

Randomised, open-label, Phase III trial
Recurrent/metastatic HNSCC
Second-line treatment: Patients have progressed on prior platinum-based CT

N=474 patients

Randomisation 2:1

Afatinib
40 mg once daily*

MTX
40 mg/m² weekly[†]

Continuous treatment until progressive disease (or adverse events requiring withdrawal)

Patients can continue treatment after progressive disease if deemed clinically beneficial

Primary endpoint: PFS