Erdafitinib THOR/BLC3001 cohort 1

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

OS

ADJUSTMENTS

Quality of life

?

QoL data pending

Serious and disabling adverse effects

Other adjustments

Erdafitinib THOR/BLC3001 cohort 1

FINAL SCORE

CURATIVE

Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE

4

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)