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/ μ L, 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.

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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 high-risk and lower-risk HRD-positive patients*

For the HRs (olaparib tablets 300 mg bid for up to 24 months plus bevacizumab 15 mg/kg q3w for up to 15 months in total vs placebo plus bevacizumab), the size of the circle is proportional to the number of events, the gray band represents the 95% CI for the overall population and the dashed line indicates the point of no effect. PFS assessed using modified RECIST v1.1

*For higher-risk patients, median PFS was 20.3 months in the olaparib plus bevacizumab group vs 14.7 months in the placebo plus bevacizumab group, 36.0 vs 16.0 months, respectively, in the HRD-positive subgroup, 16.6 vs 13.9 months, respectively, in the HRD-negative/unknown subgroup, and 36.0 vs 19.4 months, respectively, in the subgroup with a tumour BRCAm

†For lower-risk patients, median PFS was 39.3 months in the olaparib plus bevacizumab group vs 22.9 months in the placebo plus bevacizumab group, NR vs 22.1 months, respectively, in the HRD-positive subgroup, 23.8 vs 22.9 months, respectively, in the HRD-negative/unknown subgroup, and NR vs 22.2 months, respectively, in the subgroup with a tumour BRCAm

bid, twice daily; BRCAm, BRCA mutation; CI, confidence interval; HR, hazard ratio; HRD, homologous recombination deficiency; NR, not reached; PFS, progression-free survival; q3w, every 3 weeks

Abstract 18 Figure 2 Analysis of investigator-assessed PFS in higher-risk* and lower-risk† patients, including in biomarker subgroups

Introduction In the Phase III PAOLA-1/ENGOT-ov25 trial (NCT02477644), adding maintenance olaparib to bevacizumab improved progression-free survival (PFS) in patients with advanced ovarian cancer in response after first-line platinum-based chemotherapy plus bevacizumab (HR 0.59; 95% CI 0.49–0.72) (Ray-Coquard et al. NEJM 2019). Outcomes in patients classified by clinical risk according to biomarker status are unknown.

Methods Patients were classified as higher-risk (stage III patients with upfront surgery and residual disease or who received neoadjuvant chemotherapy, or stage IV patients) or lower-risk (stage III patients with upfront surgery and no residual disease). This exploratory analysis evaluated PFS in higher-risk and lower-risk patients, including by biomarker status: homologous recombination deficiency (HRD)-positive, HRD-negative/unknown and tumour BRCA mutation (BRCAm)-positive.

Results Of 806 randomized patients, 74% were higher risk and 26% were lower risk, with median follow-up of 22.4 and 23.8 months, respectively. PFS significantly favoured olaparib plus bevacizumab versus placebo plus bevacizumab in higher-risk and lower-risk patients. In both higher- and lower-risk patients, the greatest PFS benefit was seen with olaparib plus bevacizumab versus bevacizumab alone in the HRD-positive subgroup (figures 1 and 2) and the subgroup with a tumour BRCAm (figure 2). Outcomes in the higher- and lower-risk HRD-negative/unknown subgroups are shown in figure 2.

Conclusions In PAOLA-1, maintenance olaparib plus bevacizumab provided a substantial PFS benefit over bevacizumab alone in higher-risk and lower-risk patients, especially in the HRD-positive and BRCAm populations.

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OVERALL SURVIVAL AFTER SURGICAL STAGING BY LYMPH NODE DISSECTION VERSUS SENTINEL LYMPH NODE BIOPSY IN ENDOMETRIAL CANCER: A NATIONAL CANCER DATABASE STUDY

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Objectives To investigate the association between the type of lymph node (LN) assessment and overall survival (OS) in endometrial cancer (EC).

Methods Patients with stage I-III EC who underwent a hysterectomy and LN assessment from 2012 to 2015 were identified from the National Cancer Database. Multivariable Cox proportional hazards regression analysis was performed to assess factors associated with OS.

Results Of 68,614 patients identified, 64,796 underwent lymphadenectomy (LND) only, 1,777 sentinel lymph node biopsy only (SLN-B), and 2,041 both procedures (SLN-B/LND). On multivariable analysis, SLN-B and SLN-B/LND were not associated with different OS compared to LND (hazard ratio [HR]: 0.92; 95%CI: 0.73–1.17 - HR: 0.91; 95%CI: 0.77–1.07,