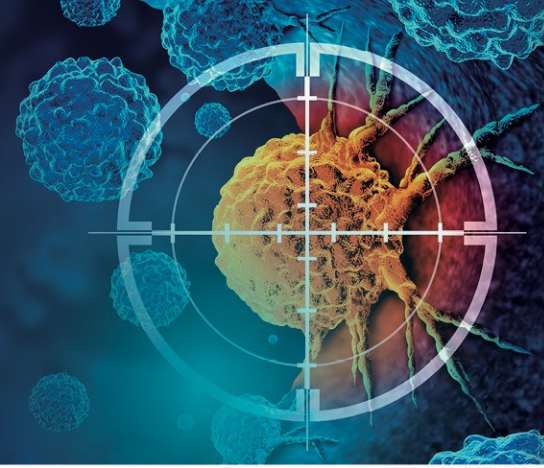
XVIII SIMPOSIUM

BASES BIOLÓGICAS DEL CÁNCER E INNOVACIÓN TERAPÉUTICA

MÁS DE 20 AÑOS A LA VANGUARDIA DE LA FORMACIÓN EN LA BIOLOGÍA Y TRATAMIENTO DEL CÁNCER



Inmunoterapia y ADC de vanguardia… día a día.

Juan Carlos Redondo González MD, PhD.

Hospital Universitario de Salamanca – Servicio de Oncología Médica.

ÍNDICE

- INTerpath-001
- KeyNote-C93
- TroFuse-005
- ARTEMIS-011

INTerpath-001

Phase 3 Study of the **mRNA-Based Individualized Neoantigen Therapy (INT) Intismeran** Autogene plus Pembrolizumab vs Pembrolizumab Alone for Adjuvant Treatment of Resected Stage IIB-IV Melanoma

Key Eligibility Criteria

- Age ≥18 years
- Resected cutaneous melanoma
- AJCC 8th ed. Stage IIB/IIC (clinical IIB/IIC permitted), III, or IV
- FFPE tumor sample suitable for NGS and intismeran generation
- No prior systemic therapy
- ECOG PS 0 or 1

R 2:1

Intismeran
1 mg IM Q3W for 9 doses
+
Pembrolizumab
400 mg IV Q6W for 9 cycles

Placebo[a]
IM Q3W for 9 doses
+
Pembrolizumab
400 mg IV Q6W for 9 cycles

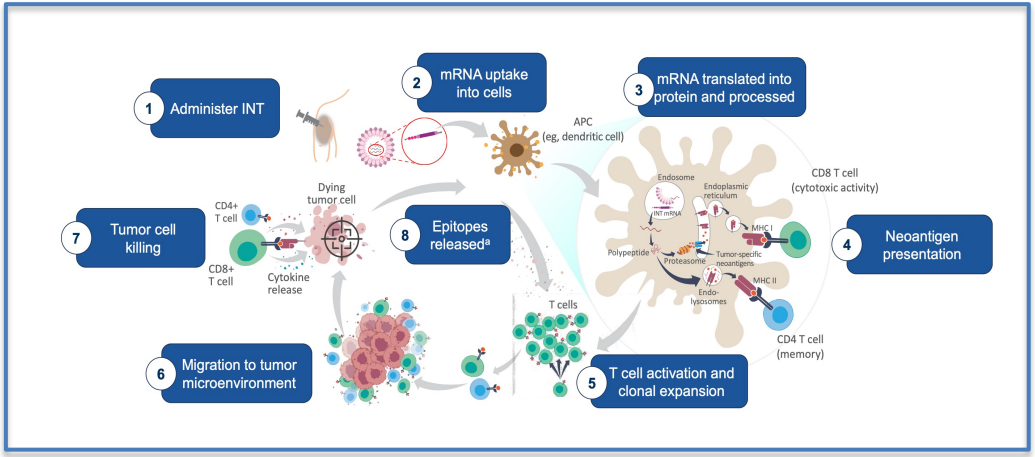
N= 1137

mSeguimiento:
24.6 meses [18.2–34.5]

- **Estadio:** IIB/IIC/IIIA/IIIB vs IIIC/IIID/IV
- **Edad <65 años vs ≥ 65 años.**

OBJETIVOS

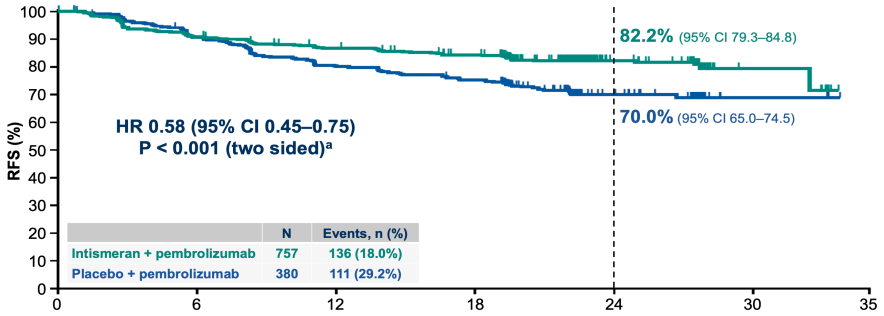
- **Objetivo primario**: RFS.
- **Objetivos secundarios**: DMFS, OS, seguridad y QoL.



