III JORNADA DE ACTUALIZACIÓN EN
URO-ONCOLOGÍA:
UPDATE 2026

Madrid, 17 de febrero de 2026

En un paciente FGFRmut, ¿cuál es el tratamiento de elección tras progresión a quimioterapia e inmunoterapia? ERDAFITINIB

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DISCLOSURES

Dr. Alonso Gordoa financial interests:

Personal conflicts of interest Scientific consultancy role (speaker and advisory roles) from Lilly, Bayer, Eisai, Novartis, MSD,Recordati, IPSEN, Pfizer, Johnson & Johnson.

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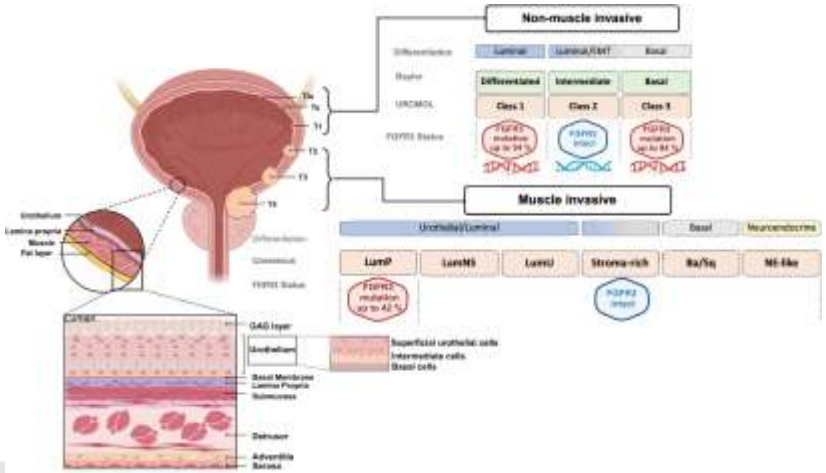
WHAT REPRESENTS THE FGFR-alt DISEASE IN mUC

- ✓ FGFR alterations are observed in approximately 20% of advanced or metastatic urothelial cancers and in approximately 36% of upper tract urothelial cancers and may function as oncogenic drivers.
- ✓ FGFR3 mutations and fusions are early events in the oncogenesis of urothelial carcinoma.
- ✓ The testing of samples from the primary tumour should be sufficient to detect FGFR3 alterations. But occasional discordant results in metachronous disease has been described.

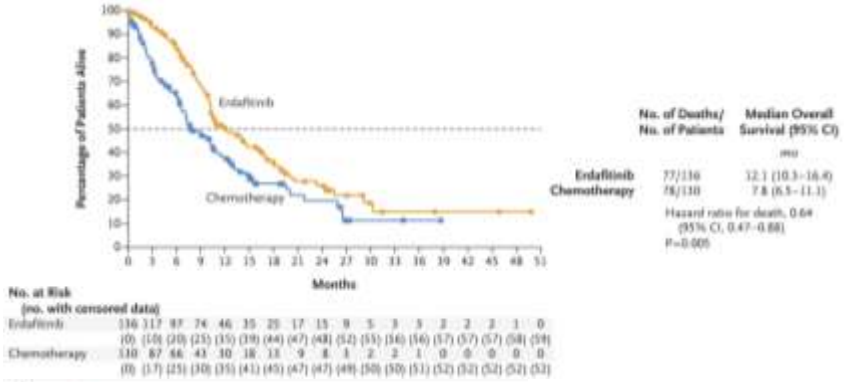


Noeraparast M, et al. Cancer Commun (Lond). 2024 Oct;44(10):1189-1208.
Guercio BJ, et al. Clin Cancer Res. 2023 Nov 14;29(22):4586–4595.

