (OS) analysis from the JAVELIN Renal 101 phase 3 trial.

- JAVELIN Renal 101 trial provides the longest follow-up for any IO +TKI combination reported to date
- OS analyses favored avelumab + axitinib vs sunitinib but did not reach statistical significance.
- PFS was longer with avelumab + axitinib vs sunitinib
- ORR was almost double for avelumab + axitinib and responses were durable in a subset of patients
- Final analysis results confirm the long-term efficacy and manageable safety profile of avelumab + axitinib treatment in patients with aRCC

ABSTRACTS RÁPIDOS : UNA DIAPO A RECORDAR

A multi-institution analysis of outcomes with first-line systemic therapy for 99 patients with metastatic chromophobe renal cell carcinoma.

A multicenter phase II study of modified FOLFIRINOX for first-line treatment for advanced urachal cancer (ULTMA; KCSG GU20-03).

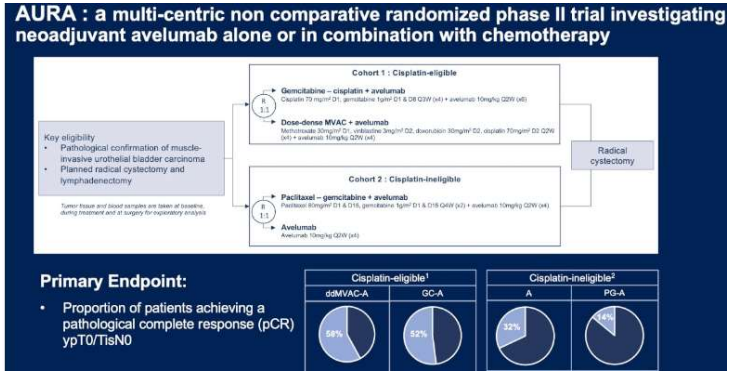
Camrelizumab plus apatinib for previously treated advanced adrenocortical carcinoma: A single-arm, open-label, phase 2 trial.

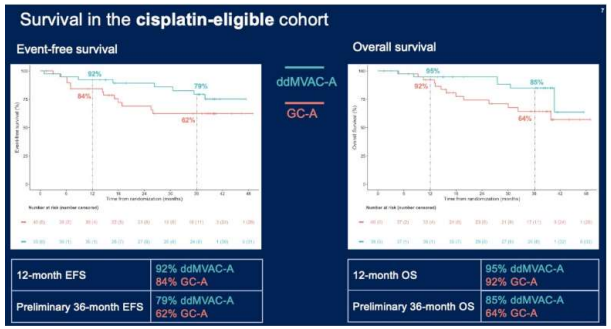
Systemic treatments in favorable and very favorable risk metastatic renal cell carcinoma (mRCC): Real world evidence from the International mRCC Database Consortium (IMDC).

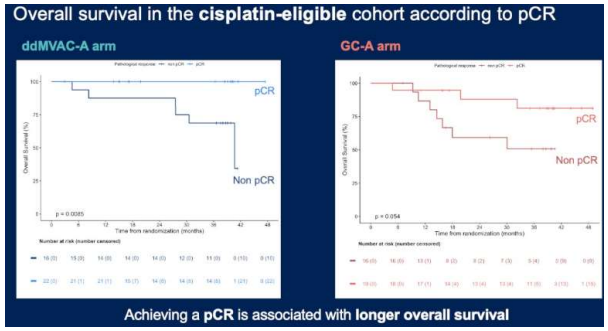
Avelumab (A) as neoadjuvant therapy in patients (pts) with muscle-invasive urothelial carcinoma (MIUC): Survival data of AURA trial, Oncodistinct 004.

