

# III JORNADA TRASLACIONAL DE ONCOLOGÍA DE PRECISIÓN:

A TRAVÉS DE LAS VÍAS DE SEÑALIZACIÓN  
SEVILLA, 12 Y 13 DE FEBRERO DE 2026

## IMPORTANCIA DE FGFR (RECEPTORES DEL FACTOR DE CRECIMIENTO FIBROBLÁSTICO) EN EL TRATAMIENTO DE TUMORES GENITOURINARIOS

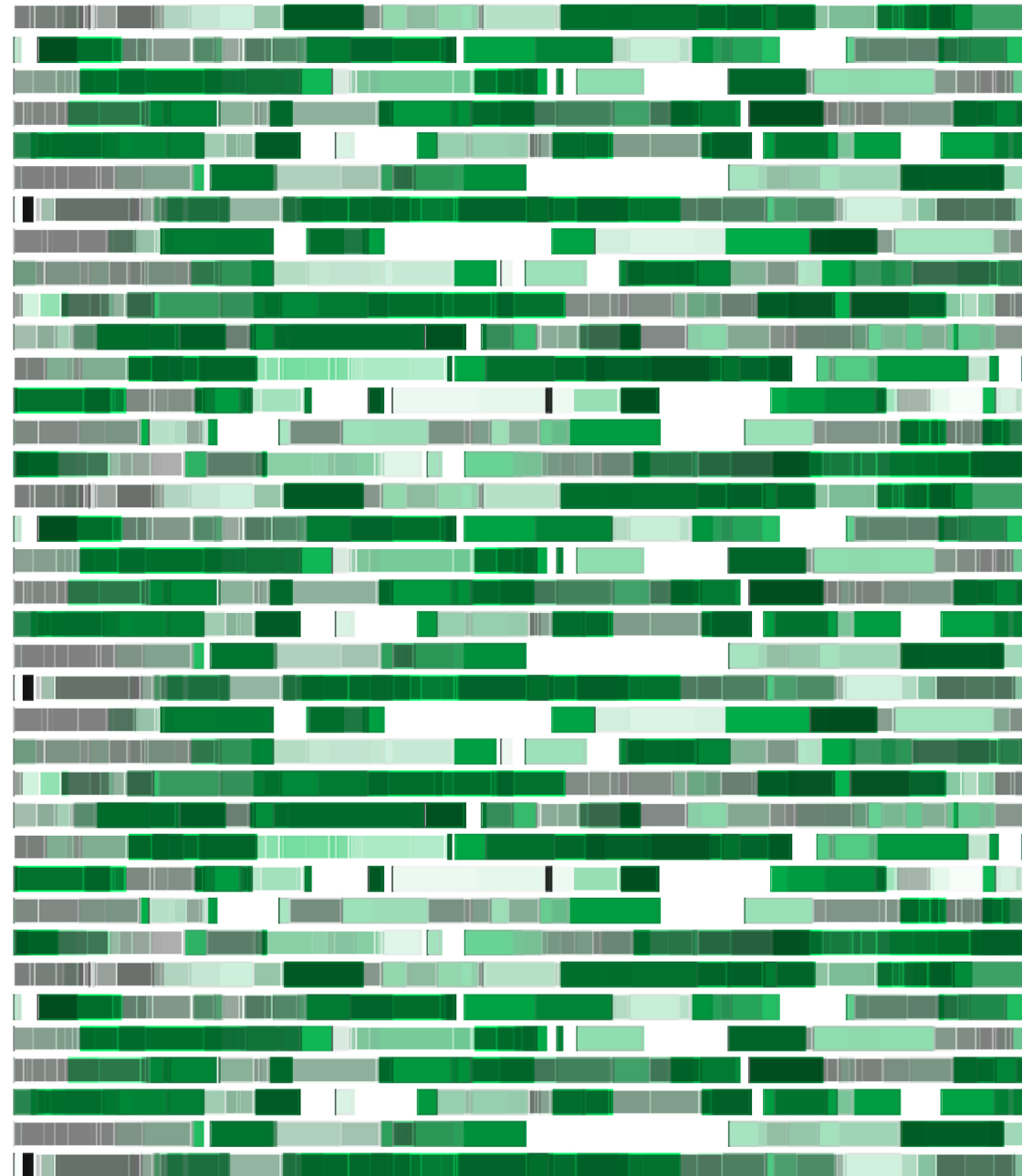
IMPORTANCE OF FGFR IN THE TREATMENT OF GENITOURINARY TUMORS.

Pablo Gajate Borau

Hospital Universitario Ramón y Cajal

Organizador por:

**HENDERE HEALTHCARE**

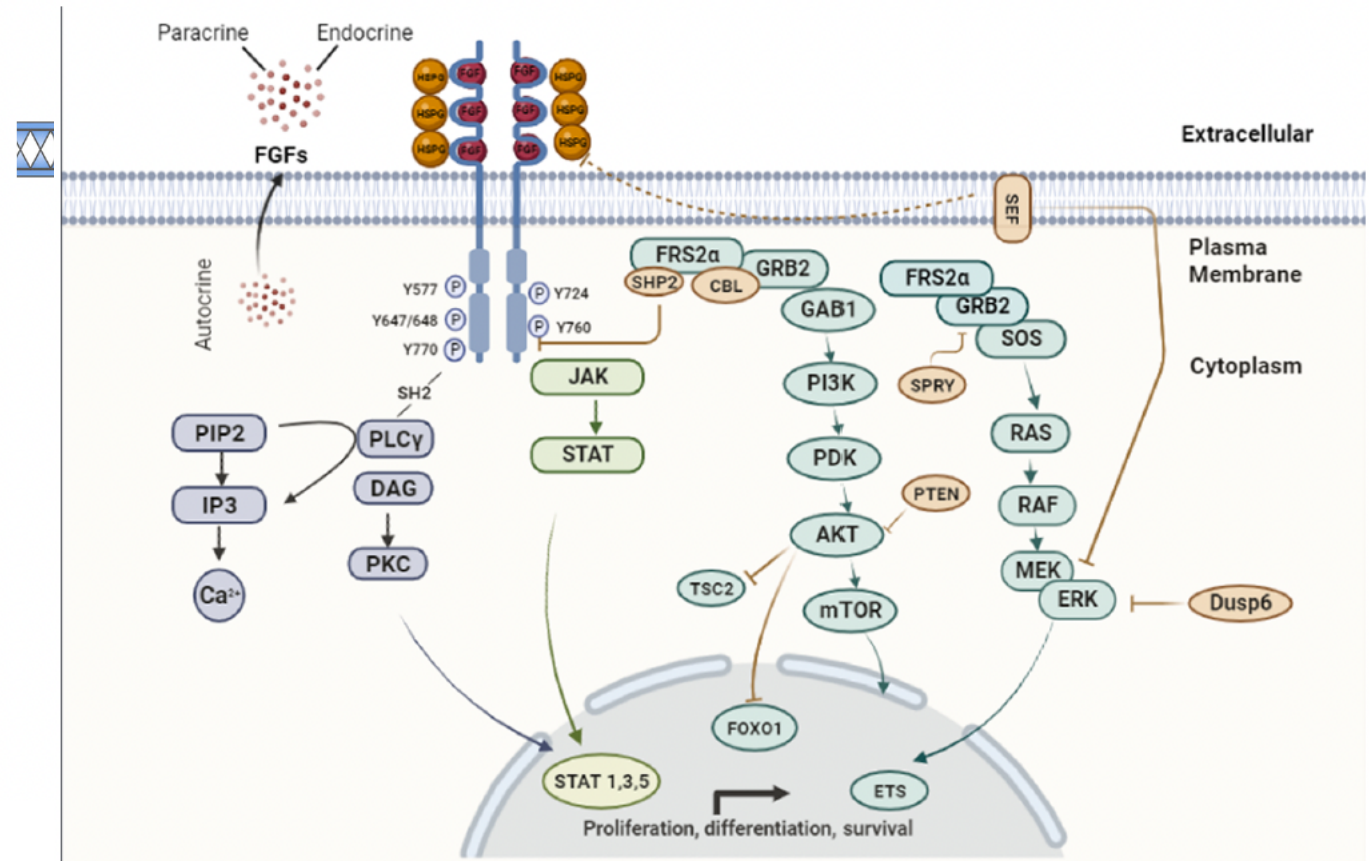
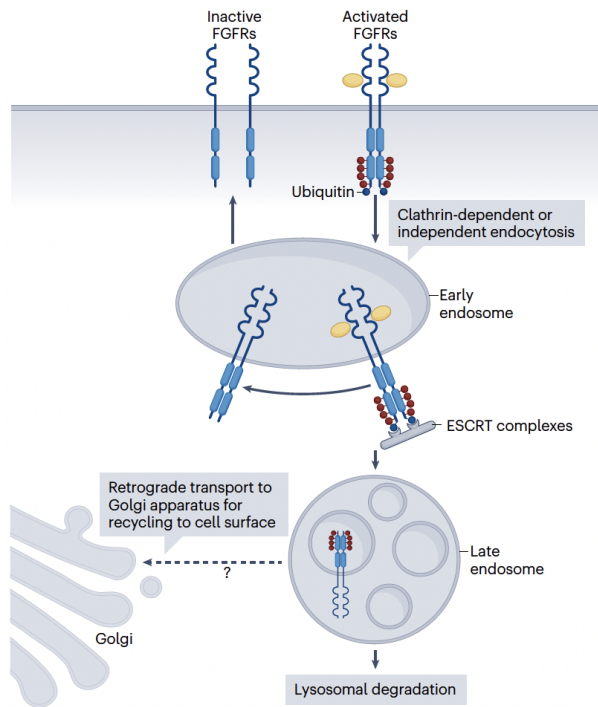