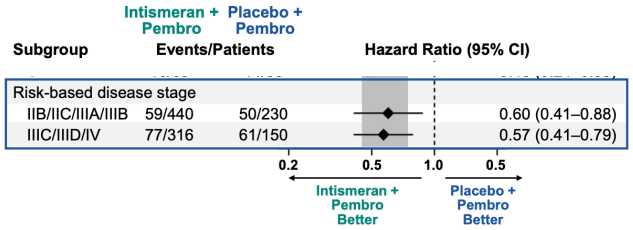
	Intismeran + pembrolizumab (N = 757)	Placebo + pembrolizumab (N = 380)
ECOG PS 0, n (%)	697 (92.1)	350 (92.1)
Risk-based disease stage, n (%)		
IIB/IIC/IIIA/IIIB	441 (58.3)	230 (60.5)
IIIC/IIID/IV	316 (41.7)	150 (39.5)
Overall disease stage, n (%)		
IIA	1 (0.1)[c]	0
IIB	155 (20.5)	73 (19.2)
IIC	92 (12.2)	42 (11.1)
IIIA	50 (6.6)	32 (8.4)
IIIB	143 (18.9)	83 (21.8)
IIIC	245 (32.4)	118 (31.1)
IIID	10 (1.3)	4 (1.1)
IV	61 (8.1)	28 (7.4)

LBA1 'INTerpath-001: Phase 3 study of the mRNA-based individualized neoantigen therapy (INT) intismeran autogene (intismeran) plus pembrolizumab (pembro) vs pembro alone for adjuvant treatment of resected stage IIB-IV melanoma (MEL)' will be presented by Dr Georgina Long during Presidential Symposium I on Saturday, 24 October 2026, from 16:30 to 18:15 (CEST) in Alicante Auditorium – Hall 6.

