Budget Impact of Introducing Erdafitinib for Previously Treated FGFR-Altered Locally Advanced or Metastatic Urothelial Carcinoma in Greece

HTA96

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INTRODUCTION

Background

Urothelial carcinoma (UC) is a malignancy of the urinary tract, with a proportion of patients presenting with or progressing to locally advanced or metastatic disease. Patients with unresectable or metastatic UC have poor prognosis and limited treatment options after disease progression on prior systemic therapy[1].

Biomarker-defined population

A subgroup of patients with UC have susceptible fibroblast growth factor receptor (FGFR) genetic alterations. Identification of these alterations allows the use of targeted treatment approaches in patients who have previously received systemic therapy[2].

Intervention

Erdafitinib is an oral FGFR tyrosine kinase inhibitor indicated for adult patients with unresectable or metastatic UC with susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing an immune checkpoint inhibitor in the unresectable or metastatic setting[3].

Aim

This analysis aimed to estimate the budget impact of introducing erdafitinib for eligible patients with previously treated unresectable or metastatic UC with susceptible FGFR3 genetic alterations in Greece.

METHODS

Budget Impact Model Structure

- An Excel-based budget impact model was adapted to estimate the financial impact of introducing erdafitinib in Greece over a 5-year time horizon.
- The analysis was conducted from the perspective of the Greek public payer, EOPYY, with costs expressed in 2026 euros (€).

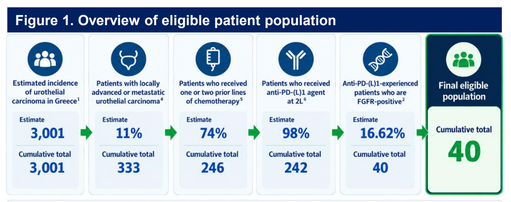
Population Inputs

- The eligible population included adults with previously treated unresectable or metastatic urothelial carcinoma with susceptible FGFR genetic alterations.
- Two scenarios were compared: a current market scenario without erdafitinib and a future market scenario with erdafitinib (**Table 1**).
- The treatment mix included erdafitinib, docetaxel, vinflunine, enfortumab vedotin, paclitaxel and platinum-based treatment (**Table 2**).
- Clinical efficacy inputs were based on the THOR trial[2] (**Tables 3-5**).
- The eligible population was estimated using Greek UC incidence, the proportion of patients with LA/mUC, prior chemotherapy exposure, prior anti-PD-(L)1 treatment and FGFR positivity (**Figure 1**).

Cost Inputs

- Included costs comprised drug acquisition and administration, subsequent treatment acquisition and administration, adverse event management, healthcare resource use and end-of-life care (**Table 4**).
- Annual per-patient costs were estimated based on modelled time on treatment, progression-free survival and progressed disease.
- The model outcomes included annual eligible population, erdafitinib-treated patients, total annual costs, annual net budget impact and cumulative net budget impact.

Figure 1. Overview of eligible patient population



Final eligible population over 5 years

Year	Year 1	Year 2	Year 3	Year 4	Year 5
Final eligible population (n)	40	40	39	39	39

Table 1. Market share scenarios

Total market shares in the current scenario (without erdafitinib)					
Current market scenario	Year 1	Year 2	Year 3	Year 4	Year 5
Erdafitinib	0%	0%	0%	0%	0%
Docetaxel	45%	47%	49%	51%	52%
Vinflunine	15%	14%	13%	12%	11%
Enfortumab vedotin	10%	9%	8%	7%	6%
Paclitaxel	5%	5%	6%	6%	6%
Platinum-based treatment	25%	25%	24%	24%	25%
Total	100%	100%	100%	100%	100%
Total market shares in the future scenario (with erdafitinib)					
Future market scenario	Year 1	Year 2	Year 3	Year 4	Year 5
Erdafitinib	25%	40%	50%	55%	60%
Docetaxel	30%	25%	20%	18%	16%
Vinflunine	10%	8%	7%	6%	5%
Enfortumab vedotin	10%	7%	6%	5%	4%
Paclitaxel	3%	3%	3%	4%	4%
Platinum-based treatment	22%	17%	14%	12%	11%
Total	100%	100%	100%	100%	100%

