

Dab/Tram (dabrafenib and trametinib) ROAR

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



Dab/Tram (dabrafenib and trametinib) ROAR

FINAL 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

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)