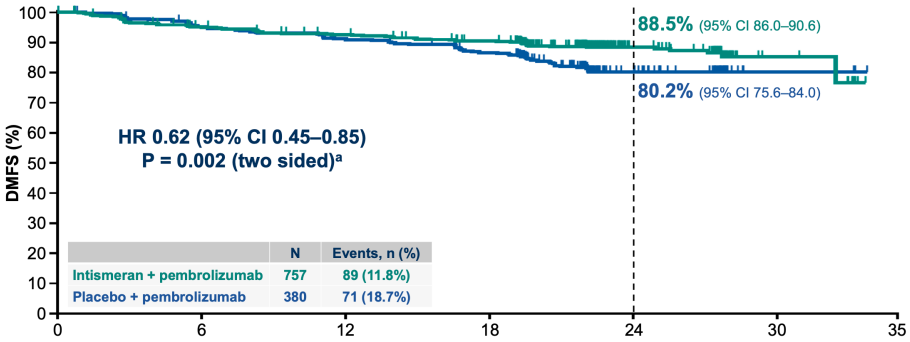
RFS Primary Analysis: ITT



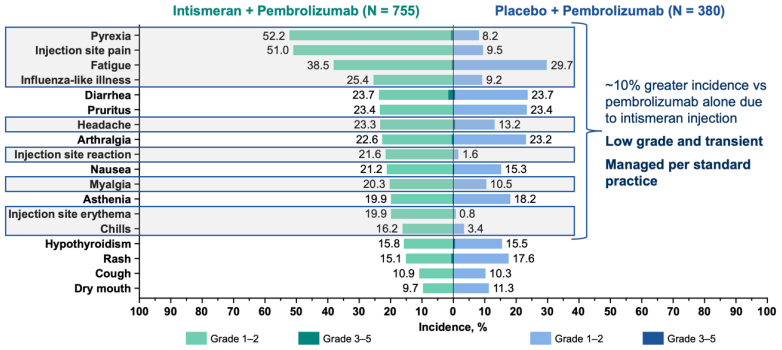
Recurrence-Free Survival



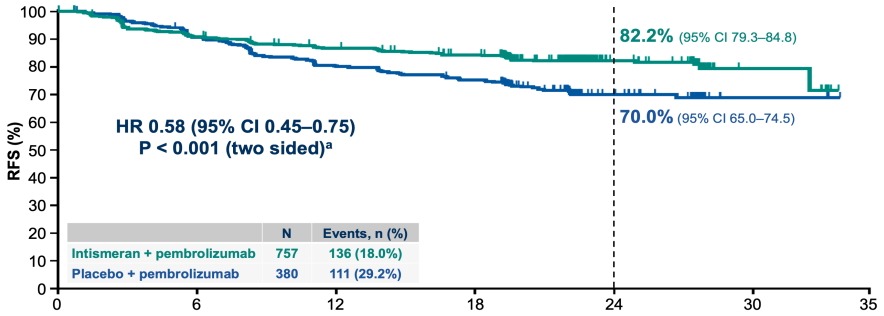
DMFS Primary Analysis: ITT



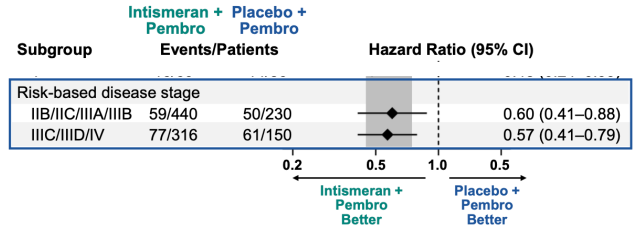
Perfil de toxicidad



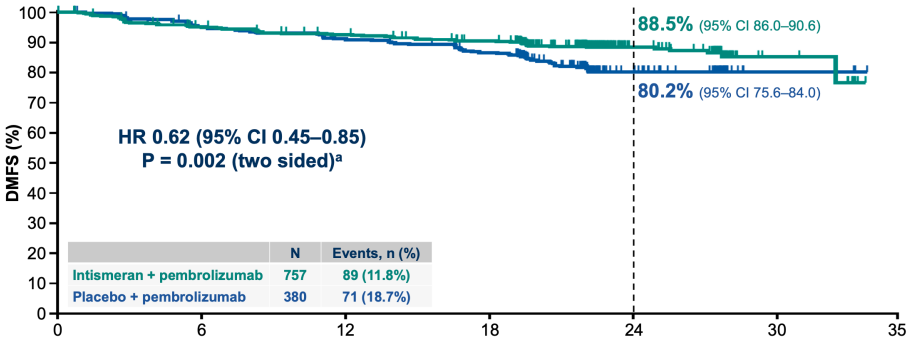
RFS Primary Analysis: ITT



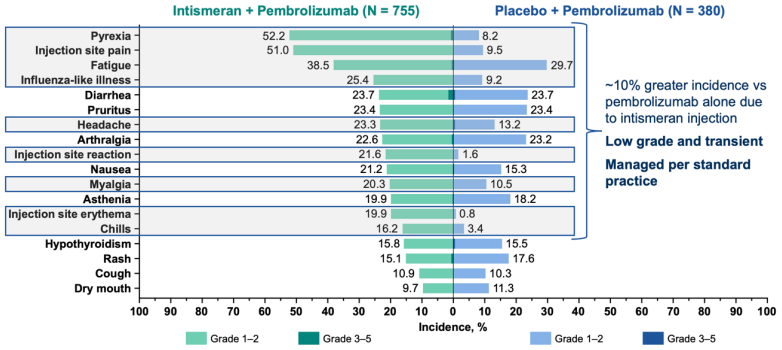
Recurrence-Free Survival



DMFS Primary Analysis: ITT



Perfil de toxicidad



¿Y nuestro día a día? 🤔

- Mejora clínicamente en **RFS** (HR 0.58) y **DMFS** (HR 0.62) frente a pembrolizumab
- Primera combinación de inmunoterapia con beneficio en escenario **adyuvante**.
- Impacto significativo en la **viabilidad y coste-efectividad** en vida real.

KeyNote-C93

Phase 3,Randomized, Open-Label **Study of First-Line Pembrolizumab** vs Carboplatin + Paclitaxel in Mismatch Repair-Deficient (dMMR) Advanced or Recurrent Endometrial Cancer

Key eligibility criteria

- Aged ≥18 y
- Histologically confirmed inoperable, advanced or recurrent endometrial carcinoma or carcinosarcoma
- Central confirmation of dMMR status
- Radiographically evaluable disease (measurable/ nonmeasurable per RECIST version 1.1)[a]
- No prior systemic therapy[b]
- ECOG PS 0/1

R (1:1)
N = 299

- Pembrolizumab 400 mg IV Q6W for up to 18 cycles[c]
- Carboplatin AUC 5 or 6 IV Q3W + Paclitaxel 175 mg/m² IV Q3W for 6 cycles[c,d]

N= 229

mSeguimiento:
36.7 meses [28.4–50.0]

- **Estadio al diagnóstico.**
- **Histología.**
- **Neoadyuvancia previa.**

OBJETIVOS

- **Objetivo primario**: PFS + OS.
- **Objetivos secundarios**: ORR.

