Durvalumab DUO-E

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

PFS

ADJUSTMENTS

Quality of life

?

QoL data pending

Serious and disabling adverse effects

Other adjustments

Long-term plateau in the PFS curve

Durvalumab DUO-E

SCORE

CURATIVE

Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE

Overall Survival

3

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

Tumour type: Gynaecological Malignancies
Therapeutic Indication: FDA: Durvalumab is indicated with carboplatin plus paclitaxel followed by single-agent durvalumab for adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR). EMA: Durvalumab in combination with carboplatin and paclitaxel is indicated for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy followed by maintenance treatment with durvalumab as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR)
Experimental Arm: Durvalumab + Carboplatin and paclitaxel
Control Arm: Carboplatin, paclitaxel, and placebo (arm A)