Abstract 12 Table 1 Baseline characteristics

Characteristic	Patients (n = 27)
Age, median (range)	62 (35-78)
Histology	
High grade serous	25 (92.6%)
Intermediate grade serous	1 (3.7%)
Mixed	1 (3.7%)
ECOG performance status	
0	17 (63%)
1	10 (37%)
Prior number of lines, median (range)	4 (2-9)
Prior platinum lines, median (range)	2 (1-5)
Platinum status at enrollment	
Platinum-resistant	13 (48%)
Platinum-refractory	14 (52%)
Prior antiangiogenic therapy with bevacizumab	
Yes	22 (81%)
No	5 (19%)
Prior PARP inhibitor therapy	
Yes	20 (74%)
No	7 (26%)
Baseline genomic profiles	
Tumor PD-L1 expression	
Positive	1 (3.7%)
Negative	25 (92.6%)
Unknown	1 (3.7%)
BRCA1/2 mutations	
Positive	8 (30%)
Negative	19 (70%)
Microsatellite instability status	
Stable	19 (70%)
Unknown	8 (30%)
Tumor mutational load	
Low	13 (48%)
Intermediate	4 (15%)
Unknown	10 (37%)
Response & PFS from last prior line before enrollment into VIRO-15 trial	
ORR by RECIST	4/27 (15%)
ORR by CA-125	5/24 (21%)
PFS (mos), median (95% CI)	4.5 (2.9–5.8)
PFS-6-month	30%

T-cells and upregulation of STAT1 expression ($p=0.008$) were demonstrated.

Conclusions Despite PRROC, prior bevacizumab, and progression on last therapy, the majority of patients achieved RECIST response with median PFS exceeding their prior line of therapy. Virus-induced changes in the tumor microenvironment may explain the apparent clinical reversal of platinum resistance.

IGCS20_1440

13 EFFICACY ON INDIVIDUALIZED STARTING DOSE (ISD) AND FIXED STARTING DOSE (FSD) OF NIRAPARIB PER INVESTIGATOR-ASSESSMENT (IA) IN NEWLY DIAGNOSED ADVANCED OVARIAN CANCER (OC)

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Introduction Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for maintenance treatment of patients with newly diagnosed or recurrent OC that responded to platinum-based

Abstract 13 Table 1

Median PFS	IA PFS in the overall population and the ISD and FSD subgroups, HR (95% CI)	
	Original data cut 17 May 2019	Updated data cut 17 Nov 2019
Overall, N=733	0.63 (0.51, 0.76) P<0.0001	0.64 (0.53, 0.77) P<0.0001
FSD, n=487	0.60 (0.47, 0.77)	0.62 (0.49, 0.78)
ISD, n=246	0.68 (0.48, 0.96)	0.68 (0.49, 0.94)

FSD, fixed starting dose; HR, hazard ratio; IA, investigator assessment; ISD, individualized starting dose; PFS, progression-free survival.

chemotherapy and treatment in heavily-pretreated recurrent OC. Here we report efficacy in patients receiving the FSD and ISD in the PRIMA/ENGOT-OV26/GOG-3012 trial (NCT02655016).

Methods This double-blind, placebo-controlled, phase 3 study randomized 733 patients to receive niraparib or placebo for 36 months or until disease progression/toxicity. A protocol amendment introduced ISD: 200 mg in patients with body weight <77 kg or platelets <150,000/ μ L, or 300 mg in all others. The primary endpoint was PFS by blinded independent central review (BICR). IA PFS was a sensitivity analysis. At the primary analysis data cut, follow-up was 11.2 months and 17.1 months in the ISD and FSD subgroups, respectively. An ad hoc analysis of IA PFS was performed using an updated data cut with additional 6 months follow-up.

Results BICR and IA PFS were highly concordant in the overall population. Efficacy of niraparib based on IA PFS in FSD vs ISD subgroups for each data cut were similar (table 1). Dose interruptions, modifications, and hematologic toxicity were lower with the ISD. Exposure–response data supported the clinical data.

Conclusions The 200- or 300-mg ISD by baseline body weight and platelet counts demonstrated comparable efficacy while improving the safety profile of niraparib. Use of this regimen for first-line maintenance of advanced OC patients is approved by the US FDA.

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Plenary V

IGCS20_1271

14 PHASE II TRIAL EVALUATING EFFICACY AND SAFETY OF STANDARD OF CARE WITH OR WITHOUT BEVACIZUMAB IN PLATINUM-RESISTANT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER

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Introduction There are no ongoing clinical trials investigating bevacizumab efficacy beyond disease progression in platinum-

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.