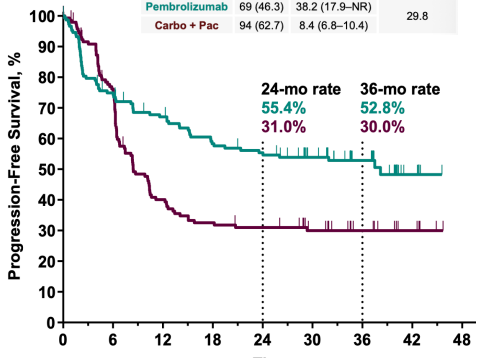
In the phase 2 KEYNOTE-158 study, participants with previously treated MSI-H/dMMR advanced EC received pembrolizumab monotherapy[6]

ORR = 48%
mDOR = NR

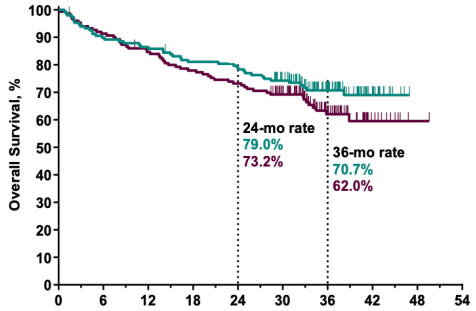
Median follow-up, 42.6 mo

HR: 0.57 (95% IC: 0.42-0.79) **p= 0.0002**

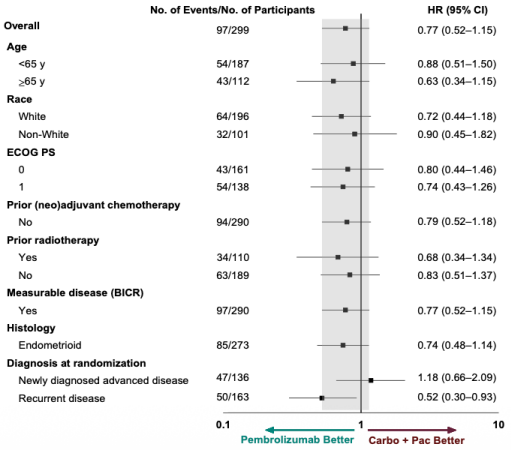
	Events, n (%)	Median (95% CI), mo	Difference in median, mo
Pembrolizumab	69 (46.3)	38.2 (17.9–NR)	29.8
Carbo + Pac	94 (62.7)	8.4 (6.8–10.4)	



HR: 0.77 (95% IC: 0.22-1.15) **p= 0.1**



Estudio SG por subgrupo



Slomovitz B, Zhu J, Yin R et al.First-line pembrolizumab versus carboplatin plus paclitaxel in dMMR advanced or recurrent endometrial cancer (KEYNOTE-C93/GOG-3064/ENGOT-en15): interim analysis of a multicentre, open-label, randomised, active-comparator controlled, phase 3 trial. The Lancet, 2026; 0

Key eligibility criteria

- Aged ≥18 y
- Histologically confirmed inoperable, advanced or recurrent endometrial carcinoma or carcinosarcoma
- Central confirmation of dMMR status
- Radiographically evaluable disease (measurable/ nonmeasurable per RECIST version 1.1)[a]
- No prior systemic therapy[b]
- ECOG PS 0/1

R (1:1)
N = 299

- Pembrolizumab 400 mg IV Q6W for up to 18 cycles[c]
- Carboplatin AUC 5 or 6 IV Q3W + Paclitaxel 175 mg/m² IV Q3W for 6 cycles[c,d]

N= 229

mSeguimiento:
36.7 meses [28.4–50.0]

- **Estadio al diagnóstico.**
- **Histología.**
- **Neoadyuvancia previa.**

OBJETIVOS

- **Objetivo primario**: PFS + OS.
- **Objetivos secundarios**: ORR.

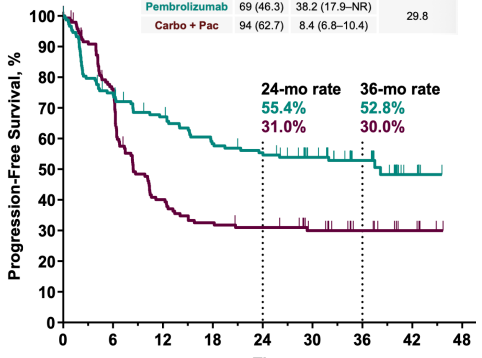
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ORR = 48%
mDOR = NR

Median follow-up, 42.6 mo

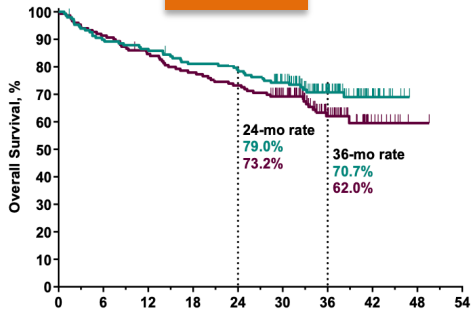
HR: 0.57 (95% IC: 0.42-0.79) **p= 0.0002**