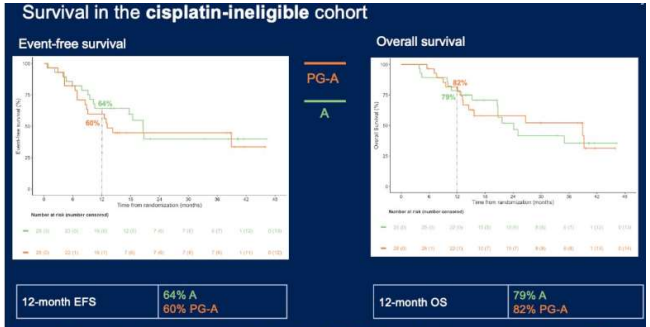
ABSTRACTS RÁPIDOS : UNA DIAPO A RECORDAR

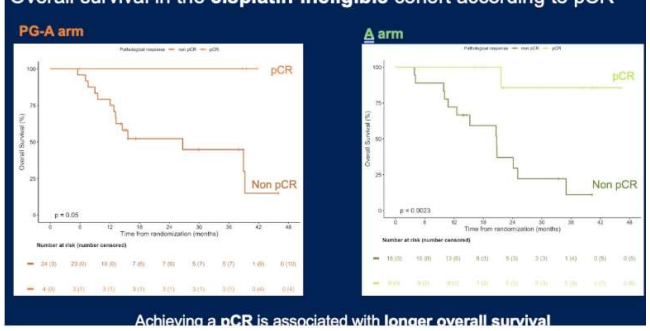
Avelumab (A) as neoadjuvant therapy in patients (pts) with muscle-invasive urothelial carcinoma (MIUC): Survival data of AURA trial, Oncodistinct 004.









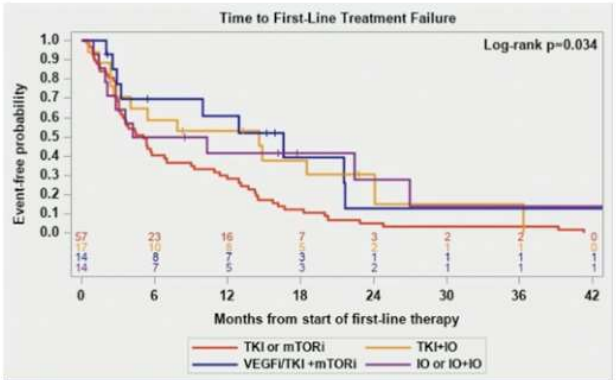


- Cisplatin-eligible cohort :
  - High event-free and overall survival rates are achieved at 12 months and 36 months in patients treated with neoadjuvant avelumab in combination with cisplatin-based chemotherapies, especially in patients treated with ddMVAC + avelumab.
- Cisplatin-ineligible cohort :
  - Lower survival outcomes are achieved at 12 months, with no additional benefit from addition of avelumab to paclitaxel/gemcitabine.
  - Longer follow-up is needed for a 36-month survival analysis.
- Achieving a complete pathologic response is correlated with better survival outcomes for each treatment arm.

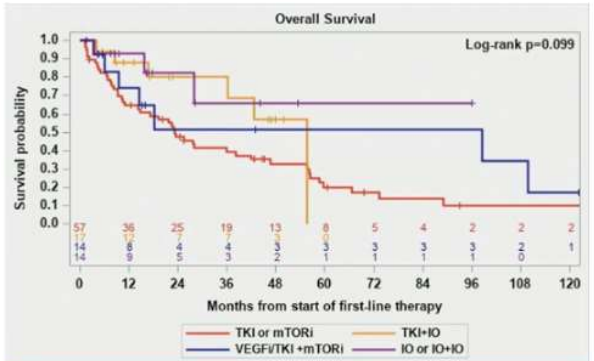
ABSTRACTS RÁPIDOS : UNA DIAPO A RECORDAR

A multi-institution analysis of outcomes with first-line systemic therapy for 99 patients with metastatic chromophobe renal cell carcinoma.

There were significant differences in time to treatment failure between the four treatment groups (log-rank p=0.034). The median time to treatment failure was longest for patients receiving VEGF/TKI + mTORi doublet therapy (17 months) and TKI + IO doublet therapy (15 months).



	N	Median TTF, months (95% CI)
TKI or mTORi monotherapy	57	5 (3, 7)
VEGFi/TKI + mTORi doublets	14	17 (3, 22)
TKI + IO doublets	17	15 (2, 24)
IO or IO + IO	14	7 (2, 27)



OS events	Median OS, months (95% CI)	12-month OS rate (95% CI)	Months f/u survivors, median (range)
44	23 (14, 42)	64% (50, 75)	45 (2, 156)
7	99 (6, NR)	74% (39, 91)	15 (1, 122)
6	56 (17, 56)	88% (59, 97)	22 (6, 50)
3	NR	93% (59, 99)	17 (4, 96)

From an overall survival standpoint, the median survival was similarly longest for patients in the VEGF/TKI + mTORi doublet therapy (99 months) and TKI + IO doublet therapy groups (56 months).

