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/ENGOT-OV61: 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

1Panagiotis Konstantinopoulos*, 2Antonio Gonzalez-Martín, 3Felipe Cruz, 4Michael Friedlander, 5Rosalind Glasspool, 6Domenica Lorusso, 7Christian Marth, 8Bradley Monk, 9Jae-Weon Kim, 10Olga Ajipa, 11Faye Su, 12Yu Han, 13Usula Matulonis, 14Dana-Farber Cancer Institute, Department of Gynecologic Oncology, Boston, USA; 15Clinica Universidad de Navarra, Department of Medical Oncology, Madrid, Spain; 16Instituto Brasileiro de Controle do Câncer, Department of Clinical Oncology, São Paulo, Brazil; 17Prince of Wales Clinical School, University of New South Wales, Department of Medical Oncology, Sydney, Australia; 18Beatson West of Scotland Cancer Centre and University of Glasgow, Department of Medical Oncology, Glasgow, UK; 19Fondazione Policlinico Gemelli IRCCS and Catholic University of Sacred Heart, Department of Gynecologic Oncology, Rome, Italy; 20Medizinische Universität Innsbruck, Department of Obstetrics and Gynaecology, Innsbruck, Austria; 21University of Arizona, Division of Gynecologic Oncology, Phoenix, USA; 22Seoul National University, Department of Obstetrics and Gynecology, Seoul, Korea; Republic of; 23Novartis Pharmaceuticals Corporation, Oncology, North Hanover, USA

10.1136/ijgc-2022-igcs.539

Objectives High-grade serous ovarian cancer (HGSOC) represents most epithelial ovarian cancer. Whilst responding to platinum-based therapy, ~75% of patients develop resistance, conferring poor prognosis. Homologous recombination repair proficiency is associated with platinum resistance and limited response to PARP inhibitors. PI3K pathway inhibition downregulates BRCA expression, abrogating homologous recombination repair proficiency, and may lead to (re)sensitization to PARP inhibitors. As alpelisib (PI3Kα inhibitor) + olaparib (PARP inhibitor) demonstrated preliminary evidence of synergism in platinum-resistant/refractory, BRCA-wild-type, recurrent HGSOC in a phase 1b study, the EPIK-O study is further evaluating this combination.

Methods EPIK-O/ENGOT-OV61 (NCT04729387) is a phase 3, randomized (1:1), open-label, active-controlled trial evaluating the efficacy and safety of alpelisib + olaparib versus single-agent chemotherapy in patients (N=358) with no germ-line BRCA mutation and platinum-resistant/refractory HGSOC. Adult patients with platinum-resistant/refractory, histologically confirmed HGSOC, high-grade endometrioid ovarian, fallopian tube, or primary peritoneal cancer, with no germ-line BRCA1/2 mutation, are included; patients must have received 1–3 prior systemic therapies. In Arm 1, patients receive alpelisib 200 mg orally OD + olaparib 200 mg orally BID; in Arm 2, patients receive paclitaxel 80 mg/m² IV weekly or pegylated liposomal doxorubicin 40–50 mg/m² IV Q28D (investigator’s choice). The primary endpoint is progression-free survival per RECIST 1.1 assessment by a blinded independent review committee. Key secondary endpoints are overall survival. Other secondary endpoints include overall response rate, clinical benefit rate, safety, and quality of life. Enrollment is planned in 26 countries; completion of data collection for the primary endpoint is anticipated in 2023.

Results No results

Conclusions Trial in progress

TP031/#1443  A PHASE II TRIAL OF PEMBROLIZUMAB AND LENVATINIB IN RECURRENT OR PERSISTENT CLEAR CELL CARCINOMA OF THE OVARY

1Elizabeth Lee*, 2Nabihay Tayob, 3BJ Rimmel, 4Andrea Wahner Hendrickson, 5Andrew Nixon, 6Usula Matulonis, 7Joyce Liu. 1Dana-Farber Cancer Institute, Medical Oncology; Gynecologic Oncology, Boston, USA; 2Dana-Farber Cancer Institute, Data Science, Boston, USA; 3Cedars Sinai Medical Center, Gynecologic Oncology, Los Angeles, USA; 4Mayo Clinic, Medical Oncology, Rochester, USA; 5Duke Cancer Institute, Department of Medicine, Durham, USA

10.1136/ijgc-2022-igcs.540

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 IL6/STAT upregulation generate a hypoxia-mimic, pro-angiogenic phenotype, suggesting a role for anti-angiogenic agents. 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.