	Events, n (%)	Median (95% CI), mo	Difference in median, mo
Pembrolizumab	69 (46.3)	38.2 (17.9–NR)	29.8
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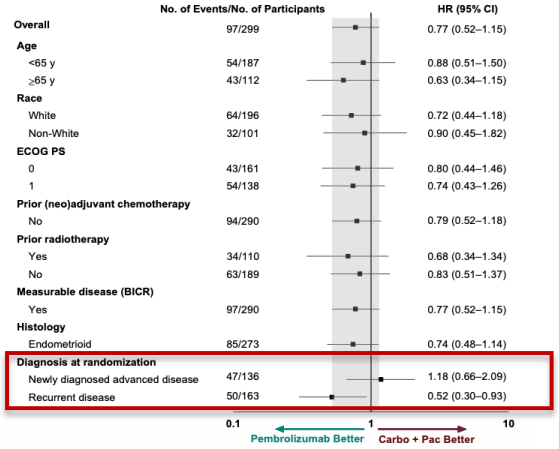


HR: 0.77 (95% IC: 0.22-1.15) **p= 0.1**

>82% IO



Estudio SG por subgrupo



Slomovitz B, Zhu J, Yin R et al.First-line pembrolizumab versus carboplatin plus paclitaxel in dMMR advanced or recurrent endometrial cancer (KEYNOTE-C93/GOG-3064/ENGOT-en15): interim analysis of a multicentre, open-label, randomised, active-comparator controlled, phase 3 trial. The Lancet, 2026; 0

¿Y nuestro día a día?



Evidencia sólida en 1L de tratamiento, **libre de QT** en subgrupo dMMR.



20% de pacientes dMMR con rápida **progresión + entrecruzamiento** <6 meses.



Esquema óptimo para priorización de **calidad de vida y tolerancia.**

TroFuse-005

Sacituzumab Tirumotecan in Previously Treated Advanced or Recurrent Endometrial Cancer: Results from the Phase 3

Key Eligibility Criteria

- Advanced or recurrent histologically confirmed diagnosis of endometrial carcinoma, including carcinosarcoma (capped at 4% by central histology)
- Radiologically apparent measurable or non-measurable disease
- Prior platinum exposure and prior anti-PD-1/PD-L1 exposure (given separately or in combination) in any setting, including neoadjuvant or adjuvant therapy
- No more than 3 total prior lines of systemic therapy
- Recurrence of endometrial cancer <12 months after completing platinum-based adjuvant therapy or regardless of platinum-free interval if received platinum or an immunotherapy-based regimen in the metastatic setting

R 1:1 N=776

- **Sac-TMT** 4 mg/kg IV Q2W
- **TPC** Doxorubicin 60 mg/m² IV Q3W[a] or Paclitaxel 80 mg/m² IV on Days 1, 8 and 15 of each 28-day cycle

OBJETIVOS

- **Objetivo primario**: PFS + OS.
- **Objetivos secundarios**: ORR, DoR.

- **Estado MMR.**
- **Expresión TROP2**
- **Líneas previas.**
- **Enfermedad medible.**

N= 776

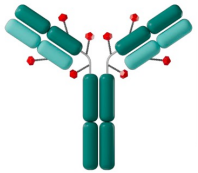
mSeguimiento:
14.0 meses [6.2–26.6]

Trophoblast cell-surface antigen 2 (TROP2) is a compelling target for ADC therapy

>90% of endometrial cancers overexpress TROP2[7-9]

TROP2 is an oncogenic transmembrane glycoprotein frequently overexpressed in endometrial cancer, with lower expression in carcinosarcoma

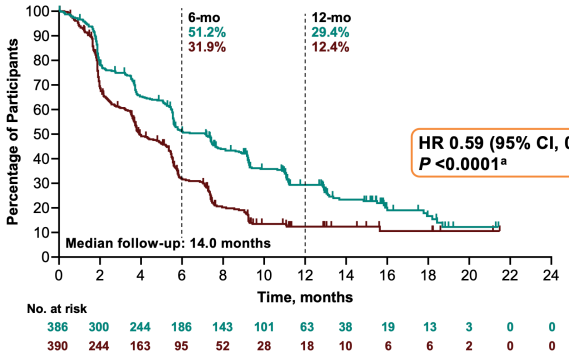
Antibody
anti-TROP2
DAR ~7.4



	Sac-TMT (N=386)	TPC (N=390)
Prior lines of therapy[e]		
≤2	289 (74.9%)	292 (74.9%)
3	97 (25.1%)	97 (24.9%)
Prior radiation	202 (52.3%)	169 (43.3%)
Histology by local review		
Endometrioid	213 (55.2%)	216 (55.4%)
Non-endometrioid	143 (37.0%)	153 (39.2%)
Serous carcinoma	105 (27.2%)	110 (28.2%)
Clear cell carcinoma	16 (4.1%)	21 (5.4%)
Other carcinoma[f]	22 (5.7%)	22 (5.6%)
Carcinosarcoma[g]	27 (7.0%)	21 (5.4%)
Unclassified	3 (0.8%)	0
Measurable disease at baseline		
Yes	374 (96.9)	378 (96.9)
No	12 (3.1)	12 (3.1)