THE DATA -> THOR TRIAL (NCT03390504)

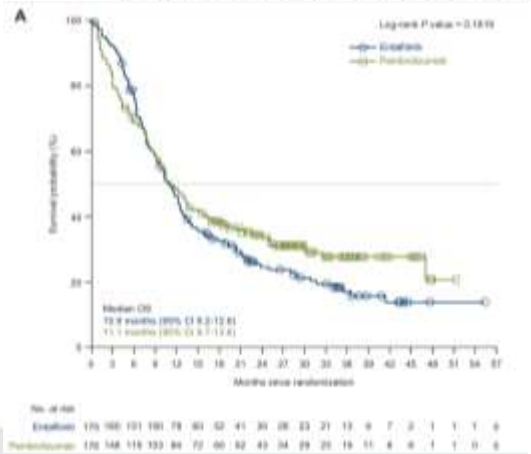
Cohort 1

Prior anti-PD(L)1
≥ 65y: 56% vs 65%
Female: 28%
ECOG 2: 10%
UTUC: 30% vs 36%
FGFRmut: 80%
Visceral: 74%
2prior lines: 66% vs 75%



Cohort 2

≥ 65y: 61%
Female: 19% vs 25%
ECOG 2: 6%
UTUC: 24%
FGFRmut: 81%
Visceral: 67% vs 75%
2prior lines: 2.3% vs 0%



Loriot Y, et al. N Engl J Med. 2023 Nov 23;389(21):1961-1971;
Siefker-Radtke AO, et al. Ann Oncol 2024 Jan;35(1):107-117.

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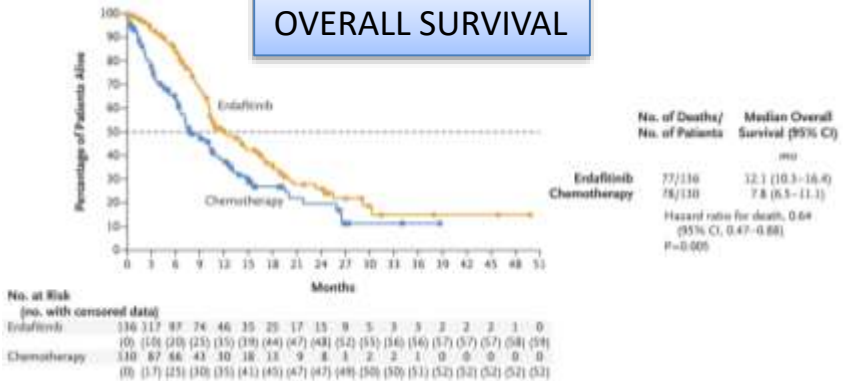
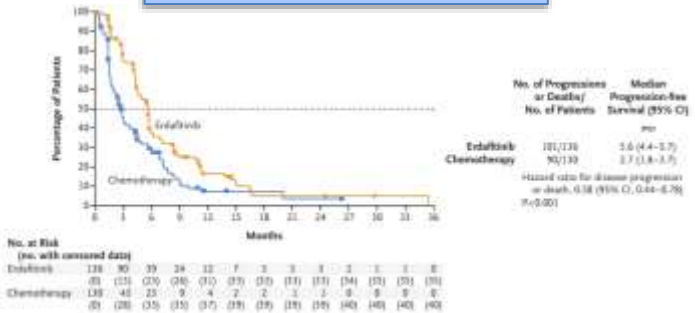
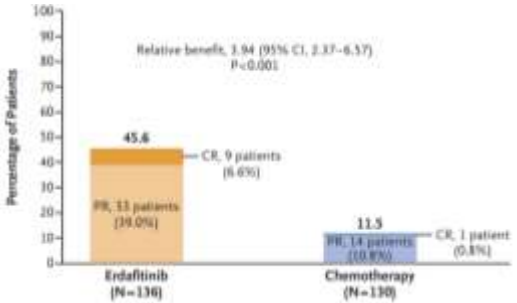
OVERALL SURVIVAL



PROGRESSION FREE SURVIVAL



ORR



Loriot Y, et al. N Engl J Med. 2023 Nov 23;389(21):1961-1971; Siefker-Radtke AO, et al. Ann Oncol 2024 Jan;35(1):107-117.