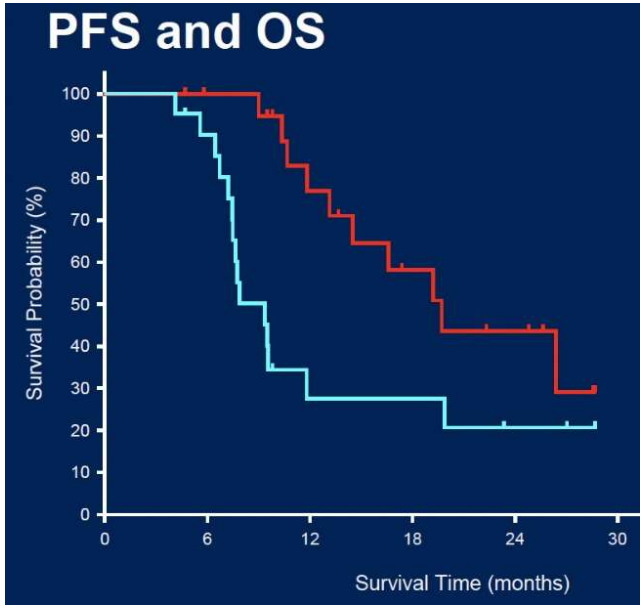
ABSTRACTS RÁPIDOS : UNA DIAPO A RECORDAR

A multicenter phase II study of modified FOLFIRINOX for first-line treatment for advanced urachal cancer (ULTMA; KCSG GU20-03).

21 patients

	No. of pts/percentage
Complete Response (CR)	2(9.5%)
Partial Response (PR)	11(52.4%)
Stable Disease (SD)	8(38.1%)
Progressive Disease (PD)	0

Overall response rate was 61.9% (95% CI, 41.1-82.7)



After a median follow-up of 24.7 months,

median PFS was 9.3 months (95% CI: 6.7 –11.9)

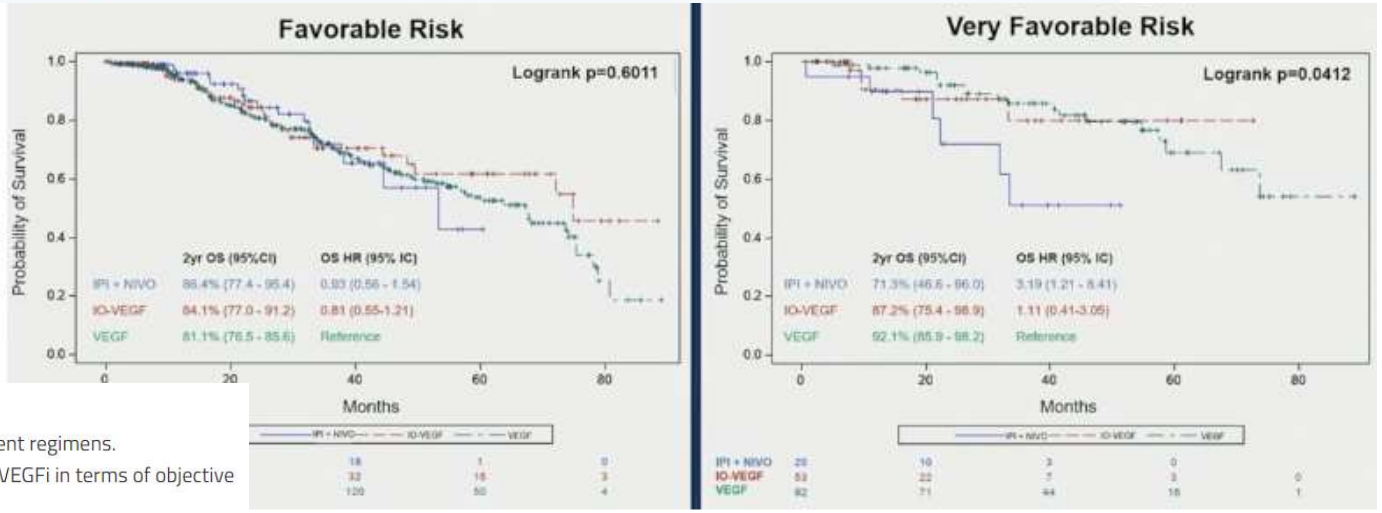
median OS was 19.7 months (95% CI: 14.3 – 25.1).