## OVERVIEW OF FGFR SIGNALLING

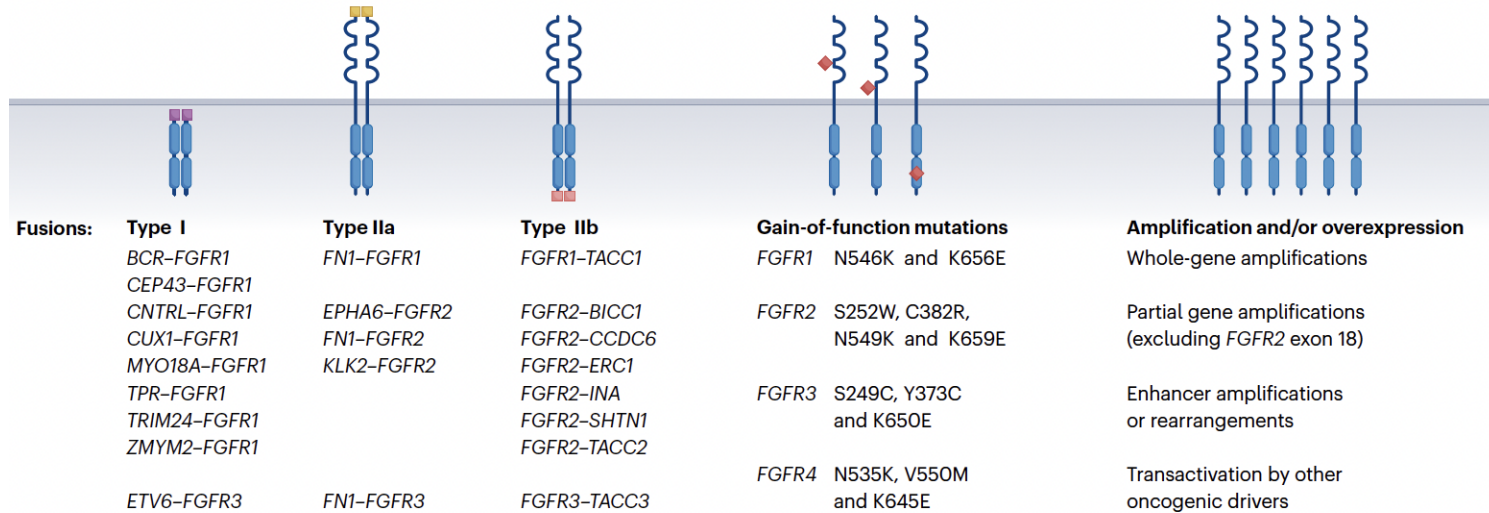


FGFRs belong to a family of four transmembrane receptor tyrosine kinases (FGFR1–4) that are highly conserved, widely distributed and regulate key cell behaviours<sup>1–4</sup>

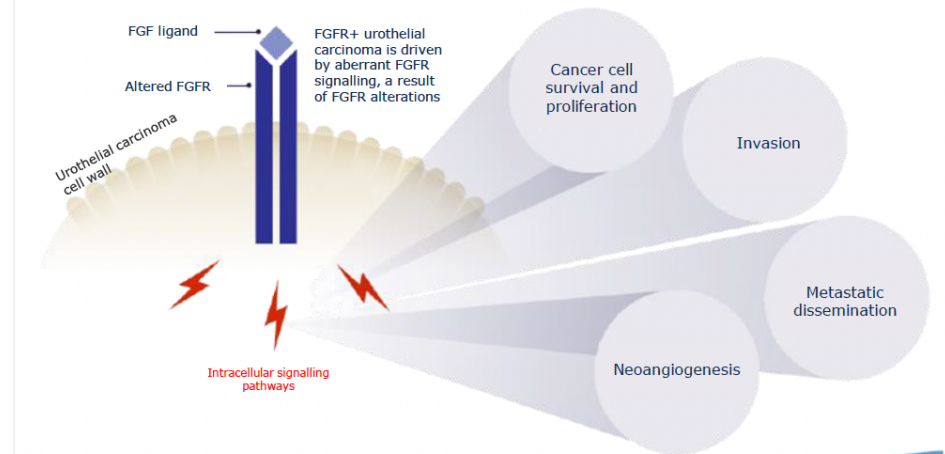




## MECHANISMS OF ONCOGENIC ACTIVATION

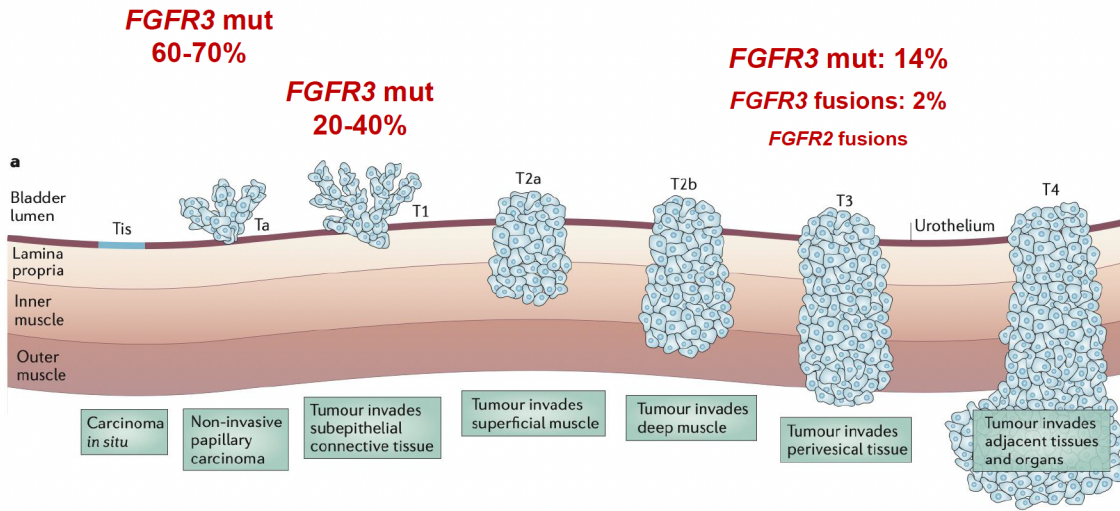


Aberrant FGFR signalling can drive oncogenesis and is implicated in cancer cell survival, neoangiogenesis, metastatic dissemination, cancer cell proliferation and invasion, and response to some types of anticancer therapies<sup>2,3</sup>





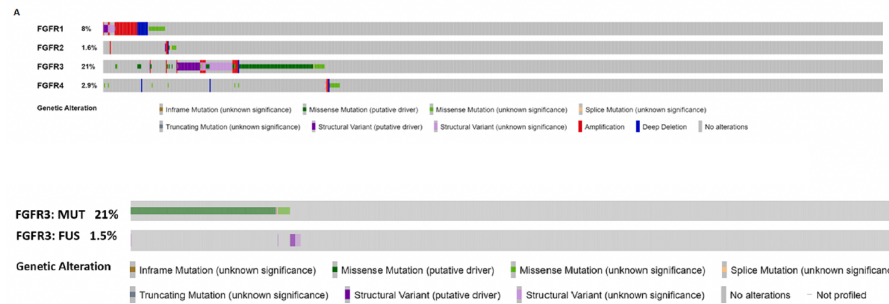
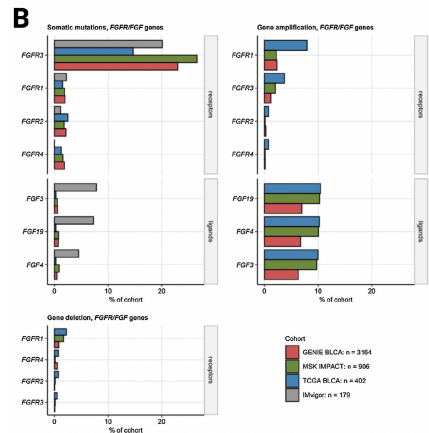
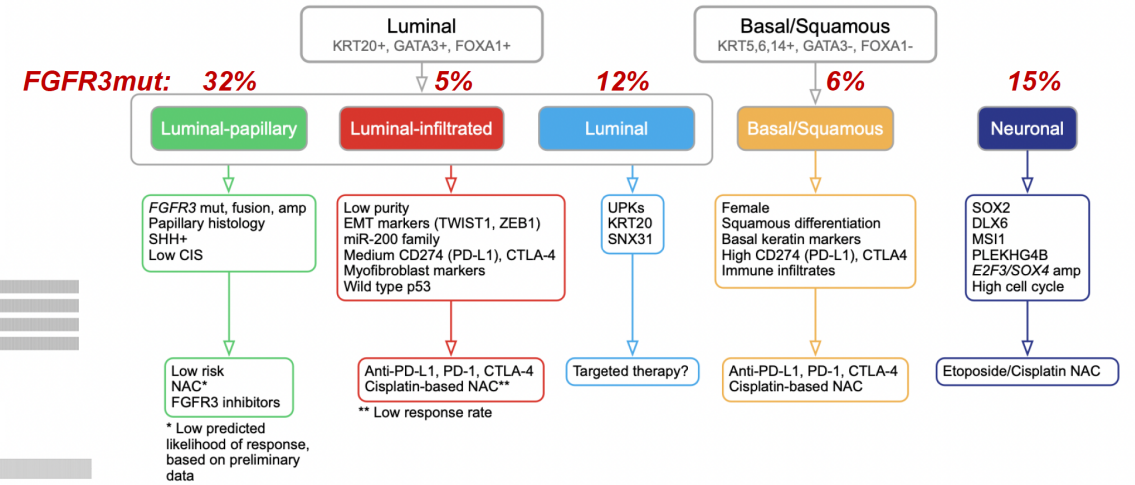
# FGFR IN UROTELIAL CARCINOMA