Progression-Free Survival by BICR

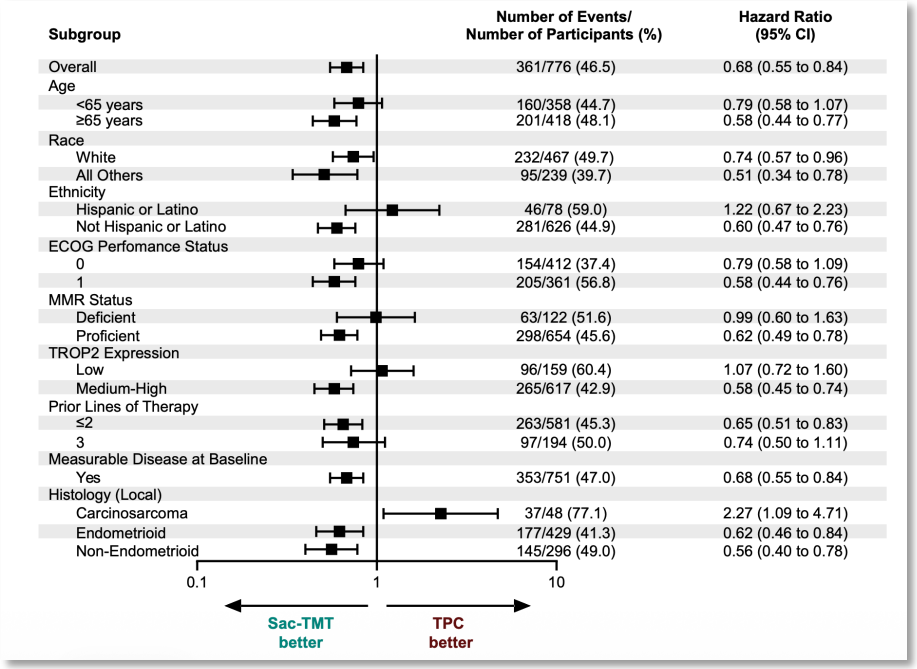
Sac-TMT reduced the risk of progression or death by 41%, extending median PFS by 3.3 months



	Pts w/ Event	Median, mo (95% CI)
Sac-TMT	70.2%	7.2 (5.6–7.6)
TPC	73.1%	3.9 (3.7–5.3)

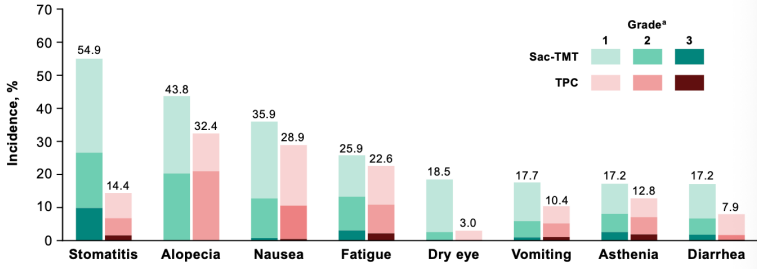
HR 0.59 (95% CI, 0.50–0.70)
***P* <0.0001[a]**

Supervivencia global por subgrupos

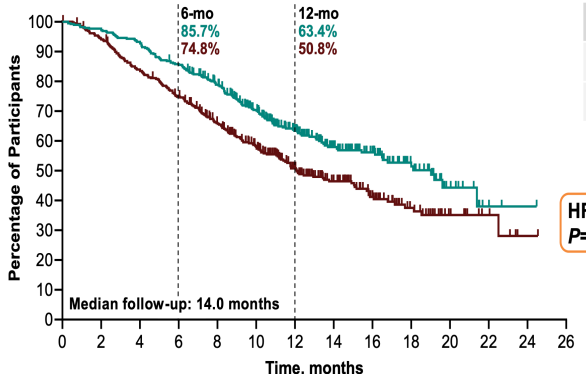


Lorusso D, Martin-Babau J, Backes F et al.Sacituzumab tirumotecan versus treatment of physician's choice in previously treated endometrial cancer (TroFuse-005/ENGOT-en23/GOG-3095): a randomised, open-label, phase 3 trial. The Lancet, 2026; 0

Treatment-Related AEs With Incidence ≥15%: Non-hematological



Supervivencia global (SG)