Table 2. Dosing scheme

Treatment	Dose applied in the model	Treatment cycle (weeks)	No. of administrations per cycle	Administration route
Erdafitinib	8 mg once daily	3	21	Oral
Docetaxel	75 mg/m²	3	1	IV
Vinflunine	320 mg/m²	3	1	IV
Enfortumab vedotin	1.25 mg/kg	4	3	IV
Paclitaxel	80 mg/m²	4	3	IV
Platinum-based Tx	1,000 mg/m²	3	2	IV (gemcitabine)

Note: All treatments included in the market-share assumptions were included in the dosing table. Erdafitinib, docetaxel and vinflunine were informed by THOR[2], while enfortumab vedotin was informed by EV-301[7]. Paclitaxel and platinum-based treatment were included as model assumptions/placeholders for the budget impact market mix.

Table 3. Grade ≥3 adverse event rates applied in the model

Adverse event	Erdafitinib	Docetaxel	Vinflunine	Enfortumab vedotin	Paclitaxel	Platinum-based Tx
Palmar-plantar erythrody-saesthesia syndrome	9.63%	0.00%	0.00%	0.00%	0.00%	0.00%
Stomatitis	8.15%	0.00%	4.65%	0.00%	0.00%	4.65%
Anaemia	7.41%	4.35%	13.95%	2.70%	4.35%	13.95%
Hyponatraemia	7.41%	0.00%	4.65%	0.00%	0.00%	4.65%
Oncholysis	5.93%	0.00%	0.00%	0.00%	0.00%	0.00%
Hyperphosphataemia	5.19%	0.00%	0.00%	0.00%	0.00%	0.00%
Neutropenia	0.00%	13.04%	16.28%	4.73%	13.04%	16.28%
Leukopenia	0.00%	11.59%	4.65%	0.00%	11.59%	4.65%
Febrile neutropenia	0.00%	8.70%	4.65%	0.68%	8.70%	4.65%
Fatigue	0.00%	4.35%	2.33%	6.42%	4.35%	2.33%
Maculopapular rash	0.00%	0.00%	0.00%	7.43%	0.00%	0.00%
Decreased neutrophil count	0.00%	0.00%	0.00%	6.08%	0.00%	0.00%

Note: Grade ≥3 treatment-emergent adverse events with incidence ≥5% were included. Erdafitinib, docetaxel and vinflunine AE inputs were informed by THOR[2]. Enfortumab vedotin AE inputs were based on EV-103[7]. Paclitaxel was assumed equivalent to docetaxel, and platinum-based treatment was assumed equivalent to vinflunine. AE costs were applied as one-off costs at treatment initiation.

Table 4. Clinical inputs included in the model

Treatment	OS, months	PFS, months	TTD, months
Erdafitinib	13.3	5.5	6.2
Docetaxel	10.1	2.7	2.4
Vinflunine	7.5	3.1	3.0
Enfortumab vedotin	13.6	5.9	5.9
Paclitaxel	13.3	5.5	5.5
Platinum-based Tx	13.3	5.5	5.5

Note: Erdafitinib, docetaxel and vinflunine inputs were informed by THOR[2]. Enfortumab vedotin was based on the modelled EV trace. Paclitaxel and platinum-based treatment were included as model assumptions/placeholders for the budget impact market mix. OS and PFS were used to estimate health-state occupancy over time, while TTD was used to estimate treatment exposure and treatment-related costs.