**FGFR alterations** are observed in **~20% of advanced or mUC of the bladder** and **~35% of high-grade upper tract UC**, and may function as oncogenic drivers<sup>1-3</sup>



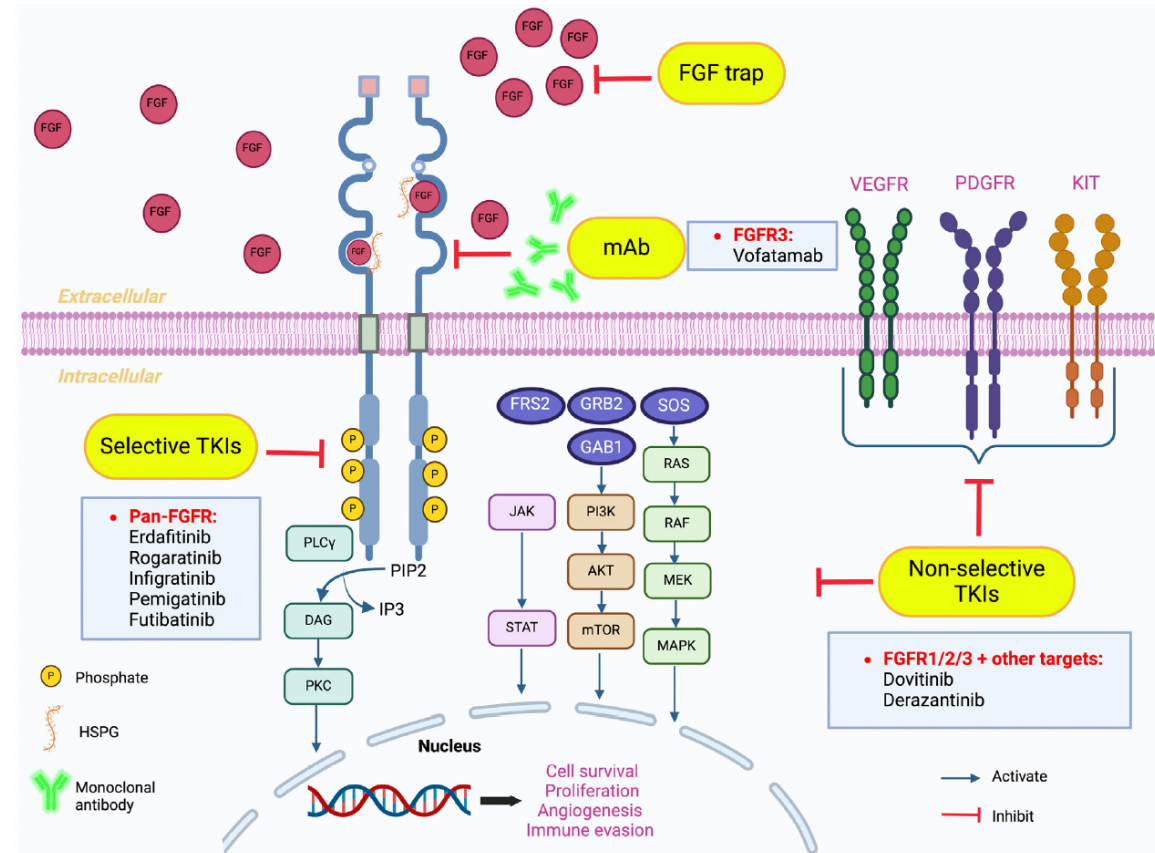
## TCGA: Molecular subtypes and systemic therapy





## FGFR INHIBITORS IN UROTHELIAL CANCER

Inhibitor	Mechanism	Target	Binding site	Delivery	Primary cancer trials
<b>Second generation (FGFR selective)</b>					
Erdafitinib (JNJ-42756493)	TKI RTI	FGFR1-4	ATPc	Oral	UC
Rogaratinib (BAY1163877)	TKI RTI	FGFR1-4	ATPc	Oral	UC
Infigratinib (BGJ398)	TKI RTI	FGFR1-3	ATPc	Oral	UC/CGC
Pemigatinib (INC054828)	TKI RTI	FGFR1-3	ATPc	Oral	UC
Fexagratinib (AZD4547)	TKI RTI	FGFR1-3	ATPc	Oral	Lung, brea:
Tasurgratinib (E7090)	TKI type V	FGFR1-3	ATPc	Oral	CGC
Derazantinib (ARQ 087)	TKI	FGFR1-3	ATPc	Oral	UC/CGC
LY2874455	TKI RTI	FGFR1-4	ATPc	Oral	Gastric/ NSCLC
Futibatinib (TAS-120)	TKI IRTI	FGFR1-4	KD P-loop	Oral	CGC
<b>Third generation (FGFR subtype-specific)</b>					
TYRA-300	TKI	FGFR3	KD GMR	Oral	UC
LOXO-435	TKI	FGFR3	KD GMR	Oral	UC
LY3076226	ADC	FGFR3	ECR	Systemic	UC
Vofatamab (B-701)	mAb	FGFR3	LBD	Systemic	UC
MFGR1877S	mAb	FGFR3	LBD	Systemic	STs
<b>First generation (nonselective TKIs)</b>					
Dovitinib (TKI258)	TKI RTI	VEGFR1-3 FGFR1-3 PDGFRA/ B	ATPc	Oral	RCC





# ERDAFITINIB IN UROTELIAL CARCINOMA

The NEW ENGLAND JOURNAL of MEDICINE

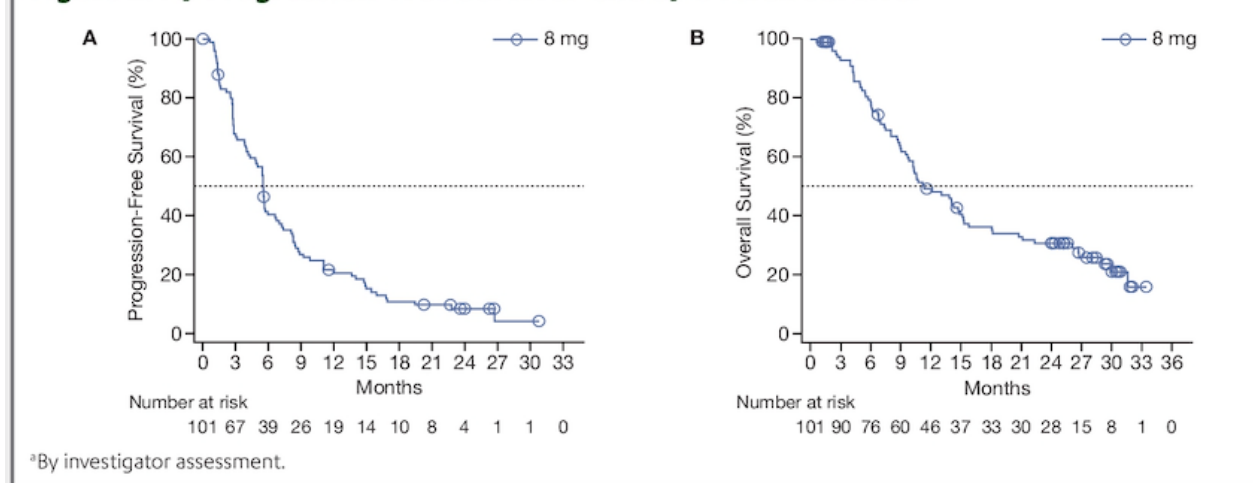
ORIGINAL ARTICLE

## Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma

Patients, n (%)		ERDA 8 mg/d UpT n = 101 <sup>a</sup>
Age, median (range), years		67 (36-87)
ECOG PS	0 1 2	51 (50) 43 (43) 7 (7)
Pretreatment	Progressed or relapsed after chemo Chemo naive Prior immunotherapy	89 (88) 12 (12) 24 (24)
Number of lines of prior treatment	0 1 2 ≥ 3	10 (10) 48 (48) 28 (28) 15 (15)
Visceral metastases	Present Absent	78 (77) 23 (23)
Hemoglobin level, g/dL	≥ 10 < 10	86 (85) 15 (15)
Tumor location	Upper tract Lower tract	25 (25) 76 (75)
Creatinine clearance rate	< 60 mL/min ≥ 60 mL/min	53 (52) 48 (48)

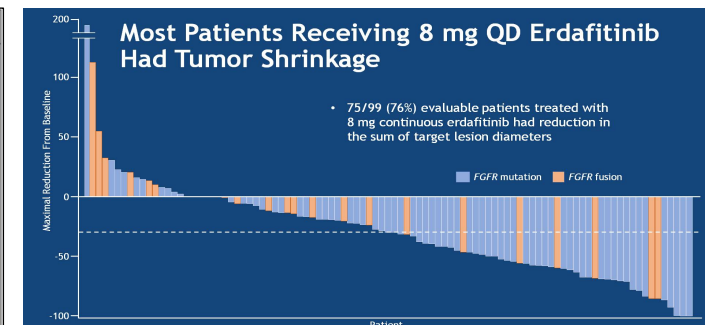
<sup>a</sup>2 patients were added to the 8 mg daily regimen since the cutoff date for the primary analysis (March 15, 2018).

