**Results** The primary endpoint of this trial is the 12-month progression-free survival (PFS) rate. The secondary endpoints are overall survival, PFS, time to first subsequent treatment, time to second progression (PFS2), time to the second subsequent treatment, and safety. All patients should provide tumor slides obtained during cytoreductive surgery, for a prospective examination of somatic homologous recombination deficiency (HRD) and homologous recombination repair gene alterations. Pre- and post-niraparib (at the time of disease progression if available) blood samples will be collected for circulating cell-free DNA analyses. Molecular biomarkers that may indicate clinical response/resistance to niraparib will be identified.

**Conclusions** In total, 102 patients will be recruited from five sites. An interim analysis is planned after recruitment of 68 participants. Accrual is expected to be completed in 2024, followed by presentation of results in 2025.

**TP028/#658** RATIONALE AND STUDY DESIGN OF THE KOV-HIPEC-02 TRIAL: A RANDOMIZED, MULTICENTER, OPEN-LABEL PHASE III TRIAL OF HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-RESISTANT RECURRENT OVARIAN CANCER

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**Objectives** Hyperthermic intraperitoneal chemotherapy (HIPEC) during cytoreductive surgery has emerged to achieve a higher concentration of chemotherapeutic agents and treat micro-metastases on peritoneal surfaces by overcoming chemoresistance with hyperthermia. At advanced staged ovarian cancer treated with neoadjuvant chemotherapy, HIPEC with cisplatin 75–100 mg/m² following interval cytoreductive surgery increases progression-free survival and overall survival (OV-HIPEC-01 and KOV-HIPEC-01). In chemotherapy-naïve ovarian cancer patients, survival benefit is not identified with HIPEC (KOV-HIPEC-01). In ovarian cancer, HIPEC is thought to overcome chemotherapy resistance.

**Methods** This trial (KOV-HIPEC-02) is a multicenter, open-label, 1:1 randomized, phase III trial that will enroll 140 patients in platinum-resistant recurrent epithelial ovarian cancer. Institutional review board approval was obtained. The experimental arm will receive cytoreductive surgery and HIPEC followed by standard chemotherapy, and the control arm will receive standard chemotherapy without HIPEC until disease progression. If patients are assigned to the HIPEC group, the HIPEC procedure is carried out using the open or closed technique by infusing 41.5–42.0°C doxorubicin 35 mg/m² and mitomycin 15 mg/m² for 90 minutes. The primary objective of the trial is to evaluate progression-free survival (PFS) between the HIPEC group and the control group. Secondary objectives are overall survival (OS), cancer-specific survival, safety, and the quality of life according to whether HIPEC was performed during surgery in patients with platinum-resistant recurrent ovarian cancer. The first patient was enrolled in April 2020.

**Results** There are no available results at the time of submission.

**Conclusions** There are no available results at the time of submission.