## TP016/#1542 A MULTICENTER STUDY OF NIRAPARIB AS MAINTENANCE THERAPY IN BRCA WILD-TYPE, NEWLY DIAGNOSED ADVANCED OVARIAN CANCER (POLO TRIAL)

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**Introduction** Poly(adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitors have revolutionized the management of ovarian cancer. However, the optimal treatment of BRCA wild-type patients with advanced ovarian cancer remains controversial. The POLO trial aims to investigate the efficacy of niraparib maintenance therapy in patients with BRCA wild-type, newly diagnosed, low-risk advanced ovarian cancer.

**Methods** The POLO is a multi-center, investigator-initiated, single-arm, phase IV trial of patients with FIGO stage III-IV high-grade serous or endometrioid ovarian cancer. This study includes patients having both germline and somatic wild-type BRCA1/2 genes, no visible residual tumor after primary cytoreductive surgery, and responses to the postoperative platinum-based combination chemotherapy. Patients who received neoadjuvant chemotherapy are excluded. All enrolled patients are treated with niraparib maintenance therapy for three years or until disease progression, unacceptable toxicity, or withdrawal of patient consent. The primary endpoint is 12-month progression-free survival (PFS) rate. The secondary endpoints are overall survival, PFS, time to first subsequent treatment, time to second progression, time to second subsequent treatment, and safety. All patients should provide tumor slides obtained during cytoreductive surgery for a prospective examination of somatic homologous recombination deficiency and homologous recombination repair gene alterations. Pre- and post-niraparib blood samples will be collected for circulating cell-free DNA analyses. Molecular biomarkers that may indicate clinical response to niraparib will be identified. In total, 102 patients will be recruited from six sites. An interim analysis is planned after recruitment of 68 participants.

**Current Trial Status** Accrual is expected to be completed in December 2023, followed by the presentation of results in 2025.

## TP017/#812 A PHASE III RANDOMIZED CONTROLLED TRIAL IN PRIMARY STAGE THREE AND FOUR OVARIAN CANCER AFTER INTERVAL CYTOREDUCTIVE SURGERY (FOCUS/KOV-HIPEC-04)

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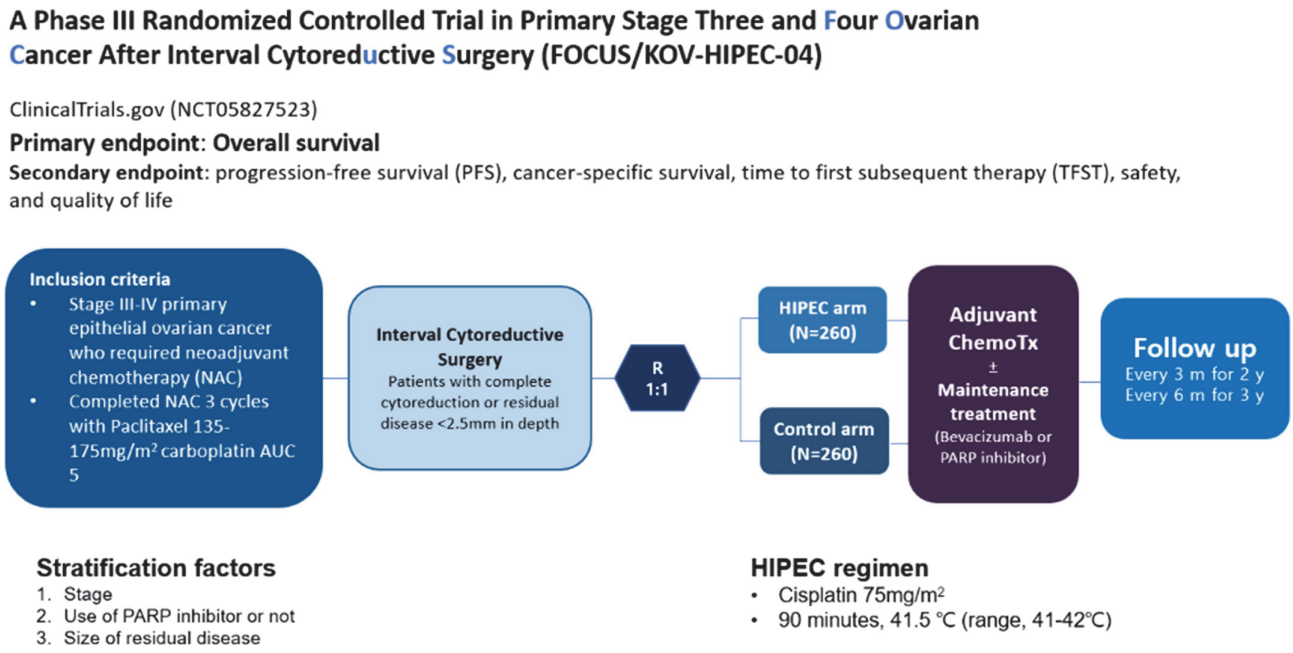


**Abstract TP017/#812 Figure 1**