**Figure 2. A) Progression-Free Survival<sup>a</sup> and B) Overall Survival**



**Table 2. Antitumor Activity of Erdafitinib in the 99 Patients in the Selected-Regimen Group.<sup>a</sup>**

Variable	Value	Rate of Response (95% CI)
		percent
Response per investigator assessment — no. of patients <sup>†</sup>		
Any objective response	40	40 (31-50)
Complete response	3	3
Partial response	37	37
Stable disease	39	39
Progressive disease	18	18
Could not be evaluated or unknown	2	2
Median time to response — mo	1.4	
Median duration of response (95% CI) — mo	5.6 (4.2-7.2)	





## ERDAFITINIB IN UROTELIAL CARCINOMA

### Phase 3 THOR Study: Erdafitinib Versus Chemotherapy of Choice in Patients With Advanced Urothelial Cancer and Selected FGFR Aberrations

#### Cohort 1

##### Key eligibility criteria

- Age  $\geq$ 18 years
- Metastatic or unresectable UC
- Confirmed disease progression
- Prior tx with anti-PD-(L)1
- 1-2 lines of systemic tx
- Select *FGFR3/2alt* (mutation/fusion)<sup>a</sup>
- ECOG PS 0-2

1:1  
N=266<sup>b</sup>

**Erdafitinib**  
(n=136)  
Once-daily erdafitinib 8 mg with pharmacodynamically guided uptitration to 9 mg

**Chemotherapy of Choice**  
(n=130)  
docetaxel or vinflunine once every 3 weeks

Stratification factors: region (North America vs European Union vs rest of world), ECOG PS (0 or 1 vs 2), and disease distribution (presence vs absence of visceral [lung, liver, or bone] metastases)

##### Primary end point:

- OS

##### Key secondary end points:

- PFS
- ORR
- Safety

NCT03390504

### Phase 3 THOR Study: Erdafitinib Versus Pembrolizumab in Patients With Metastatic Urothelial Carcinoma and Select *FGFR* Alterations

#### Cohort 2

##### Key eligibility criteria

- Age  $\geq$ 18 years
- Metastatic or unresectable UC
- Confirmed disease progression on 1 prior tx
- Naive to anti-PD-(L)1 tx
- Select *FGFR3/2alt* (mutation/fusion)<sup>a</sup>
- ECOG PS 0-2

1:1  
N=351<sup>b</sup>

**Erdafitinib**  
(n=175)  
Once-daily erdafitinib 8 mg with pharmacodynamically guided uptitration to 9 mg

**Pembrolizumab**  
(n=176)  
200 mg once every 3 weeks

Stratification factors: region (North America vs European Union vs rest of world), ECOG PS (0 or 1 vs 2), and disease distribution (presence vs absence of visceral [lung, liver, or bone] metastases)

##### Primary end point

- OS

##### Secondary end points

- PFS
- ORR
- Safety

NCT03390504



# ERDAFITINIB IN UROTELIAL CARCINOMA

## Phase 3 THOR Study: Erdafitinib Versus Chemotherapy of Choice in Patients With Advanced Urothelial Cancer and Selected FGFR Aberrations

### Cohort 1

#### Key eligibility criteria

- Age ≥18 years
- Metastatic or unresectable UC
- Confirmed disease progression
- Prior tx with anti-PD-(L)1
- 1-2 lines of systemic tx
- Select *FGFR3/2alt* (mutation/fusion)<sup>a</sup>
- ECOG PS 0-2

1:1  
N=266<sup>b</sup>  
R

**Erdafitinib**  
(n=136)  
Once-daily erdafitinib 8 mg with pharmacodynamically guided uptitration to 9 mg

**Chemotherapy of Choice**  
(n=130)  
docetaxel or vinflunine once every 3 weeks

Stratification factors: region (North America vs European Union vs rest of world), ECOG PS (0 or 1 vs 2), and disease distribution (presence vs absence of visceral [lung, liver, or bone] metastases)

#### Primary end point:

- OS

#### Key secondary end points:

- PFS
- ORR
- Safety

NCT03390504

## Demographics and Disease Characteristics

Characteristic	Erdafitinib (n=136)	Chemotherapy (n=130)
Age, median (range), years	66 (32-85)	69 (35-86)
Men, n (%)	96 (70.6)	94 (72.3)
Race, n (%)		
White	81 (59.6)	63 (48.5)
Asian	37 (27.2)	40 (30.8)
Black or African American	0	1 (0.8)
Multiple	0	1 (0.8)
Not reported	18 (13.2)	25 (19.2)
Presence of visceral metastases, n (%)	101 (74.3)	97 (74.6)
Liver	31 (22.8)	38 (29.2)

Characteristic	Erdafitinib (n=136)	Chemotherapy (n=130)
ECOG PS 0-1, n (%)	124 (91.2)	117 (90)
Primary tumor upper tract, n (%)	41 (30.1)	48 (36.9)
PD-L1 low (CPS <10), n (%)	89 (92.7) <sup>a</sup>	68 (86.1) <sup>a</sup>
<i>FGFRalt</i> , n (%) <sup>b</sup>	(n=135)	(n=129)
Mutations	108 (79.4)	107 (82.3)
Fusions	25 (18.4)	19 (14.6)
Mutations and fusions	2 (1.5)	3 (2.3)
Prior lines of systemic therapy <sup>c</sup>		
1 line	45 (33.1)	33 (25.4)
2 lines	90 (66.2)	97 (74.6)

- Patient baseline characteristics were generally balanced between treatment arms

## All Patients Enrolled in the Study Had Received Anti-PD-1 in the First- or Second-Line Setting

Patients receiving prior therapy, n (%)	Erdafitinib (n=136) <sup>a</sup>	Chemotherapy (n=130)
<b>1 line of prior systemic therapy</b>	<b>45 (33.1)</b>	<b>33 (25.4)</b>
Chemotherapy + anti-PD-(L)1 <sup>b</sup>	33 (24.3)	15 (11.5)
Anti-PD-(L)1 <sup>c</sup>	11 (8.1)	16 (12.3)
Chemotherapy	1 (0.7)	2 (1.5)
<b>2 lines of prior systemic therapy</b>	<b>90 (66.2)</b>	<b>97 (74.6)</b>
First line of therapy		
Chemotherapy	77 (56.6)	76 (58.5)
Chemotherapy + anti-PD-(L)1	6 (4.4)	10 (7.7)
Other	7 (5.1)	11 (8.5)
Second line of therapy		
Anti-PD-(L)1	76 (55.9)	76 (58.5)
Chemotherapy	10 (7.4)	14 (10.8)
Other	4 (2.9)	7 (5.4)



# ERDAFITINIB IN UROTELIAL CARCINOMA

## Phase 3 THOR Study: Erdafitinib Versus Chemotherapy of Choice in Patients With Advanced Urothelial Cancer and Selected FGFR Aberrations

### Cohort 1

#### Key eligibility criteria

- Age ≥18 years
- Metastatic or unresectable UC
- Confirmed disease progression
- Prior tx with anti-PD-(L)1
- 1-2 lines of systemic tx
- Select *FGFR3/2alt* (mutation/fusion)<sup>a</sup>
- ECOG PS 0-2

