

Erdafitinib

THOR/BLC3001 cohort 1

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



QoL data pending



Serious and disabling adverse effects



Other adjustments



SCORE

CURATIVE



Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE



Overall Survival



Progression-Free Survival



Non-inferiority (Improved Quality of Life or Reduced Adverse Events) / Response Rate



Overall Response Rate / Duration of Response

Overall Survival / Disease-Free Survival / Pathological Complete Response

INFORMATION

Tumour type: Genitourinary Cancers

Therapeutic Indication: FDA: For adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible FGFR3 genetic alterations, whose disease has progressed on or after at least one line of prior systemic therapy.

Erdafitinib is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy./ EMA: Erdafitinib as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting

Experimental Arm: Erdafitinib

Control Arm: ChT (docetaxel or vinflunine)