- The ULTIMA study, the first prospective study in advanced urachal cancer, showed that a modified FOLFIRINOX showed an encouraging objective response rate (62%) and progression-free survival (9.3 months).
- This regimen is well tolerated with no febrile neutropenic events using prophylactic long-acting G-CSF
- Modified FOLFIRINOX should be considered for the 1st line treatment of advanced urachal cancer

ABSTRACTS RÁPIDOS : UNA DIAPO A RECORDAR

Systemic treatments in favorable and very favorable risk metastatic renal cell carcinoma (mRCC): Real world evidence from the International mRCC Database Consortium (IMDC).

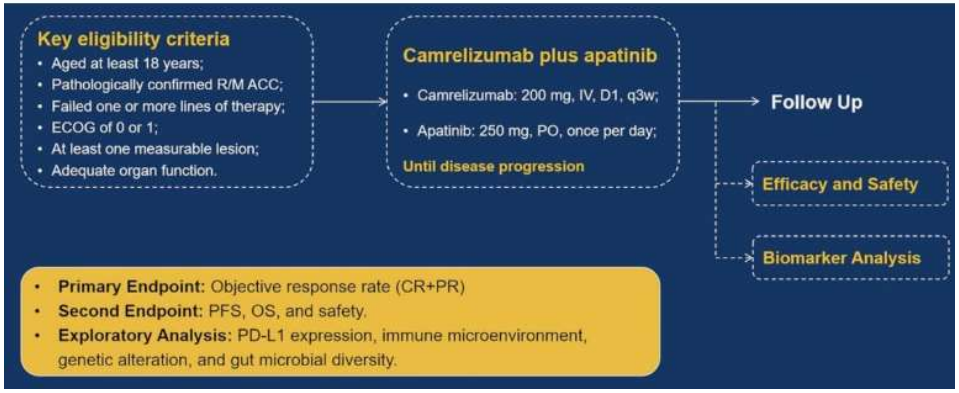
- Primary diagnosis to systemic therapy ≥3 year
- Absence of brain, liver, or bone metastases
- Karnofsky Performance Status of 90–100%



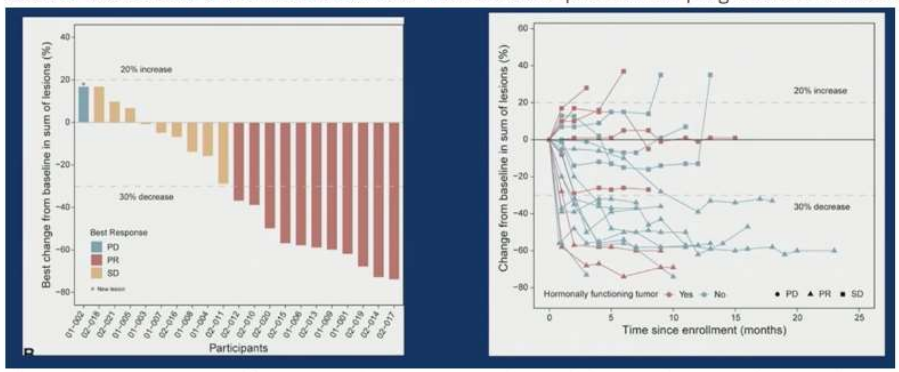
- In all favorable risk patients
  - There was no significant difference in 2-year overall survival between the treatment regimens.
  - However, the IO + VEGFi regimen demonstrated superior outcomes compared to VEGFi in terms of objective response rate, treatment duration, and time to next therapy,
- In the subgroup of patients with very favorable risk disease:
  - There was a statistically significant worse 2-year OS (HR 3.19; p=0.041) and objective response rate (p=0.039) with IPI-NIVO compared to other regimens
  - This suggests the importance of including a VEGF inhibitor in the treatment regime for this patient subset.

ABSTRACTS RÁPIDOS : UNA DIAPO A RECORDAR

Camrelizumab plus apatinib for previously treated advanced adrenocortical carcinoma: A single-arm, open-label, phase 2 trial.



From an efficacy standpoint, the objective response rate was 52% in the patient cohort (all partial responses). Stable disease was observed in an additional 43%. There was one patient with progressive disease as best response.



The median progression-free survival was 12.6 months, and the median overall survival was 20.9 months. The corresponding 1-year rates were 57.1% and 74.5%, respectively.

Camrelizumab and apatinib combination therapy for adrenocortical carcinoma patients with disease progression following ≥1 line of therapy is associated with an objective response rate of 52%, which is higher than what has been historically reported in this setting.

GRACIAS