PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

ORR

ADJUSTMENTS

Quality of life

Not qualified for an ESMO-MCBS credit

Serious and disabling adverse effects

Other adjustments

Belzutifan MK-6482 (Study 004)

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

3

Overall Response Rate / Duration of Response

Overall Survival / Disease-Free Survival / Pathological Complete Response

INFORMATION

Tumour type: Genitourinary Cancers
Therapeutic Indication: EMA: Belzutifan as monotherapy for the treatment of adult patients with von Hippel-Lindau disease who require therapy for associated, localised renal cell carcinoma (RCC), central nervous system (CNS) haemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable. FDA: For adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.
Experimental Arm: Belzutifan
Control Arm: Single arm