(18%). Local therapy included radiotherapy (44%), surgery (43%), both (7%), cryotherapy or radiofrequency (3%) and other (3%). Median PFS post-LT was 11.5 months [95% CI 7.4; 17.2]. After median follow up of 14.8 months, 5 patients (6.8%) discontinued PARPi due to toxicity. The 1-year overall survival rate was 90.7% [95% CI 79.1; 96.0].

Conclusions: With close to one year without progression or introduction new line of systemic therapy, this study reports the feasibility and potential benefit of this original strategy in patients with oligometastatic progression under PARPi.

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529MO Phase II study of olaparib plus durvalumab with or without bevacizumab (MEDIOLA): Final analysis of overall survival in patients with non-germline BRCA-mutated platinum-sensitive relapsed ovarian cancer

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Background: The MEDIOLA (NCT02734004) study evaluated the efficacy and safety of olaparib+durvalumab (O+D doublet cohort) and O+D+bevacizumab (O+D+B triplet cohort) in patients (pts) with non-germline BRCA-mutated (non-gBRCAm) platinum-sensitive relapsed ovarian cancer (PSR OC). Previous efficacy data showed median progression-free survival (PFS) (95% CI) of 5.5 (3.6—7.5) and 14.7 (10.0—18.1) months (mo) with O+D and O+D+B, respectively (Drew *et al*, ESMO 2020). We now present the final analysis of overall survival (OS) and disease control rate (DCR) at 56 weeks (wks) in the O+D and O+D+B cohorts.

Methods: Pts had confirmed non-gBRCAm PSR OC and received 1—2 prior lines of platinum-based chemotherapy. Pts received O (300 mg bid) and D (1.5 g IV q4w), and B (10 mg/kg IV q2w; O+D+B cohort only) until disease progression. Survival follow-up took place at treatment discontinuation, monthly for 4 mo, and every 2—3 mo thereafter. OS and DCR at 56 wks were secondary endpoints.

Results: 32 pts received O+D and 31 pts received O+D+B; 24/32 (75%) O+D and 20/31 (65%) O+D+B pts had received one prior line of chemotherapy. At data cutoff (17 Sep 2021), median follow-up for OS was 23.2 mo for O+D and 31.9 mo for O+D+B. Kaplan—Meier estimates of median OS (95% CI) were 26.1 (18.7—not calculable [NC]) mo for O+D and 31.9 (22.1—NC) mo for O+D+B. Probabilities of survival (95% CI) in the O+D and O+D+B cohorts, respectively, were 77.6 (58.6—88.6) and 96.8 (79.2—99.5) at 12 mo and 50.8 (32.1—66.8) and 64.5 (45.2—78.5) at 24 mo. DCR at 56 wks (90% CI) was 9.4% (2.6—22.5) for O+D and 38.7% (24.1—55.0) for O+D+B. Safety data are shown in the Table.

Table: 529MO

	O+D N = 32	O+D+B N = 31
Patients on treatment at data cutoff, n (%)	0	5 (16) on O; 4 (13) on D; 2 (6) on B
Grade ≥3 AEs in ≥10% of patients in any cohort, n (%)		
Anaemia	7 (22)	6 (19)
Hypertension	1 (3)	5 (16)
Patients with AEs leading to any treatment discontinuation,* n (%)	1 (3)	10 (32)
Occurring in ≥1 patient, n (%)		
Proteinuria	0	4 (13)
Deaths, n/N (%)	20/32 (62.5)	17/31 (54.8)
Patients starting subsequent therapy, n/N (%)	26/32 (81.3)	19/31 (61.3)

*Discontinuation of O, D, or B

Conclusions: Based on the reported final OS and DCR at 56 wks data, treatment with O+D+B demonstrated promising efficacy in pts with non-gBRCAm PSR OC. O+D and O+D+B safety profiles were consistent with that expected for the single agents; no new safety signals emerged with longer follow-up.

Clinical trial identification: NCT02734004.

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530P PRIMA/ENGOT-OV26/GOG-3012 study: Updated long-term PFS and safety

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Background: Niraparib (nir) has shown PFS benefit as a first-line (1L) maintenance therapy (MT) in the PRIMA primary analysis (data cut 17 May 2019) in all subgroups regardless of biomarker status. These results were the basis for approval of nir as MT after response to 1L platinum-based chemo (CT). Here we report updated long-term efficacy and safety in the PRIMA study.

Methods: This double-blind, placebo (PBO)-controlled phase 3 trial evaluated nir in pts with newly diagnosed advanced high-grade serous or endometrioid ovarian, primary peritoneal, or fallopian tube cancer (OC) with a complete or partial response (CR or PR) to 1L platinum-based CT. Stratification factors were best response to 1L CT regimen (CR/PR), receipt of neoadjuvant CT (NACT; yes/no), and homologous recombination deficiency (HRD) status (HRd/HRp/HRnd) per Myriad myChoice HRD test. Pts received nir or PBO QD (2:1 ratio). The primary endpoint of PFS by blinded independent central review was concordant with investigator assessment (INV). Updated (ad hoc) data are by INV, as of 17 Nov 2021.

Results: Of 733 randomized pts (nir, 487; PBO, 246), 373 (51%) were HRd (nir, 247; PBO, 126), and 249 (34%) were HRp (nir, 169; PBO, 80). Overall, 35% had stage IV disease, 67% received NACT, and 33% had a PR to 1L CT. As of 17 Nov 2021, median PFS follow-up time was 3.5 y. Nir-treated pts (HRd/HRp/overall) received continued PFS benefit vs PBO (Table). All subgroups showed a sustained and durable treatment effect. The most common grade ≥3 adverse events in the nir arm were thrombocytopenia (40%), anemia (32%), and neutropenia (21%). No related on-treatment deaths occurred. MDS/AML were reported at the same incidence in nir 6/484 (1.2%) and PBO 3/244 (1.2%) arms. OS remains immature at 41% for the overall population; 33% of PBO vs 9% of nir pts received subsequent PARPi.

Conclusions: Nir maintained clinically significant improvement in PFS with 3.5 y of follow-up in pts with newly diagnosed advanced OC at high risk of progression irrespective of HRD status. No new safety signals were identified.

Table: 530P

	Primary efficacy analysis 17 May 2019		Updated efficacy analysis (INV) 17 Nov 2021
	BICR	INV	
Median PFS, mo			
Overall			
Nir vs PBO	13.8 vs 8.2	13.8 vs 8.2	13.8 vs 8.2
HR (95% CI)	0.62 (0.50—0.76)	0.63 (0.51—0.76)	0.66 (0.56—0.79)
p	<0.0001	<0.0001	<0.0001
HRd			
Nir vs PBO	21.9 vs 10.4	21.9 vs 11.2	24.5 vs 11.2
HR (95% CI)	0.43 (0.31—0.59)	0.46 (0.34—0.63)	0.52 (0.40—0.68)
p	<0.0001	<0.0001	<0.0001
HRp			
Nir vs PBO	8.1 vs 5.4	8.3 vs 5.4	8.4 vs 5.4
HR (95% CI)	0.68 (0.49—0.94)	0.62 (0.45—0.85)	0.65 (0.49—0.87)
p	0.0203	0.0025	0.0038
Estimated probability of no progressive disease or death for ≥4y			**Overall** Nir: 24% PBO: 14% **HRd** Nir: 38% PBO: 17%

BICR, blinded independent central review; INV, investigator assessed.

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