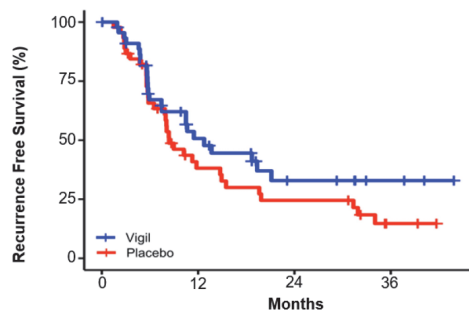


**A** RFS (PP) from time of randomization

	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

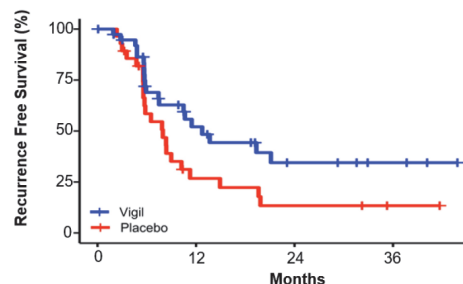


No. at Risk	0	12	24	36
Vigil	46	17	7	3
Placebo	45	14	9	2

**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



No. at Risk	0	12	24	36
Vigil	39	14	6	3
Placebo	28	6	3	1

**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

16

**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.

IGCS20\_1131

17

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

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Abstract 17 Table 1

Grade ≥3 TEAE, n (%)	Niraparib		Placebo	
	FSD n=315	ISD n=169	FSD n=158	ISD n=86
Thrombocytopenia event	152 (48)	36 (21)	0	1 (1)
Anemia event	112 (36)	38 (22)	3 (2)	1 (1)
Neutropenia event	75 (24)	25 (15)	2 (1)	1 (1)

FSD, fixed starting dose; ISD, individualized starting dose; TEAE, treatment-emergent adverse event.

**Introduction** Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for treatment in heavily pretreated patients and maintenance of patients with newly diagnosed or recurrent ovarian cancer following a response to platinum-based chemotherapy. Here we report safety and patient-reported outcomes (PROs) in the overall population and subgroups from PRIMA/ENGOT-OV26/GOG-3012 (NCT02655016).

**Methods** This double-blind, placebo-controlled, phase 3 study randomized 733 patients. Patients received a 300-mg QD fixed starting dose (FSD) of niraparib or placebo for 36 months or until progression/toxicity. A protocol amendment introduced an individualized starting dose (ISD): 200 mg in patients with body weight <77 kg or platelets <150,000/μL, or 300 mg in all others. The primary endpoint was PFS; safety and PROs were secondary endpoints. Safety data were collected at each visit and graded using CTCAE v4.03. PRO instruments (FOSI, EQ-5D-5L, EORTC-QLQ-C30, and EORTC-QLQ-OV28) were collected Q8W for 56 weeks, then Q12W while a patient received treatment.

**Results** In the overall population, the most common grade ≥3 treatment-emergent adverse events (TEAEs) were hematologic (table 1). In patients receiving ISD, these TEAEs decreased. No treatment-related deaths occurred. PRO analysis showed

no difference in niraparib-treated patients versus placebo in the overall population or in the homologous recombination deficient, homologous recombination proficient, FSD, and ISD subgroups.

**Conclusions** ISD incorporation improved the safety profile of niraparib without compromising efficacy. Niraparib was well tolerated, with similar PRO scores across the treatment period. Hematologic toxicities were manageable through implementation of dose interruptions and reductions.

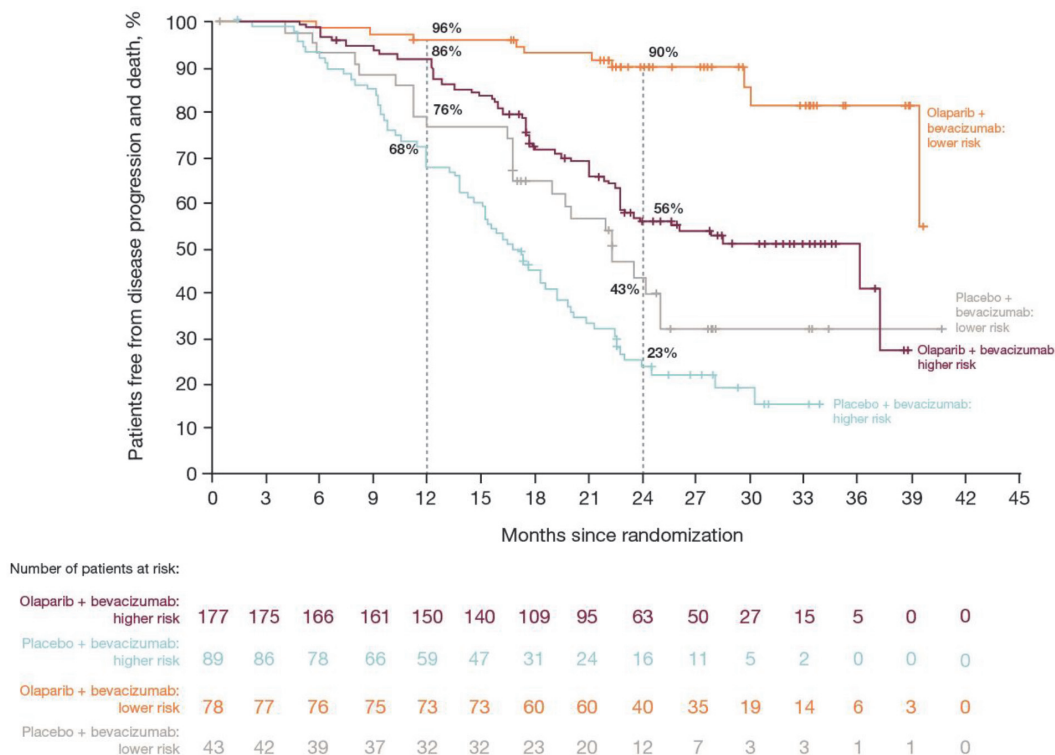
**Funding** GlaxoSmithKline  
NCT: NCT02655016

## IGCS20\_1207

### 18 EFFICACY OF MAINTENANCE OLAPARIB PLUS BEVACIZUMAB BY BIOMARKER STATUS IN CLINICAL HIGHER- AND LOWER-RISK PATIENTS WITH NEWLY DIAGNOSED, ADVANCED OVARIAN CANCER IN THE PAOLA-1 TRIAL

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\*HRD-positive defined as a tumour BRCAm and/or genomic instability score of ≥42. BRCAm, BRCA mutation; HRD, homologous recombination deficiency; PFS, progression-free survival

Abstract 18 Figure 1 Kaplan-Meier estimates of investigator-assessed PFS in higher-risk and lower-risk HRD-positive patients\*