1:1  
N=266<sup>b</sup>  
R

#### Erdafitinib (n=136)

Once-daily erdafitinib 8 mg with pharmacodynamically guided uptitration to 9 mg

#### Chemotherapy of Choice (n=130)

docetaxel or vinflunine once every 3 weeks

#### Primary end point:

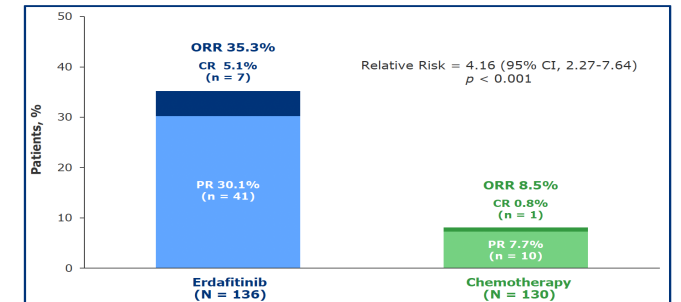
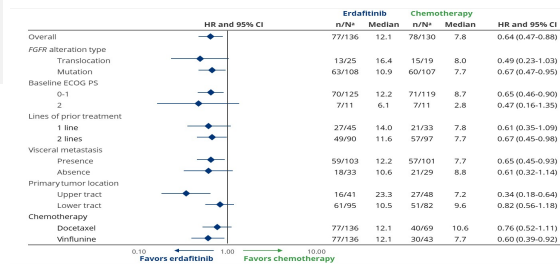
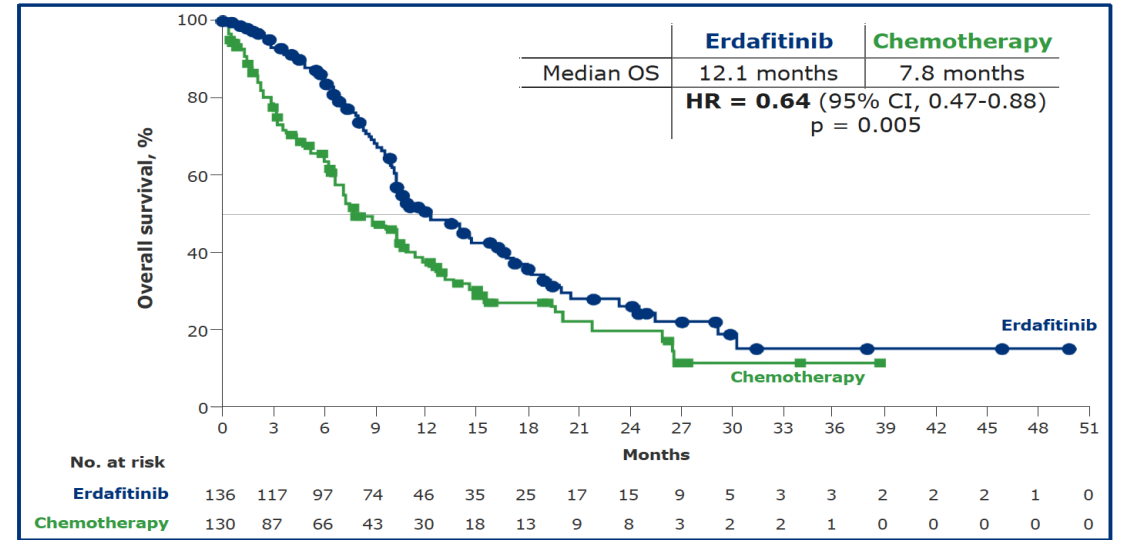
- OS

#### Key secondary end points:

- PFS
- ORR
- Safety

Stratification factors: region (North America vs European Union vs rest of world), ECOG PS (0 or 1 vs 2), and disease distribution (presence vs absence of visceral [lung, liver, or bone] metastases)

NCT03390504





## ERDAFITINIB IN UROTELIAL CARCINOMA

### Phase 3 THOR Study: Erdafitinib Versus Pembrolizumab in Patients With Metastatic Urothelial Carcinoma and Select *FGFR* Alterations

#### Cohort 2

##### Key eligibility criteria

- Age ≥18 years
- Metastatic or unresectable UC
- Confirmed disease progression on 1 prior tx
- Naive to anti-PD-(L)1 tx
- Select *FGFR3/2alt* (mutation/fusion)<sup>a</sup>
- ECOG PS 0-2

1:1  
N=351<sup>b</sup>

**Erdafitinib**  
(n=175)  
Once-daily erdafitinib 8 mg with pharmacodynamically guided up-titration to 9 mg

**Pembrolizumab**  
(n=176)  
200 mg once every 3 weeks

Stratification factors: region (North America vs European Union vs rest of world), ECOG PS (0 or 1 vs 2), and disease distribution (presence vs absence of visceral [lung, liver, or bone] metastases)

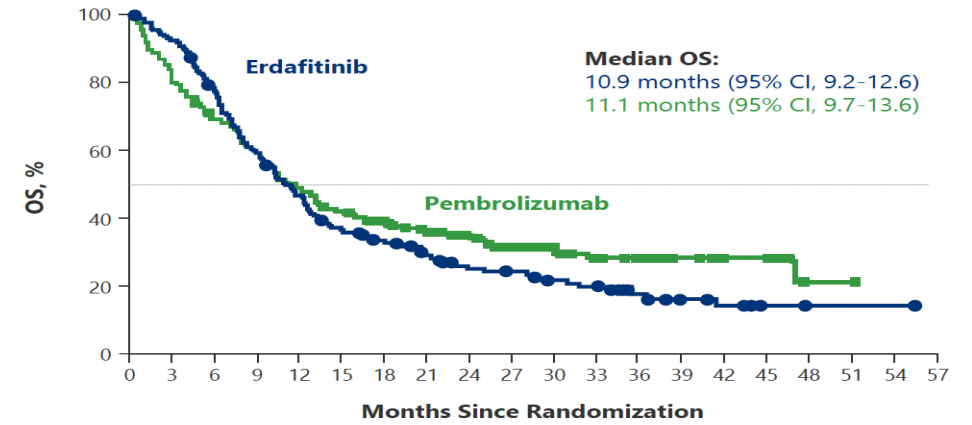
##### Primary end point

- OS

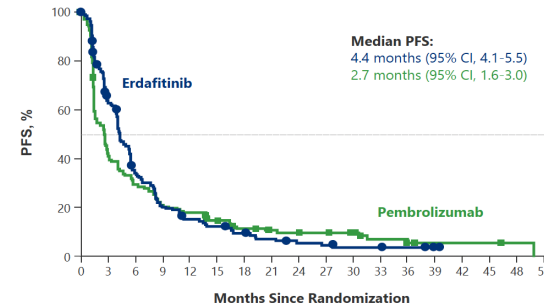
##### Secondary end points

- PFS
- ORR
- Safety

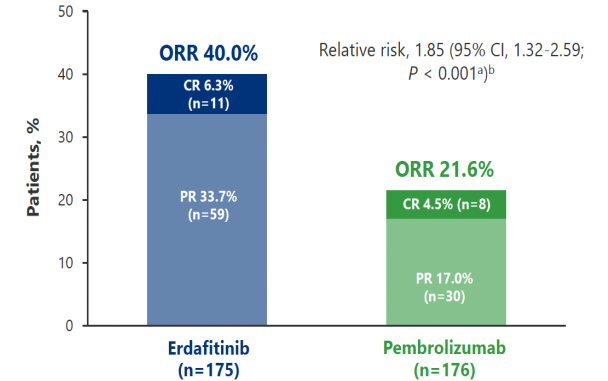
NCT03390504



No. at risk	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57
<b>Erdafitinib</b>	175	160	131	100	78	60	52	41	30	28	23	21	13	9	7	2	1	1	1	0
<b>Pembrolizumab</b>	176	148	119	103	84	72	60	52	43	34	29	23	19	11	8	8	1	1	0	0



No. at risk	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
<b>Erdafitinib</b>	175	107	57	34	23	19	14	10	7	6	4	4	3	1	0	0	0	0
<b>Pembrolizumab</b>	176	75	50	36	30	23	16	13	12	11	9	5	3	2	2	2	1	0





## OTHERS FGFR INHIBITORS

### PEMIGATINIB

Inhibidor selectivo potente de FGFR 1-3

Fase II (FIGHT 201) con:

- Cohorte A: 64 pts UCm mut/fusión **FGFR3**
- Cohorte B: 36 pts UCm otras alteraciones de FGFR

**ORR 25%**

### INFRIGATINIB

Inhibidor selectivo oral ATP-competitivo de FGFR 1-3

Fase I

67 pts UCm con alteraciones FGFR3

**ORR 25,4%**

### ROGARATINIB

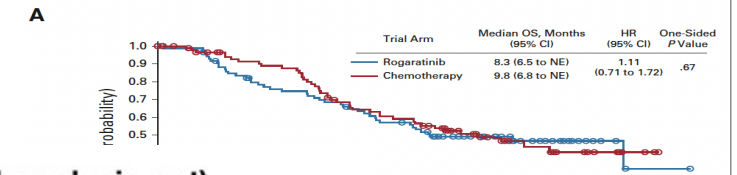
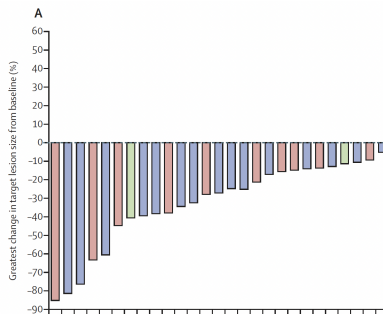
Inhibidor selectivo potente de FGFR 1-4

**FORT-1: Phase II/III Study of Rogaratinib  
Versus Chemotherapy in Patients With Locally  
Advanced or Metastatic Urothelial Carcinoma**

**Table 3.** Exploratory analysis of tumor response by *FGFR3* DNA alteration (full analysis set)

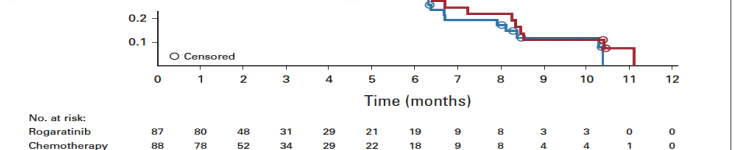
	Rogaratinib (n=82) <sup>a</sup>		Chemotherapy (n=79) <sup>a</sup>	
	<i>FGFR3</i> DNA <sup>alt</sup> n=21	<i>FGFR3</i> WT n=61	<i>FGFR3</i> DNA <sup>alt</sup> n=15	<i>FGFR3</i> WT n=64
ORR, n (%)	11 (52)	6 (10)	4 (27)	11 (17)
DCR, n (%)	16 (76)	27 (44)	10 (67)	33 (52)

DCR, n (%) [95% CI]	43 (49) [39, 60]	49 (56) [45, 66]
1-sided p value (Fisher's exact test)	0.84	



