resistant recurrent ovarian cancer; however, improving outcomes in these patients is a critical unmet need.

Methods This open-label, randomized phase II trial (JGOG3023; UMIN000017247) enrolled patients aged ≥20 years with histologically confirmed epithelial ovarian, fallopian tube, or primary peritoneal carcinoma with platinum-resistant disease (progression occurring ≤6 months from completing ≥3 platinum cycles, including bevacizumab). Patients were randomized 1:1 to single-agent chemotherapy (group A) or single-agent chemotherapy combined with bevacizumab (group B). The primary endpoint was investigator-assessed PFS. Secondary endpoints included OS, ORR, and safety.

Results Patient characteristics were balanced between group A (n=51) and group B (n=52). Median PFS was longer in group B versus group A (4.0 [95% CI: 3.0–5.7] vs 3.1 [2.5–4.6] months; HR, 0.54 [0.32–0.90]; one-sided p=0.0082) (figure 1). Maximum tumor diameter and ascites were significantly associated with greater prolongation in PFS in group B (figure 2). Median OS was numerically longer in group B versus group A (15.3 vs 11.3 months; HR, 0.67 [0.38–1.17]; two-sided p=0.1556). ORR was 13.7% and 25.0% in group A and B, respectively. The safety profile was similar across both groups (table 1).

Conclusion These results suggest chemotherapy combined with bevacizumab has efficacy beyond disease progression. A phase III trial is warranted to confirm our findings.

IGCS20_1306

15 RANDOMIZED DOUBLE-BLIND PLACEBO CONTROLLED TRIAL OF FRONTLINE MAINTENANCE VIGIL IMMUNOTHERAPY (VITAL STUDY) IN STAGE III/IV OVARIAN CANCER: EFFICACY ASSESSMENT IN BRCA1/2-WT PATIENTS

Introduction Vigil is an autologous tumor cell vaccine constructed from tumor tissue transfected with a DNA plasmid encoding GMCSF and bi-shRNA-furin thereby reducing TGFβ expression.

Methods A randomized double-blind placebo-controlled trial of Vigil was performed in advanced stage frontline (1L) Ovarian Cancer (OC) patients. Relapse-free survival (RFS), overall survival (OS), and safety were endpoints. Patients were randomized [1:1 to placebo (control group, CG) or Vigil (Vigil group, VG), 1 × 10^7 cells/dose for up to 12 doses] after complete response to 1L surgery and chemotherapy.

Results 91 patients were randomized in the per-protocol population (PP), (VG: n=46; CG: n=45). VG demonstrated no Grade 3 or 4 toxicity. From time of randomization median RFS (mRFS) for all 91 patients was favorable in the VG (HR 0.67, one-sided p 0.065). All 91 patients were tested for BRCA1/2 status. An advantage in mRFS was seen in the BRCA1/2-wt patients in VG (12.7 mo) compared to CG (8 mo), (HR 0.493, 90% CI [0.287 to 0.846], one-sided p 0.014) from time of randomization as well as OS benefit in VG (median not reached) vs. CG (41.4 mo) (HR of 0.417, 90% CI [0.202 to 0.86], p 0.02). 51% BRCA1/2-wt Vigil treated patients relapsed compared to 79% of placebo (median follow-up of 38.6 mo for PP). Homologous recombination deficiency status (HRD) and further determination of predictive biomarkers of response are underway.
Conclusions Vigil immunotherapy as 1L maintenance in Stage III/IV ovarian cancer is well tolerated and showed significant RFS clinical benefit, particularly in BRCA1/2-wt disease.

IGCS20_1101

Objective Veliparib, a poly (ADP-ribose) polymerase inhibitor, was evaluated in a Phase 3 trial (VELIA, NCT02470585) among patients with newly diagnosed stage III/IV high-grade serous epithelial ovarian/tubal/laparic tube/primary peritoneal cancer. VELIA examined veliparib added to CP followed by veliparib maintenance compared to placebo added to CP followed by placebo maintenance. This analysis compared QA progression-free survival among patients enrolled in VELIA.

Methods Patient-centered outcomes were assessed in 344 Veliparib+ CP and 351 CP alone subjects. Progression-free survival (PFS) time was partitioned into two health states: time with toxicity (Tox) and time without Tox. Tox included three clinically meaningful adverse events (AEs) including nausea, vomiting and fatigue. QA-PFS was assessed for duration of good quality of life, incorporating PFS and health states. Q-TWiST (QA time without disease symptoms or treatment Tox) was calculated as utility-weighted sums of mean health state durations. Sensitivity analyses were conducted utilizing Grade 2+ or Grade 3+ AEs. Similar analyses were conducted on HRD and BRCA-deficient subgroups.

Results A significant difference in mean QA-PFS was seen in favor of Vel throughout compared to CP alone (19.5 months vs 16.5 months; 95% CI 1.42, 4.61; p<0.0001). Mean Q-TWiST was longer for patients in Vel throughout arm compared to CP alone (20.82 months vs 18.06 months; 95% CI 1.09, 4.47; p<0.001). Similar differences in mean Q-TWiST were observed for sensitivity and subgroup analyses.

Conclusion Compared to CP alone, Veliparib added to CP and continued as maintenance had significant patient-centered benefits in terms of QA-PFS and on-treatment Q-TWiST.

IGCS20_1131

Objective The PATRICIA trial compared niraparib (NIR) to placebo in the postprogression setting of patients with platinum-sensitive PD from high-grade serous ovarian cancer (HGSOC) in the phase III ENGOT-OV26/GOG-3012 trial. This analysis assessed overall survival (OS) in a subset of 812 patients with BRCA1/2-mutated (BRCA-mut) HGSOC randomized 2:1 to niraparib vs placebo. In this cohort, the median OS times were 26.2 vs 20.0 months, respectively (HR 0.62; 95% CI 0.44-0.87; p=0.0041).

Methods The PATRICIA trial randomized patients with platinum-sensitive PD from HGSOC to placebo or niraparib. The analysis included 812 patients with BRCA-mut HGSOC (60% of patients). The median OS times were 26.2 vs 20.0 months, respectively (HR 0.62; 95% CI 0.44-0.87; p=0.0041).

Results In the subset of patients with BRCA-mut HGSOC, the median OS times were 26.2 vs 20.0 months, respectively (HR 0.62; 95% CI 0.44-0.87; p=0.0041). The benefit was consistent across subgroups.

Conclusion Niraparib improved OS in patients with BRCA-mut HGSOC, with a median OS of 26.2 months vs 20.0 months with placebo (HR 0.62; 95% CI 0.44-0.87; p=0.0041).