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.

Abstract 14 Figure 1 PFS by investigator assessment (ITT population)

Abstract 14 Figure 2 Forest plot of PFS by subgroup (ITT population)

Abstract 14 Table 1 Summary of grade ≥ 3 adverse events with a causal relationship with treatment occurring in $\geq 3\%$ of patients

Preferred term	Group A (N=50)	Group B (N=51)
Neutrophil count decreased	16 (32.0)	19 (37.3)
Platelet count decreased	7 (14.0)	5 (9.8)
Anemia	4 (8.0)	5 (9.8)
Anorexia	1 (2.0)	3 (5.9)
Febrile neutropenia	3 (6.0)	1 (2.0)
Palmar-plantar erythrodysesthesia syndrome	2 (4.0)	0
Infections and infestations (other)	0	3 (5.9)
Proteinuria	0	3 (5.9)
Hypertension	0	2 (3.9)
Mucositis oral	0	2 (3.9)
n (%)		

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

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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 TGF β 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.

A RFS (PP) from time of randomization

	Number of events / patients	Median RFS in mo
Vigil	25 / 46 (54%)	12.7
Placebo	34 / 45 (76%)	8.4

Stratified HR for recurrence or death 0.67, 90% CI [0.432 to 1.042], one-sided p 0.065

B RFS (BRCAwt) from time of randomization

	Number of events / patients	Median RFS in mo
Vigil	20 / 39 (51%)	12.7
Placebo	22 / 28 (79%)	8.0

Stratified HR for recurrence or death 0.493, 90% CI [0.287 to 0.846], one-sided p 0.014

Abstract 15 Figure 1 RFS from randomization. (A) RFS of all PP. (B) RFS of *BRCA1/2*-wt population

Conclusion 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

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QUALITY-ADJUSTED (QA) PROGRESSION-FREE SURVIVAL ANALYSES OF VELIPARIB + CARBOPLATIN/PACLITAXEL (CP) VS CP ALONE IN PATIENTS WITH NEWLY DIAGNOSED OVARIAN CANCER

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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/fallopian 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.

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SAFETY AND PATIENT-REPORTED OUTCOMES IN PATIENTS RECEIVING NIRAPARIB IN THE PRIMA/ENGOT-OV26/GOG-3012 TRIAL

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