Time (months)	7	8	9	10	11	12	13	14	15	16	17
Rogaratinib	45	41	33	28	19	16	8	4	1	1	0
Chemotherapy	46	43	33	24	16	14	10	6	2	0	0

	Median PFS, Months (95% CI)	HR (95% CI)	One-Sided P Value
Rogaratinib	2.7 (1.6 to 4.6)	1.23	.86
Chemotherapy	3.2 (2.7 to 4.4)	(0.84 to 1.80)	

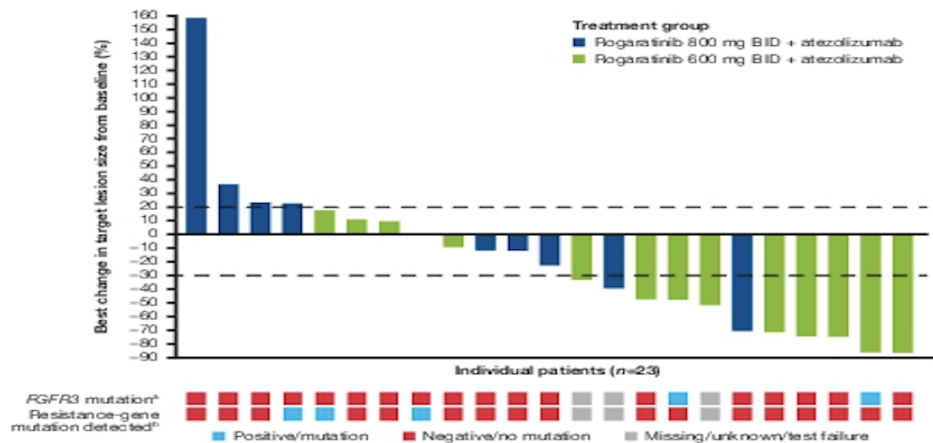




## COMBINATIONS OF FGFR:

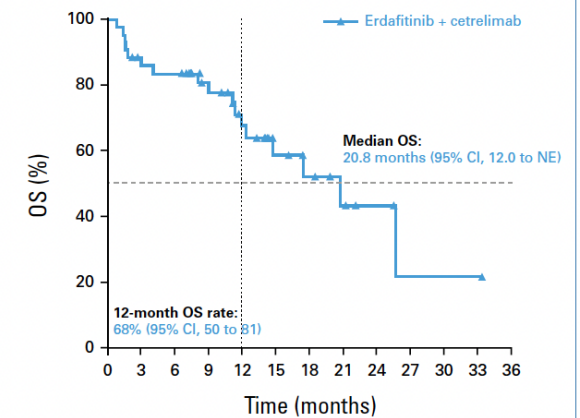
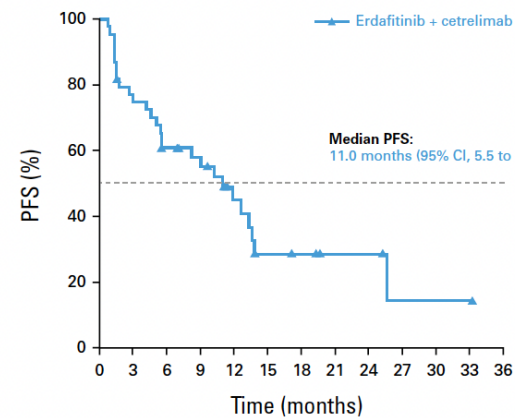
### Rogaratinib Plus Atezolizumab in Cisplatin-Ineligible Patients With *FGFR* RNA-Overexpressing Urothelial Cancer The FORT-2 Phase 1b Nonrandomized Clinical Trial

n (%) [95% CI]	Rogaratinib 800 mg BID + atezolizumab 1200 mg (n=10)	Rogaratinib 600 mg BID + atezolizumab 1200 mg (n=15)	Total (N=25)
<b>Best response</b>			
Complete response	1 (10)	3 (20)	4 (16)
Partial response	1 (10)	6 (40)	7 (28)
Stable disease	2 (20)	4 (27)	6 (24)
Progressive disease	6 (60)	2 (13)	8 (32)
<b>Objective response rate</b>	2 (20) [3, 56]	9 (60) [32, 84]	11 (44) [24, 65]
<b>Disease control rate</b>	4 (40) [12, 74]	13 (87) [60, 98]	17 (68) [47, 85]



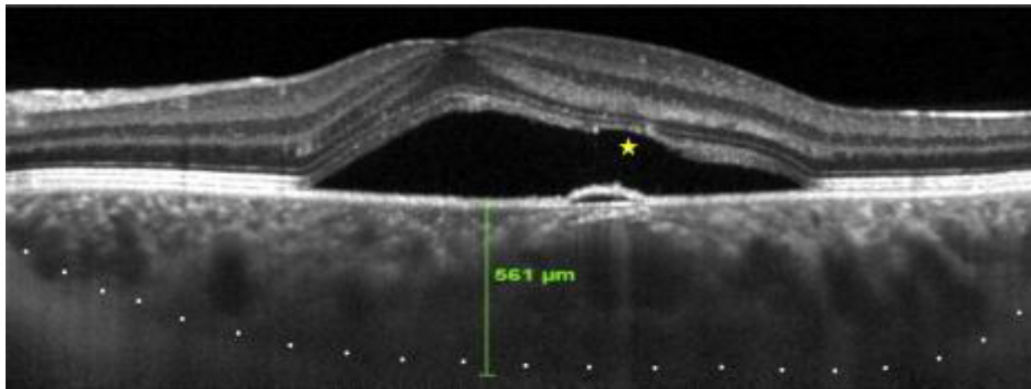
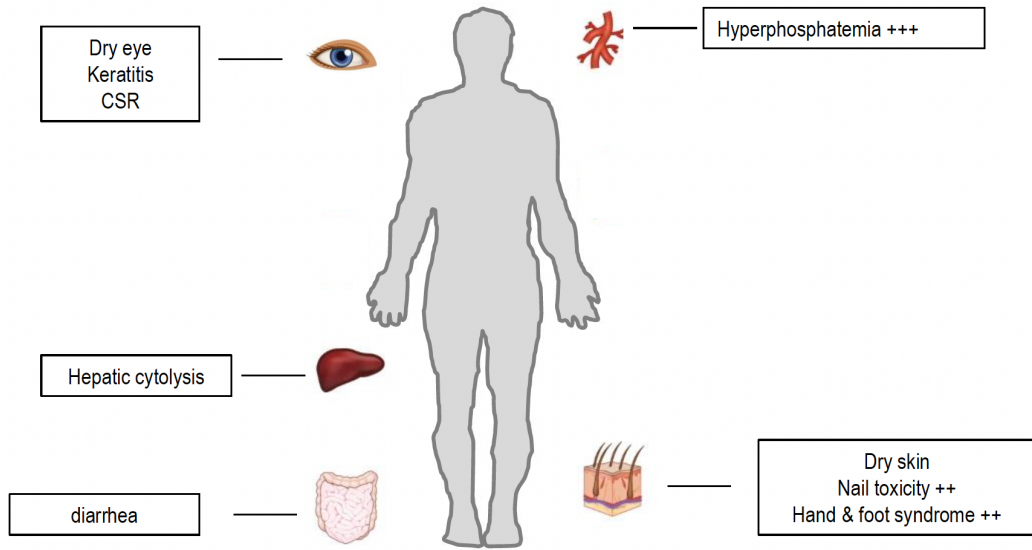
### Erdafitinib or Erdafitinib Plus Cetrelimab for Patients With Metastatic Urothelial Carcinoma and *FGFR* Alterations: Final Results From the Phase II NORSE Study

	Erdafitinib (n = 18)	Erdafitinib + Cetrelimab (n = 19)
ORR <sup>a</sup> , n (%) [95% CI]	6 (33%) [13%-59%]	13 (68%) [43%-87%]
Complete response, n (%)	1 (6%)	4 (21%)
Partial response, n (%)	5 (28%)	9 (47%)
DOR, median, months [95% CI]	NE [4.4-NE]	6.9 [1.6-NE]

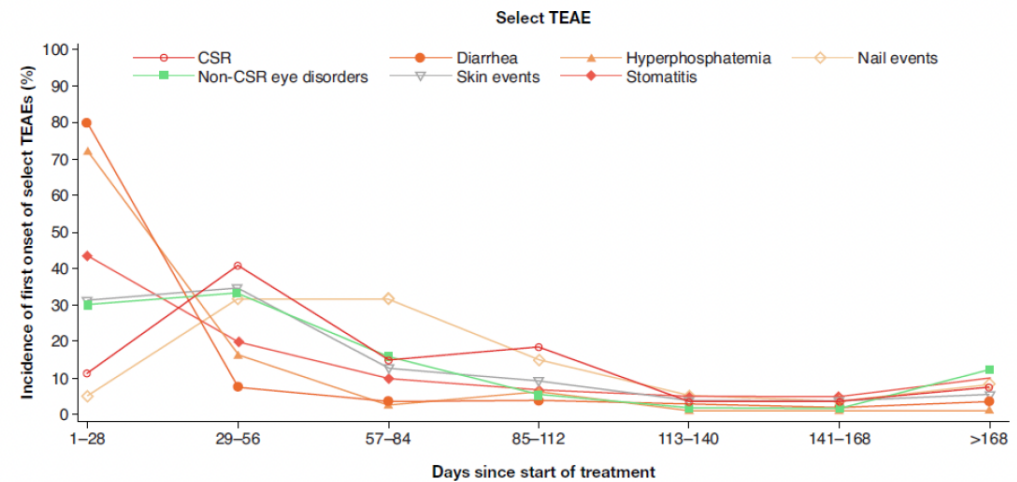




## SAFETY PROFILE



	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 <sup>a</sup>	22 (22)	23 (23)	15 (15)	60 (59)	25 (61)	35 (58)
Non-CSR eye disorders <sup>a</sup>	28 (28)	23 (23)	5 (5.0)	57 (56) <sup>b</sup>	21 (51)	36 (60)
Skin events <sup>a</sup>	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)