SAFETY DATA

	Grade 1 *n* (%)	Grade 2 *n* (%)	Grade 3 *n* (%)	Total *n* (%)	UpT *n* (%)	No UpT *n* (%)
				N = 101	*N* = 41	*N* = 60
Hyperphosphatemia	54 (54)	23 (23)	2 (2.0)	79 (78)	27 (66)	52 (87)
Stomatitis	21 (21)	25 (25)	14 (14)	60 (59)	23 (56)	37 (62)
Nail events[a]	22 (22)	23 (23)	15 (15)	60 (59)	25 (61)	35 (58)
Non-CSR eye disorders[a]	28 (28)	23 (23)	5 (5.0)	57 (56)[b]	21 (51)	36 (60)
Skin events[a]	25 (25)	22 (22)	8 (7.9)	55 (55)	23 (56)	32 (53)
Diarrhea	34 (34)	17 (17)	4 (4.0)	55 (55)	24 (59)	31 (52)
CSR	12 (12)	11 (11)	4 (4.0)	27 (27)	12 (29)	15 (25)

	Hyperphosphatemia	Stomatitis	Nail events	Non-CSR eye disorders	Skin events	Diarrhea	CSR
Developed select TEAE, *n*/*N* with ≥1 TEAE (%)	79/101 (78)	60/101 (59)	60/101 (59)	57/101 (56)	55/101 (55)	55/101 (55)	27/101 (27)
Time to first onset of select TEAE (d), median (IQR)	20 (14–29)	32 (18–85)	69 (50–89)	50 (28–80)	42 (22–83)	14 (8–23)	53 (32–100)
Had dose modification for select TEAE, *n*/*N* with TEAE (%)[c]							
Dose reduction	11/79 (14)	19/60 (32)	20/60 (33)	15/57 (26)	11/55 (20)	0	13/27 (48)
Dose interruption	24/79 (30)	27/60 (45)	17/60 (28)	10/57 (18)	13/55 (24)	6/55 (11)	8/27 (30)
Discontinuation	1/79 (1.3)	2/60 (3.3)	1/60 (1.7)	3/57 (5.3)	3/55 (5.5)	1/55 (1.8)	3/27 (11)
Received treatment for select TEAE, *n*/*N* with TEAE (%)	31/79 (39)	44/60 (73)	34/60 (57)	34/57 (60)	31/55 (56)	30/55 (55)	5/27 (19)
Time treatment was withheld for select TEAE (d), median (IQR)[d]	13 (7–16)	16 (7–32)	14 (14–14)[e] 18 (12–21)	NA	3 (3–3)[e] 25 (15–35)	5 (3–11)	22 (21–24)[e]
Resolution of ≥1 event of select TEAE by data cutoff, *n*/*N* with TEAE (%)	74/79 (94)	48/60 (80)	6/19 (32)[f] 11/19 (58)	21/28 (75)[f]	19/34 (56)[g] 12/25 (48)	50/55 (91)	6/8 (75)[f]
Time to resolution of select TEAE (d), median (IQR)	17 (9–37)	34 (22–75)	122 (100–237)[f] 75 (16–138)	44 (29–91)[f]	42 (15–91)[g] 93 (41–121)	20 (7–34)	27 (17–133)[f]

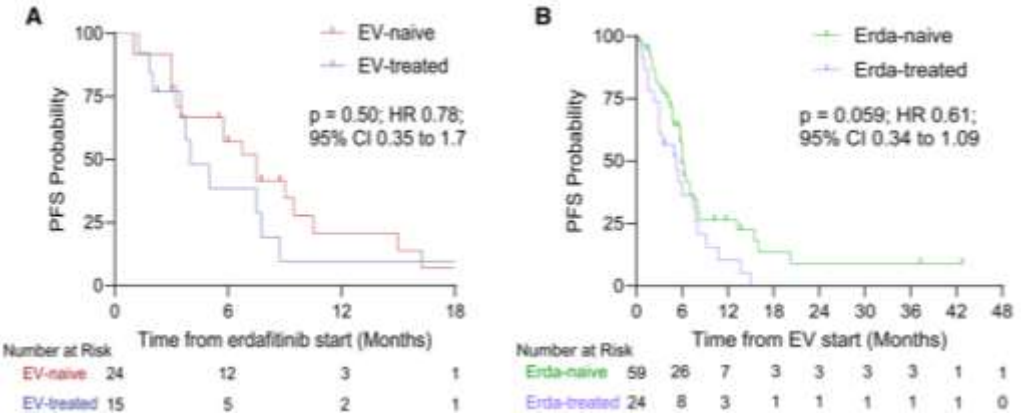
45.9% AE G≥3
8.1% discontinuation

O Siefker-Radtke A, et al. Eur Urol Open Sci. 2023 Feb 16:50:1-9.

