A RANDOMISED CLINICAL TRIAL INVESTIGATING OLAPARIB, DURVALUMAB AND AN ANTICANCER VACCINE, UV1 AS MAINTENANCE THERAPY IN PATIENTS WITH RECURRENT OVARIAN CANCER. ENGOT-OV56-NSGO-CTU-DOVACC

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 subjectsArm B (olaparib plus durvalumab): 46 subjectsArm C (olaparib plus durvalumab plus UV1): 92 subjectsPatients are stratified according to:HRD statusPrevious use of PARP inhibitor. Primary objective is to compare the preliminary efficacy of maintenance treatment with olaparib (arm A) to that of olaparib plus durvalumab and UV1 (arm C). Study sponsor is the Nordic Society of Gynaecological Oncology – Clinical Trial Unit and is being conducted in six ENGOT cooperative groups (AGO-A, BGOG, DGOG, HeGOG, NOGGO),(NCT04742075)

Results Expected results Study is enrolling patients in 11 ENGOT countries

Conclusion The positive outcome will further improve the outcome of our patients