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 chemotherapy resistance 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.

TP029/#1459 PROSPECTIVE MULTI-INSTITUTIONAL PHASE III TRIAL OF STANDARD OF CARE THERAPY WITH OR WITHOUT STEROTACTIC ABLATIVE RADIATION THERAPY FOR RECURRENT OVARIAN CANCER (SABR-ROC, KGOG 3064/KROG 2204)

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Objectives Stereotactic ablative radiotherapy (SABR) is the latest treatment that uses an intensity modulated technique to increase the fractional dose, reduces the number of treatments, and destroys the tumor with high accuracy. According to the result of the preliminary analysis of patients with recurrent ovarian cancer (ROC) treated with radiotherapy (RT), there might be a survival benefit, irrespective of favorable clinical features; such as no ascites, platinum-sensitive, normal CA-125, and good performance status.

Methods This study aims to evaluate whether the addition of SABR improves 3-year overall survival in patients with ROC. The secondary objectives are to check whether it significantly affects quality of life, patient-reported outcome and to develop an AI-based predictive model for the treatment response using image genomic analysis. Patients with pathologically confirmed epithelial ovarian cancer who have completed standard treatment initially will be included in this study. The patients will...
be stratified by stratification factors; the number of no ascites, platinum-sensitive, normal CA125 and ECOG performance status, location of the lesion and the use of PARP inhibitor. The patients will be randomized into two groups and the experimental arm will be treated with standard salvage therapy plus SABR. With an alpha ratio of 0.05, power of 80%, the estimated 1-year drop-out rate of 5% in each arm and the compliance rate of 95%, a total of 270 patients will be required.

**Results** Trial in progress: there are no available results at the time of submission.

**Conclusions** Trial in progress: there are no available conclusions at the time of submission.

### TP030/#1426

**EPIK-O/ENGT-0V61: A PHASE 3, RANDOMIZED STUDY OF ALPELISIB + OLAPARIB IN PATIENTS WITH NO GERMLINE BRCA MUTATION DETECTED, PLATINUM-RESISTANT OR -REFRACTORY, HIGH-GRADE SEROUS OVARIAN CANCER**

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**Objectives** Clear cell ovarian carcinoma (CCOC) is an uncommon subtype of epithelial ovarian cancer that is inherently chemoresistant. Evidence suggests that immune checkpoint inhibition (ICI) may be more effective in CCOC compared to other ovarian cancer subtypes. Loss-of-function mutations in SWI/SNF complex members, PI3K pathway alterations, and VEGFR/FGFR inhibition remodels the tumor microenvironment to promote anti-tumor immunity. Therefore, lenvatinib (anti-VEGFR/FGFR) may augment the activity of pembrolizumab (anti-PD1).

**Methods** NCT05296512 is a single cohort two-stage phase 2 trial evaluating the safety and efficacy of pembrolizumab + lenvatinib in adult women (n=31) with recurrent or persistent histologically-confirmed CCOC (≥50% clear cell histology). At least 1 prior platinum-based chemotherapy is required. Use of prior ICI or prior lenvatinib is prohibited. Participants will receive lenvatinib 20 mg orally daily with pembrolizumab 200 mg IV every 3 weeks. Up to 35 cycles of pembrolizumab can be given; if disease is stable or better, lenvatinib can be continued alone. Participants progressing on lenvatinib alone may resume treatment with pembrolizumab for up to an additional 17 cycles of therapy. Co-primary endpoints are the objective response rate (ORR) and rate of PFS at 6 months (PFS6) per RECIST 1.1 radiologic tumor assessment. Key secondary endpoints include median progression free survival, median overall survival, and clinical benefit rate by RECIST 1.1 and immune-RECIST (iRECIST), and correlation of PD-L1 expression with response. Enrollment is ongoing.

**Results** Trial in progress: Not applicable.

**Conclusions** Trial in progress: Not applicable.

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