UNITE Trial

RWE

PROGRESSION FREE SURVIVAL



	EV → Erda (15)	Erda → EV (24)
Age	74	66
Visceral M1	80%	58%
ECOG 0-1	92%	67%
Basal NPT	20%	42%
Prior 1L or 2L	53%/33%	37%/46%

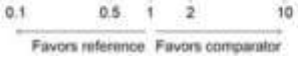
Jiang CY, et al. Oncologist. 2025 Nov 11;30(11).

RWE

Systematic review and M-A

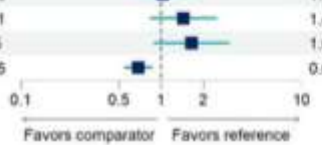
A) ORR

Parameters (ref/comparator)	n	Pooled OR (95% CI)	*p* value	I^2
Sex (male /female)	963	1.03 (0.82-1.30)	0.759	0%
Age (<75 / ≥75 yr)	1039	0.88 (0.54-1.45)	0.566	42%
ECOG status (0-1 / >1)	572	0.43 (0.20-0.95)	0.041	24%
Bellmunt risk factor (0-1 / >1)	438	0.57 (0.37-0.96)	0.040	7%
Liver metastasis (absent /present)	1052	1.02 (0.65-1.59)	0.921	45%
Tumor location (bladder /upper tract)	1194	1.29 (1.01-1.63)	0.041	0%
Histology (pure urothelial /mixed histology)	526	0.72 (0.37-1.41)	0.265	27%
Response to platinum (non-resp /resp)	106	2.65 (1.04-6.72)	0.046	0%
Response to ICI (non-resp /resp)	595	1.51 (1.12-2.04)	0.017	0%
PD-L1 immunostaining (negative /positive)	338	0.70 (0.43-1.16)	0.113	0%
FGFR3 alteration (positive /negative)	346	0.84 (0.33-2.16)	0.504	0%
NLR (≥5 / <5)	288	1.17 (0.13-10.73)	0.789	46%
GFR (≥60 / <60)	400	0.59 (0.47-0.74)	0.010	0%



B) OS

Parameters (ref/comparator)	n	Pooled HR (95% CI)	*p* value	I^2
Sex (male /female)	221	0.85 (0.58-1.24)	0.386	0%
Age (<75 / ≥75 years)	523	1.16 (0.83-1.62)	0.382	0%
ECOG status (0-1 / >1)	236	2.93 (1.64-5.22)	<0.001	68%
Liver metastasis (absent /present)	538	1.38 (1.10-1.74)	0.005	0%
Tumor location (bladder /upper tract)	480	1.16 (0.87-1.55)	0.317	0%
Histology (pure urothelial /mixed histology)	337	1.17 (0.85-1.62)	0.328	0%
PD-L1 immunostaining (negative /positive)	159	1.03 (0.61-1.72)	0.922	0%
FGFR3 alteration (positive /negative)	221	1.44 (0.84-2.46)	0.185	0%
NLR (≥5 / <5)	85	1.65 (0.89-3.03)	0.109	0%
Hemoglobin level (<10 g/dl /≥ 10 g/dl)	105	0.69 (0.55-0.86)	0.001	0%