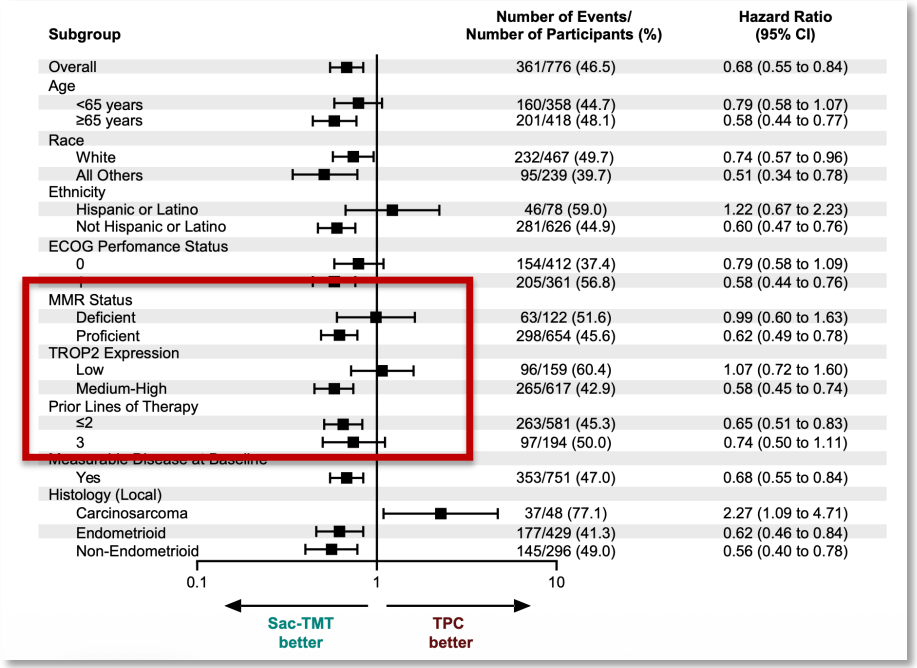


	Pts w/ Event	Median, mo (95% CI)
Sac-TMT	40.7%	19.0 (16.1–NR)
TPC	52.3%	12.1 (11.0–15.2)

Information fraction, 67.5%

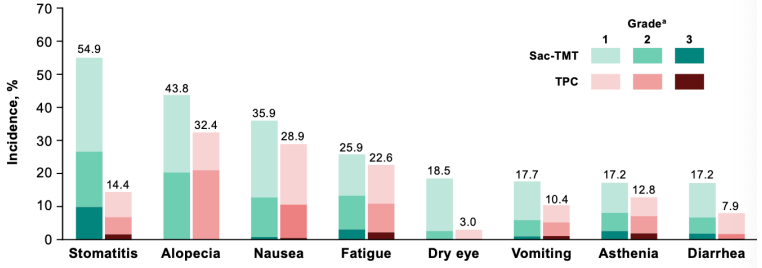
HR 0.68 (95% CI, 0.55–0.84)
P=0.0001[a]

Supervivencia global por subgrupos

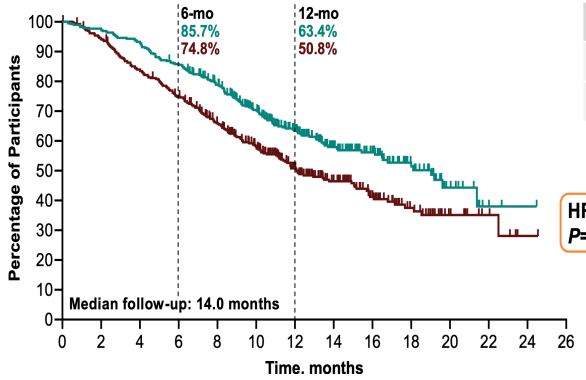


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Treatment-Related AEs With Incidence ≥15%: Non-hematological



Supervivencia global (SG)



	Pts w/ Event	Median, mo (95% CI)
Sac-TMT	40.7%	19.0 (16.1–NR)
TPC	52.3%	12.1 (11.0–15.2)

Information fraction, 67.5%

HR 0.68 (95% CI, 0.55–0.84)
P=0.0001[a]

¿Y nuestro día a día?

- ☑ Nuevo SoC en cáncer de endometrio tras progresión a **1L con QT+IO**.
- 🤕 Manejo de **toxicidad específica** (estomatitis >55%), interrupción y reducción de dosis.
- 🧬 Futuro prometedor guiado por **biomarcadores** en CE (HER2+, B7-H4, FRα…)

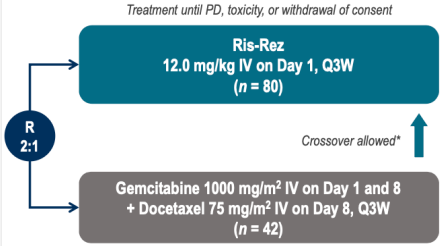
ARTEMIS-011

Risvutatug Rezetecan Versus Gemcitabine and Docetaxel in Heavily Pretreated Patients With Relapsed or Refractory Osteosarcoma:Primary Results From the Phase 3