Table 5. Subsequent treatment distribution usedi n the model

Initial treatment	Subsequent active treatments
Erdafitinib	Carboplatin 7.55%; Gemcitabine 5.66%; Paclitaxel 7.55%; Docetaxel 3.77%; Vinflunine 3.77%; Pembrolizumab 3.77%; Enfortumab vedotin 17.92%; Sacituzumab govitecan 2.83%; No active treatment 58.49%
Docetaxel	Carboplatin 6.45%; Gemcitabine 9.68%; Paclitaxel 1.61%; Docetaxel 1.61%; Pembrolizumab 6.45%; Enfortumab vedotin 14.52%; No active treatment 51.61%
Vinflunine	Carboplatin 12.50%; Gemcitabine 10.00%; Paclitaxel 12.50%; Docetaxel 2.50%; Enfortumab vedotin 10.00%; No active treatment 57.50%
Enfortumab vedotin	Carboplatin 7.55%; Gemcitabine 5.66%; Paclitaxel 7.55%; Docetaxel 12.74%; Vinflunine 12.74%; Pembrolizumab 3.77%; Sacituzumab govitecan 2.83%; No active treatment 58.49%
Paclitaxel	Carboplatin 6.45%; Gemcitabine 9.68%; Paclitaxel 1.61%; Docetaxel 1.61%; Pembrolizumab 6.45%; Enfortumab vedotin 14.52%; No active treatment 51.61%
Platinum-based Tx	Carboplatin 12.50%; Gemcitabine 10.00%; Paclitaxel 12.50%; Docetaxel 2.50%; Enfortumab vedotin 10.00%; No active treatment 57.50%

Note: Subsequent treatment distributions were informed by THOR[2] where available. Enfortumab vedotin was assumed equivalent to the erdafitinib arm, with subsequent-line enfortumab vedotin redistributed to docetaxel and vinflunine. Paclitaxel was assumed equivalent to docetaxel, and platinum-based treatment was assumed equivalent to vinflunine.

Table 6. Non-drug acquisition cost inputs included in the model

Cost category	Cost item	Unit cost	Value year	Source
Drug administration	IV administration of docetaxel for adult population	€489.23	2026	Government Gazette: FEK B'7262/21-12-2023 and FEK B'3563/08-07-2025
	IV administration of vinflunine for adult population	€297.05	2026	
	IV administration of enfortumab vedotin / pembrolizumab / sacituzumab govitecan for adult population	€406.22	2026	
	IV administration of paclitaxel for adult population	€1,039.18	2026	
	IV administration of gemcitabine for adult population	€507.83	2026	
Healthcare resource use	Oncologist consultation	€13.00	2026	FEK A'17/06.02.2026
	Urologist consultation	€13.00	2026	
	Blood sample	€1.84	2025	EOPYY reimbursed medical procedures list[8]
	CT scan	€135.00	2025	
	MRI	€40.00	2025	
	PET-CT scan	€400.00	2025	
Adverse event management	Palmar-plantar erythrodysaesthesia syndrome	€71.79	2021	Data on file
	Stomatitis	€301.94	2018	Gourzoulidis G. et al., 2019[9]
	Maculopapular rash	€182.57	2018	
	Hyperphosphataemia	€534.52	2018	
	Anaemia	€92.00	2024	Koulentaki M. et al., 2024[10]
	Hyponatraemia	€289.00	2024	
	Neutropenia	€117.00	2024	
	Leukopenia	€138.00	2024	
	Febrile neutropenia	€117.00	2024	
	Fatigue	€49.00	2024	
	Decreased neutrophil count	€189.00	2024	
	Oncholysis	€18.03	2026	Micro-costing approach
End-of-life care	End-of-life care	€1,251.50	2026	Kokkotou E. et al., 2021[11], inflated to 2026 values

