safety of niraparib vs PBO in older patients. The primary endpoint was PFS assessed by blinded independent central review.

Results Of 733 enrolled pts, 444 were <65 yo (297 niraparib, 147 PBO), and 289 were ≥65 yo (190 niraparib, 99 PBO). Efficacy was comparable in pts <65 yo (HR 0.61; 95% CI 0.47–0.81) and ≥65 yo (HR 0.53; 95% CI 0.39–0.74) who received niraparib compared with PBO. Any-grade and grade ≥3 treatment emergent adverse events were similar across age groups (table 1). Grade ≥3 thrombocytopenia events in pts <65 yo were reported in 43% of pts receiving a FSD and 18% of pts receiving ISD. In pts ≥65 yo, the values were 57% and 26%, respectively. Patient reported outcomes (PROs) and quality of life (QOL) were similar in both age groups as assessed by FOSI and EQ-5D-5L.

Conclusion Niraparib efficacy, safety, and QOL were similar in compared age groups. Implementation of an ISD regimen improved rates of grade ≥3 thrombocytopenia events in older pts.

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364 EFFICACY OF NIRAPARIB THERAPY IN PATIENTS WITH NEWLY DIAGNOSED ADVANCED OVARIAN CANCER BY BRCAWT STATUS: PRIMA/ENGOT-OV26/GOG-3012 STUDY

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Introduction/Background Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for maintenance treatment of patients with newly diagnosed advanced or platinum-sensitive, recurrent ovarian cancer (OC). Niraparib is also approved in the United States for the treatment of patients with OC who received ≥3 lines of therapy and whose cancer is either BRCA mutated or homologous recombination deficient (HRd) platinum-sensitive disease. The PRIMA/ENGOT-OV26/GOG-3012 trial showed that niraparib significantly improves progression-free survival (PFS) in patients with newly diagnosed advanced OC that responded to first-line platinum-based chemotherapy (hazard ratio, 0.62; 95% CI, 0.50–0.76). Here we report the efficacy of niraparib in patients by BRCA wild-type (BRCAwt) status.

Methodology This double-blind, placebo-controlled, phase 3 trial evaluated niraparib in patients with newly diagnosed, advanced, high-grade serous or endometrioid ovarian, primary peritoneal or fallopian tube cancer with a complete response (CR) or partial response (PR) to first-line platinum-based chemotherapy. Patients were stratified by best response to the first-line chemotherapy (CR/PR), receipt of neoadjuvant chemotherapy (yes/no), and homologous recombination status (deficient/proficient and not determined). Patients were randomised 2:1 to receive either niraparib or placebo once daily. The primary endpoint of PFS, assessed by blinded independent central review, was analysed using a stratified log-rank test and Cox proportional hazards model and hierarchically tested in HRd patients, then the overall population. BRCA and HRd status were determined by tumour samples at screening via the myChoice® test (Myriad, Salt Lake City, Utah). The prespecified BRCAwt subgroup PFS analysis was performed using a stratified log-rank test and Cox proportional hazards model and using Kaplan-Meier methodology. BRCAwt subgroups included the intention-to-treat/BRCAwt (all patients who were homologous recombination not determined [HRnd]/BRCAwt, HRd/BRCAwt, and homologous recombination proficient [HRp]/BRCAwt); subgroup analyses on the HRd/BRCAwt and HRp/BRCAwt were performed.

Results Of 733 randomised patients, 473 (64.5%) had BRCAwt tumours (74 patients had unknown BRCA status). Of these 473, 150 (31.7%) had HRd/BRCAwt tumours, 249 (52.6%) had HRp/BRCAwt tumours, and 74 (15.7%) had HRnd/BRCAwt tumours. Niraparib-treated patients with BRCAwt tumours had a clinically meaningful PFS benefit regardless of homologous recombination status (table 1).

Abstract 364 Table 1

	ITT/*BRCA*wt* n=473	HRd/*BRCA*wt n=150	HRp/*BRCA*wt n=249
Hazard ratio (95% CI),	0.69 (0.54–0.88)	0.50 (0.31–0.83)	0.68 (0.49–0.94)
mPFS, months			
Niraparib	10.9	19.6	8.1
Placebo	7.4	8.2	5.4
ΔmPFS, months	3.5	11.4	2.7

*Includes patients who were HRnd but known to be *BRCA*wt.
HRd, homologous recombination deficient; HRnd, homologous recombination not determined; HRp, homologous recombination proficient; ITT, intention-to-treat; mPFS, median progression-free survival; wt, wild-type.

Conclusion Niraparib improved PFS when utilised as maintenance therapy after front-line treatment of OC in patients with BRCAwt tumours, including in the most difficult to treat subgroup of patients with BRCAwt and HRp tumours.

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366 FEASIBILITY STUDY OF A NETWORK META-ANALYSIS AND UNANCHORED POPULATION-ADJUSTED INDIRECT TREATMENT COMPARISON OF NIRAPARIB, OLAPARIB, AND BEVACIZUMAB AS MAINTENANCE THERAPIES IN PATIENTS WITH NEWLY DIAGNOSED ADVANCED OVARIAN CANCER

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Introduction/Background Although randomised controlled trials (RCTs) have demonstrated the benefit of PARP inhibitors and bevacizumab as monotherapies and combination therapies, there is limited direct head-to-head evidence of their relative clinical efficacy.

In the PRIMA study, niraparib demonstrated a clinically significant improvement in progression-free survival (PFS) compared with placebo, as a first-line (1L) ovarian cancer (OC) maintenance therapy.

The objectives of the study were to assess feasibility of an indirect treatment comparison (ITC) and a population-adjusted indirect treatment comparison (PAIC) for estimating the relative efficacy of niraparib compared with olaparib, olaparib plus bevacizumab, and bevacizumab as maintenance following 1L chemotherapy in OC. The study focused on fully powered statistical cohorts.

Methodology Trials included in the ITC analysis were based on a systematic literature review conducted in February 2020.

Guidelines from the Cochrane Handbook for Systematic Reviews of Interventions were used to assess the level of heterogeneity across the studies in terms of designs, population characteristics, treatment arms and outcome measures.