Key Eligibility Criteria

- Age ≥12 years
- Pathologically confirmed diagnosis of osteosarcoma
- Progression or intolerance to at least two previous lines of therapy
- ≥1 measurable target lesion per RECIST v1.1
- ECOG PS 0–1

Study Treatment



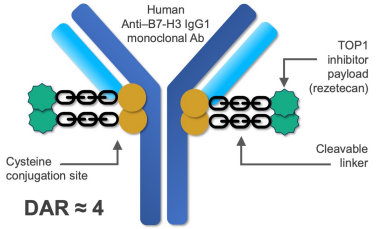
- **Edad 12-18 vs >18 años.**
- **Metástasis pulmonares.**

OBJETIVOS

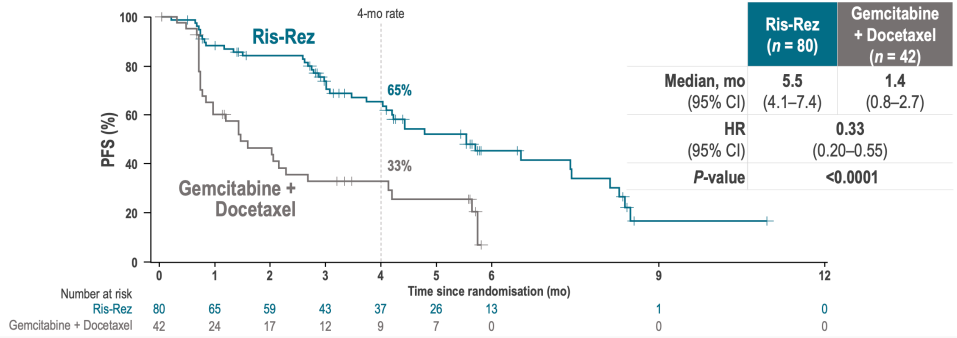
- **Objetivo primario**: PFS (BICR)
- **Objetivos secundarios**: OS, PFS (i), ORR, DCR.

N= 122

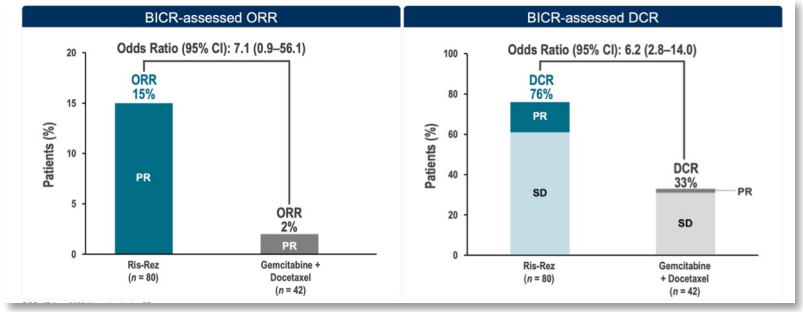
mSeguimiento: 7.1 meses



Supervivencia libre progresión (SLP)



	Ris-Rez (*n* = 80)	Gemcitabine + Docetaxel (*n* = 42)
Median, mo (95% CI)	5.5 (4.1–7.4)	1.4 (0.8–2.7)
HR (95% CI)	0.33 (0.20–0.55)	
P-value	<0.0001	



Xie L, et al.. Efficacy and safety of risvutatug rezetecan versus gemcitabine plus docetaxel in relapsed/refractory advanced osteosarcoma: Primary results from the ARTEMIS-011 phase 3 trial. Ann Oncol. 2026 Oct 26:S0923-7534(26)08076-2.

¿Y nuestro día a día?

✔ Beneficio clínico muy claro en **PFS (HR 0.33)** en una población altamente pretratada

👥 Éxito en la integración de población **adulta y adolescente** (>12 años).

🤕 Alta incidencia de **eventos grado ≥3 (93%),** reducción de dosis en el 71%.

¿Y nuestro día a día?



- Beneficio clínico muy claro en **PFS (HR 0.33)** en una población altamente pretratada
- Éxito en la integración de población **adulta y adolescente** (>12 años).
- Alta incidencia de **eventos grado ≥3 (93%),** reducción de dosis en el 71%.

TAKE HOME MESSAGES



- ✓ Cuatro **ensayos fase III** con resultados positivos y *n* considerable.
- ✓ Potencial **impacto en clínica diaria**, aunque con limitaciones derivadas a logística y selección de pacientes.
- ✓ Desarrollo y adaptación de **biomarcadores** con capacidad predictiva.



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Hospital Universitario de Salamanca
Instituto de Investigación Biomédica de Salamanca (IBSAL)

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https://orcid.org/0009-0001-7368-2263