

Pembrolizumab ENGOT-cx11/GOG-3047/KEYNOTE-A18

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



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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

Tumour type: Gynaecological Malignancies
Therapeutic Indication: FDA: Pembrolizumab with chemoradiotherapy for patients with FIGO 2014 Stage III-IVA cervical cancer. EMA: Pembrolizumab, in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), is indicated for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy.
Experimental Arm: Pembrolizumab + Chemoradiotherapy (Cisplatin)
Control Arm: Placebo + Chemoradiotherapy (Cisplatin)