## SAFETY PROFILE

### Phase 3 THOR Study: Erdafitinib Versus Chemotherapy of Choice in Patients With Advanced Urothelial Cancer and Selected FGFR Aberrations

#### Cohort 1

##### Key eligibility criteria

- Age ≥18 years
- Metastatic or unresectable UC
- Confirmed disease progression
- Prior tx with anti-PD-(L)1
- 1-2 lines of systemic tx
- Select *FGFR3/2alt* (mutation/fusion)<sup>a</sup>
- ECOG PS 0-2

1:1  
N=266<sup>b</sup>

R

##### Erdafitinib (n=136)

Once-daily erdafitinib 8 mg with pharmacodynamically guided uptitration to 9 mg

##### Chemotherapy of Choice (n=130)

docetaxel or vinflunine once every 3 weeks

##### Primary end point:

- OS

##### Key secondary end points:

- PFS
- ORR
- Safety

Stratification factors: region (North America vs European Union vs rest of world), ECOG PS (0 or 1 vs 2), and disease distribution (presence vs absence of visceral [lung, liver, or bone] metastases)

NCT03390504

Patients with AEs of interest, n (%)	Erdafitinib (n=135)		Chemotherapy (n=112)	
	Any grade	Grade 3-4	Any grade	Grade 3-4
Nail disorders <sup>a</sup>	90 (66.7)	15 (11.1)	6 (5.4)	0
Skin disorders <sup>b</sup>	74 (54.8)	16 (11.9)	14 (12.5)	0
Eye disorders (excluding central serous retinopathy) <sup>c</sup>	57 (42.2)	3 (2.2)	6 (5.4)	0
Central serous retinopathy <sup>d</sup>	23 (17.0)	3 (2.2)	0	0

### THOR Cohort 1 Safety<sup>1</sup>

Safety profiles were consistent with the known profiles of erdafitinib and chemotherapy

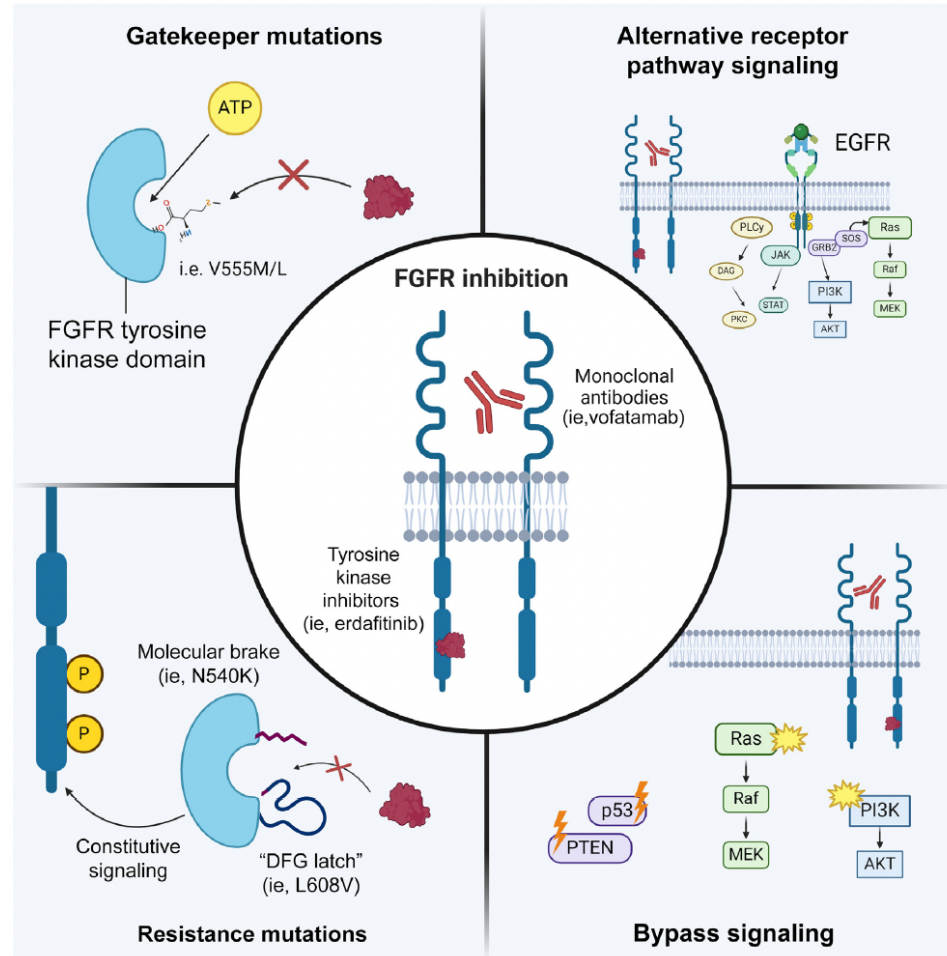
- 18 patients (13.3%) had serious TRAEs with **erdafitinib**
  - 1 treatment-related death occurred (sudden death)
  - AEs with erdafitinib were mostly manageable with dose modifications and supportive care
- 27 patients (24.1%) had serious TRAEs with **chemotherapy**
  - 6 treatment-related deaths occurred (due to febrile bone marrow aplasia, febrile neutropenia, septic shock, and atypical pneumonia)

Patients with TRAEs, n (%) <sup>a</sup>	Erdafitinib (N = 135)		Patients with TRAEs, n (%) <sup>c</sup>	Chemotherapy (N = 112)	
	Any grade	Grade 3-4		Any grade	Grade 3-4
≥ 1 TRAE	131 (97.0)	62 (45.9)	≥ 1 TRAE	97 (86.6)	52 (46.4)
Hyperphosphatemia	106 (78.5)	7 (5.2)	Anemia	31 (27.7)	7 (6.3)
Diarrhea	74 (54.8)	4 (3.0)	Alopecia	24 (21.4)	0
Stomatitis	62 (45.9)	11 (8.1)	Nausea	22 (19.6)	2 (1.8)
Dry mouth	52 (38.5)	0	Neutropenia	21 (18.8)	15 (13.4)
PPES	41 (30.4)	13 (9.6)	Leukopenia	13 (11.6)	9 (8.0)
Onycholysis	31 (23.0)	8 (5.9)	Febrile neutropenia	9 (8.0)	10 (8.9)
Discontinuation due to TRAEs	11 (8.1) <sup>b</sup>		Discontinuation due to TRAEs	15 (13.4) <sup>d</sup>	

Adverse events leading to treatment discontinuation	19 (14.1)	20 (17.9)
Related adverse events leading to treatment discontinuation	11 (8.1)	15 (13.4)
Adverse events leading to dose reduction	93 (68.9)	27 (24.1)
Related adverse events leading to dose reduction	89 (65.9)	24 (21.4)
Adverse events leading to dose interruption	97 (71.9)	35 (31.3)
Related adverse events leading to dose interruption	89 (65.9)	22 (19.6)



# MECANISMOS DE RESISTENCIA







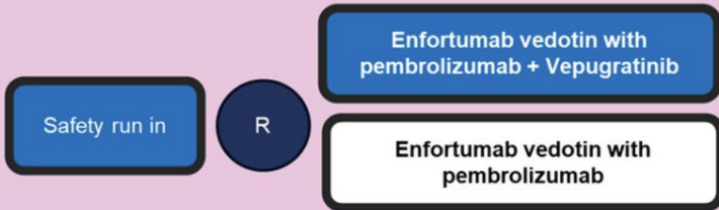
## NEW FGFR INHIBITORS

### Vepugratinib

### Dabogratinib

**A randomised phase III Study of Enfortumab vedotin with pembrolizumab +/-Vepugratinib 1<sup>st</sup> line in FGFR3 altered advanced urothelial cancer (FORAGER-2) NCT07218380**

- 1<sup>st</sup> line metastatic UC
- FGFR3 DNA+ve
- Fit for EVP
- PS 0-2



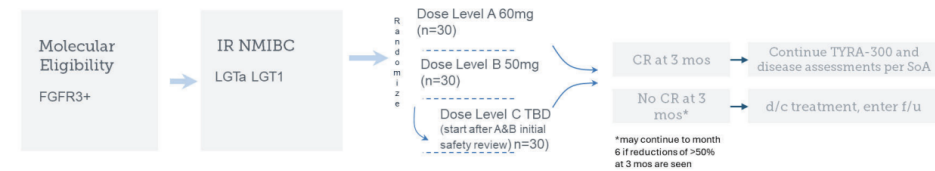
Initial safety run-in enrolling Phase I data suggest tolerable and safe (n=6)

FGFR 3 screening from plasma with expected positivity of 25%  
PFS is primary endpoint

Global randomized phase III needs 450 patients. EVP can start prior to randomisation to allow FGFR3 results.

