Trastuzumab emtansine (T-DM1)

EMILIA

Trastuzumab emtansine (T-DM1) EMILIA

PRELIMINARY SCORE

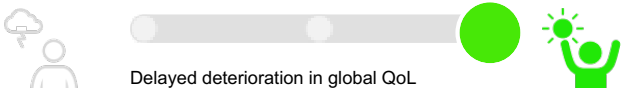
CURATIVE

NON-CURATIVE

PFS

ADJUSTMENTS

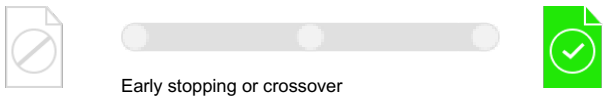
Quality of life



Delayed deterioration in global QoL

Serious and disabling adverse effects

Other adjustments



Early stopping or crossover

Trastuzumab emtansine (T-DM1) EMILIA

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: As a single agent for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy
Experimental Arm: Trastuzumab emtansine (T-DM1)
Control Arm: Lapatinib + capecitabine