RESULTS

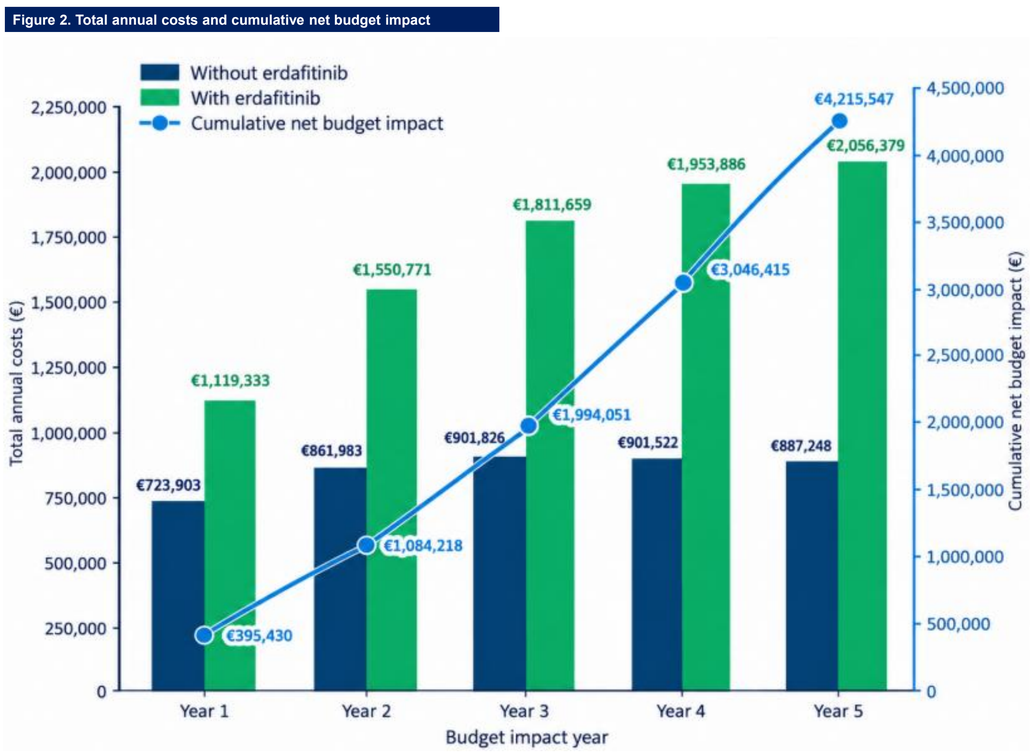
Eligible population and erdafitinib uptake

The eligible population was estimated at 40 patients in Year 1, decreasing slightly to 39 patients by Year 5. The number of patients expected to receive erdafitinib increased from 10 patients in Year 1 to 23 patients in Year 5, reflecting gradual uptake over the 5-year time horizon.

Budget impact

- Total annual costs in the current market scenario without erdafitinib ranged from €723,903 in Year 1 to €887,248 in Year 5 (**Figure 2**).
- In the future market scenario with erdafitinib, total annual costs ranged from €1,119,333 in Year 1 to €2,056,379 in Year 5 (**Figure 2**).
- The annual net budget impact increased from €395,430 in Year 1 to €1,169,132 in Year 5. Over 5 years, cumulative costs were €4,276,482 in the current market scenario and €8,492,028 in the future market scenario, resulting in a cumulative net budget impact of €4,215,547 (**Figure 2**).
- The average annual budget impact was estimated at €843,109, calculated as the cumulative 5-year net budget impact divided by the model time horizon.

Figure 2. Total annual costs and cumulative net budget impact



CONCLUSION

Introducing erdafitinib in Greece is expected to result in a moderate and predictable budget impact over 5 years, reflecting the small biomarker-defined eligible population and gradual treatment uptake.

The cumulative net budget impact was estimated at €4.22 million over 5 years, corresponding to an average annual budget impact of €843,109.

Overall, the analysis indicates that erdafitinib would have a manageable financial impact on the Greek public payer while providing access to a targeted treatment option for patients with previously treated FGFR3-altered unresectable or metastatic urothelial carcinoma.

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ABBREVIATIONS

AE, adverse event; **BIA**, budget impact analysis; **BIM**, budget impact model; **EOPYY**, Greek National Organization for Health Care Services Provision; **FGFR**, fibroblast growth factor receptor; **HCRU**, healthcare resource use; **IV**, intravenous; **LA/mUC**, locally advanced or metastatic urothelial carcinoma; **OS**, overall survival; **PD**, progressed disease; **PD-(L)1**, programmed death receptor-1/programmed death ligand-1; **PFS**, progression-free survival; **TTD**, time to treatment discontinuation; **UC**, urothelial carcinoma.

ACKNOWLEDGMENTS & DISCLOSURES

This study was funded by Johnson & Johnson Innovative Medicine.

MK and SR are employees of ECONCARE LP. DK is an employee of Johnson & Johnson Innovative Medicine. GK provided scientific support for the analysis.

ISPOR EUROPE 2026 | 8-11 November 2026 | Vienna, Austria