**Tyra Biosciences Doses First Patient in Phase 2 Study of TYRA-300 in Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (SURF302)**

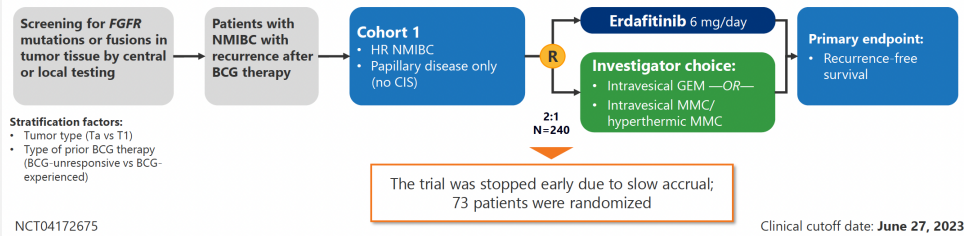
Figure 1: Study Schema



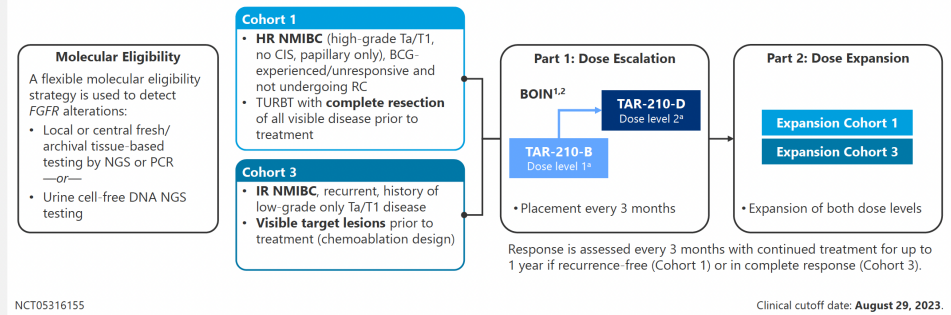


## FGFR IN OTHER GU MALIGNANCIES

### THOR-2 Cohort 1: Erdafitinib Versus Investigator's Choice of Intravesical Chemotherapy in Patients With High-Risk NMIBC



### Open-label, Multicenter Phase 1 Study to Evaluate Safety, PK, and Efficacy of TAR-210: Cohorts 1 and 3

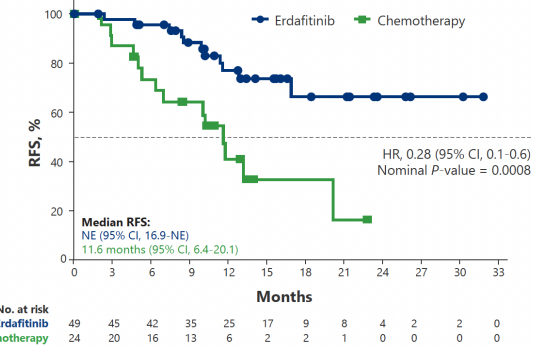


### Safety Results Were Generally Consistent With Known Profiles for Erdafitinib and Intravesical Chemotherapy

Patients with events, n (%)	Erdafitinib (n=49)		Chemotherapy (n=23)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any	49 (100.0)	19 (38.8)	19 (82.6)	4 (17.4)
Hyperphosphatemia	36 (73.5)	0	0	0
Diarrhea	27 (55.1)	1 (2.0)	3 (13.0)	0
Dry mouth	23 (46.9)	0	0	0
Stomatitis	20 (40.8)	5 (10.2)	0	0
Nail dystrophy	15 (30.6)	2 (4.1)	0	0
Dry skin	11 (22.4)	0	0	0
Dry eye	11 (22.4)	0	0	0
Dysgeusia	11 (22.4)	0	0	0
Constipation	10 (20.4)	1 (2.0)	1 (4.3)	0
Decreased appetite	10 (20.4)	0	0	0
Central serous chorioretinopathy	10 (20.4)	0	0	0
Alopecia	9 (18.4)	0	0	0
Onycholysis	9 (18.4)	0	0	0
Urinary tract infection	9 (18.4)	0	4 (17.4)	0
Fatigue	9 (18.4)	0	1 (4.3)	0
Hematuria	1 (2.0)	0	4 (17.4)	0

#### Erdafitinib group:

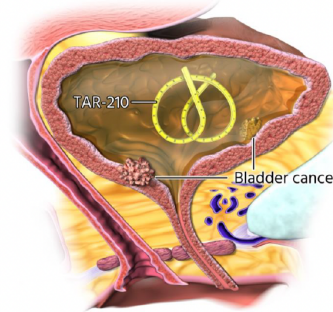
- 14 patients (28.6%) had AEs leading to



#### Erdafitinib group:

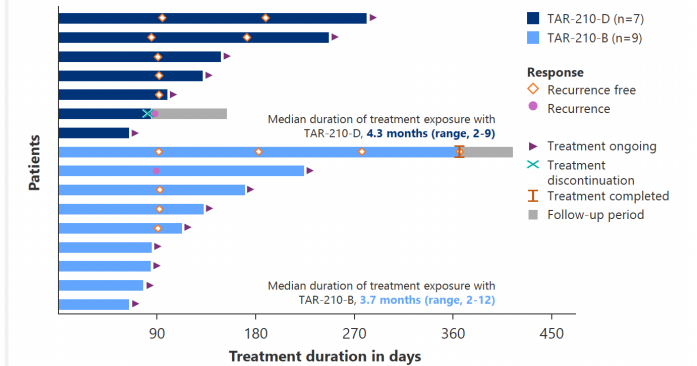
- 14 patients (28.6%) had AEs leading to treatment discontinuation<sup>b</sup>
- No treatment-related deaths were reported<sup>c</sup>

### TAR-210 is designed to provide local, sustained release of erdafitinib within the bladder for 3 months while limiting systemic toxicities



TAR-210 is inserted into the bladder through a dedicated urinary placement catheter and removed via cystoscopy.

#### Cohort 1 FGFR-altered HR NMIBC (N=16)

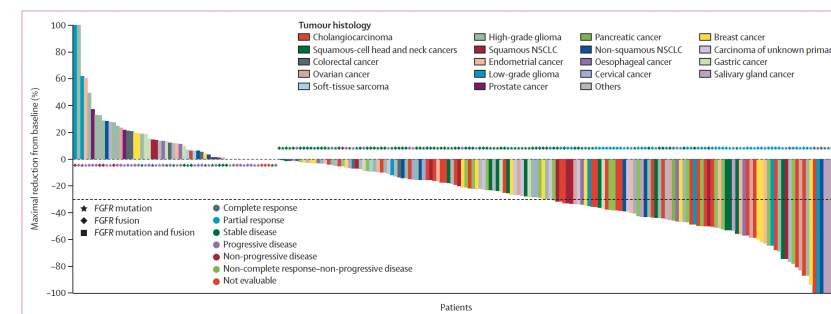




## FGFR IN OTHER GU MALIGNANCIES

### Erdafitinib in patients with advanced solid tumours with FGFR alterations (RAGNAR): an international, single-arm, phase 2 study

Tumour types	
Cholangiocarcinoma	31 (14%)
High-grade glioma	30 (14%)
Pancreatic cancer	18 (8%)
Breast cancer	16 (7%)
Squamous-cell head and neck cancers	15 (7%)
Squamous non-small-cell lung cancer	14 (6%)
Non-squamous non-small-cell lung cancer	9 (4%)
Carcinoma of unknown primary	8 (4%)
Colorectal cancer	8 (4%)
Endometrial cancer	8 (4%)
Oesophageal cancer	8 (4%)
Gastric cancer	8 (4%)
Ovarian cancer	8 (4%)
Low-grade glioma	7 (3%)
Cervical cancer	6 (3%)
Salivary gland cancer	5 (2%)
Soft-tissue sarcoma	3 (1%)
Prostate cancer	2 (1%)
Other	13 (6%)



### Erdafitinib for the Treatment of Patients With Castration-Resistant Prostate Cancer

ClinicalTrials.gov ID [NCT04754425](#)

Sponsor [M.D. Anderson Cancer Center](#)

Information provided by [M.D. Anderson Cancer Center \(Responsible Party\)](#)

Last Update Posted [2026-02-06](#)

### Erdafitinib and Abiraterone Acetate or Enzalutamide in Treating Patients With Double Negative Prostate Cancer

ClinicalTrials.gov ID [NCT03999515](#)

Sponsor [University of Washington](#)

Information provided by [Michael Schweizer, University of Washington \(Responsible Party\)](#)

Last Update Posted [2023-09-28](#)



## *CONCLUSIONES Y FUTURO*

- Testar FGFR en pacientes con carcinoma urotelial avanzada
- Erdafitinib aprobado en pacientes con carcinoma urotelial avanzado tras fallo a ICI
- Favorecer adherencia
  - Familiaridad efectos secundarios
  - Nuevos inhibidores
- Posicionamiento inhibidores FGFR
  - No músculo invasivo
  - Primera línea

# GRACIAS!

II JORNADA TRASLACIONAL  
DE ONCOLOGÍA DE PRECISIÓN: A TRAVÉS DE LAS VÍAS  
DE SEÑALIZACIÓN  
SEVILLA, 6 Y 7  
DE FEBRERO DE 2025

[pgajateborau@gmail.com](mailto:pgajateborau@gmail.com)

