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Niraparib significantly improves outcome of ovarian cancer patients in landmark trial

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The PARP inhibitor niraparib significantly improves the outcome of platinum-sensitive recurrent ovarian cancer, according to full data from the ENGOT-OV16/NOVA trial presented for the first time at the ESMO 2016 Congress in Copenhagen and published in the *New England Journal of Medicine* (*NEJM*). The trial met its primary endpoint, with niraparib considerably prolonging progression-free survival compared to placebo.

"There are limited treatment options in recurrent ovarian cancer," said lead author Dr Mansoor Raza Mirza, chief oncologist, Rigshospitalet, Copenhagen University Hospital, Denmark and medical director of the Nordic Society of Gynaecological Oncology (NSGO). "Cumulative toxicity with platinum-based chemotherapy and lack of additional benefit limits its use. We then pause treatment until the next relapse and start combination chemotherapy."

"The current options for maintenance therapy in the EU are bevacizumab, which can only be given once and improves progression-free survival by just a few months, and the PARP inhibitor olaparib, which is only approved in patients with a germline BRCA mutation (about 10-15% of ovarian cancer patients). No maintenance therapy is approved outside the EU," he continued.

This phase III trial was performed in collaboration with European Network of Gynaecological Oncology Trial groups (ENGOT). The ENGOT-OV16/NOVA trial evaluated the efficacy and safety of the

PARP inhibitor niraparib as maintenance therapy in patients with recurrent ovarian cancer who respond to platinum-based chemotherapy. Patients were assigned to cohorts by BRCA mutation status and randomised 2:1 to receive niraparib 300 mg or placebo once daily.

The trial included 553 patients, of whom 203 had the germline BRCA mutation and 350 did not. Niraparib significantly improved the primary endpoint of progression-free survival compared to placebo in both cohorts, as well as in all subgroups.

Median progression-free survival with niraparib compared to placebo was 21.0 vs 5.5 months in the germline BRCA mutation group (hazard ratio [HR] 0.27, 95% confidence interval [CI] 0.173 to 0.410, p