Introduction/Background: Outcome of ovarian cancer patients has considerably improved by introduction of maintenance PARP inhibitors; however, most patients subsequently relapse and there is a need for further improvement. Combinations of targeted therapy and immunotherapy are of interest due to their single agent efficacy in different stages of ovarian cancer. To further enhance the response rate, one approach may be to integrate an anticancer vaccine aiming to activate an immune response against tumour-related antigens into a regime of combined targeted therapy and immunotherapy. This prospective, multicenter, open-label, randomized phase II maintenance study is evaluating the efficacy of UV1-olaparib-durvalumab combination as maintenance therapy after platinum combination therapy for BRCAwt patients with relapsed ovarian cancer.

Methodology: Patients with BRCAwt epithelial ovarian cancer, relapsed >6 months after last chemotherapy (maximum 4 prior lines of chemotherapy), in response to last chemotherapy, ECOG performance status 0–1 are eligible.

Patients are randomized into one of the three treatment arms, (A:B:C), in a 1:1:2 randomization (n=184): Arm A (olaparib): 46 subjects; Arm B (olaparib plus durvalumab): 46 subjects; Arm C (olaparib plus durvalumab plus UV1): 92 subjects. Patients are stratified according to: HRD status; Previous therapy on the bases of the diagnosis obtained by US, where 102 (80%) patients underwent surgery. Accuracy of US-guided biopsy was 94% (96/102), with 6 false negative cases at US (6%). Site (pre-vescical peritoneum) and size (< 8 mm) of the nodules resulted as major predictive factors for US-guided biopsy failure. US-guided biopsy correctly identified 86 primary invasive tubo-ovarian carcinomas and 10 metastatic tumours.

Conclusion: US-guided biopsy is a feasible, safe, and accurate method to provide histologically diagnosis in suspicious advanced tubo-ovarian cancer patients.