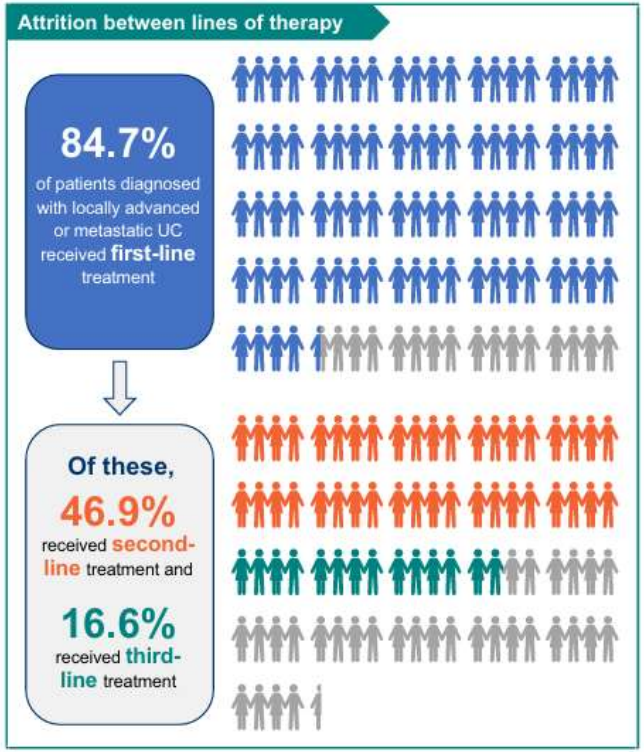
C) PFS

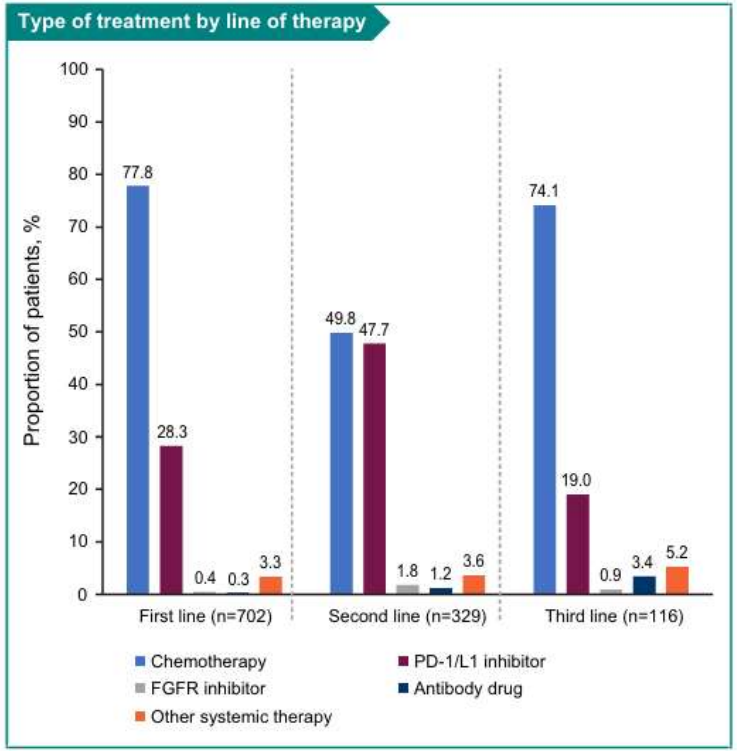
Parameters (ref/comparator)	n	Pooled HR (95% CI)	*p* value	I^2
Sex (male /female)	330	0.92 (0.69-1.24)	0.726	0%
ECOG status (0-1 / >1)	235	2.14 (1.60-2.86)	<0.001	0%
Liver metastasis (absent /present)	302	1.07 (0.79-1.44)	0.671	0%
Tumor location (bladder /upper tract)	312	0.99 (0.74-1.31)	0.926	0%
Histology (pure urothelial /mixed histology)	168	1.62 (1.10-2.38)	0.015	0%
FGFR3 alteration (positive /negative)	221	1.22 (0.72-2.07)	0.460	0%
NLR (≥5 / <5)	85	0.97 (0.61-1.54)	0.884	0%
Hemoglobin level (<10 g/dl /≥10 g/dl)	167	0.67 (0.56-0.79)	<0.001	0%

Jiang CY, et al. Oncologist. 2025 Nov 11;30(11).

Spain 2015 - 2020

Not to miss a targeted drug
OR
What happens during EV?





Puente J, et al. Clin Transl Oncol. 2025 May;27(5):2232-2240.

There is currently no clear evidence regarding the optimal sequencing of erdafitinib and EV in patients with FGFR3/2 alterations progressing after platinum-based chemotherapy and a CPI. But the drug that is targeting FGFR3/2 is erdafitinib.

ERDAFITINIB

- FGFR altered-tumor patients who have one additional treatment option, and we should not miss the opportunity for them to receive both erdafitinib and EV; consider patient profile & availability of FGFR assessment.

- The challenge is how subsequent lines of treatment are often lost.

- Erdafitinib allows switching to an oral treatment, avoiding the need for visits to the day hospital and potentially improving time toxicity.

- Oral treatment does not mean better tolerability; adequate treatment related adverse events management is required.