Dab/Tram (dabrafenib and trametinib)

ROAR

Dab/Tram (dabrafenib and trametinib) ROAR

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

ORR

ADJUSTMENTS

Quality of life

Not qualified for an ESMO-MCBS credit

Serious and disabling adverse effects

Other adjustments

Dab/Tram (dabrafenib and trametinib) ROAR

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: Brain Tumours
Therapeutic Indication: For the treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options
Experimental Arm: Dab/Tram (dabrafenib and trametinib)
Control Arm: Single arm (Phase II)