LBA29 Final overall survival (OS) in patients (pts) with newly diagnosed advanced ovarian cancer (aOC) treated with niraparib (nir) first-line (1L) maintenance: Results from PRIMA/ENGOT-OV26/GOG-3012

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Background: The phase 3 PRIMA trial met its primary endpoint, demonstrating that nir 1L maintenance significantly extended progression-free survival (PFS) in pts with aOC that responded to 1L platinum-based chemotherapy (PBCT) in the homologous recombination-deficient (HRd) and overall populations (González-Martín A, et al. *N Engl J Med*. 2019;381(25);2391–2402). Here, we report final planned OS and updated ad hoc PFS results.

Methods: In PRIMA, 733 pts were randomized 2:1 to maintenance nir or placebo (PBO), stratified by response to 1L PBCT, receipt of neoadjuvant PBCT, and tumor homologous recombination deficiency (HRD) status. OS testing occurred after 60% maturity was reached in the overall population (pop), and was hierarchical (overall first, then HRd). Other secondary efficacy outcomes and long-term safety were assessed; an updated, ad hoc analysis of investigator-assessed PFS was also conducted (data cutoff, 08Apr2024).

Results: Median follow-up was 73.9 mo; OS, time to first subsequent therapy, and PFS2 are shown in the table. In the overall pop, the OS hazard ratio (HR) was 1.01 (95% CI, 0.84–1.23) for nir vs PBO. OS HR was 0.95 (95% CI, 0.70–1.29) in the HRd pop and was 0.93 (95% CI 0.69–1.26) in the homologous recombination-proficient pop. In the overall pop, 11.7% of nir and 37.8% of PBO pts received subsequent PARP inhibitor (PARPi) therapy (HRd pop: nir, 15.8%; PBO, 48.4%). 5 y PFS in the overall pop was 22% for nir vs 12% for PBO (HRd pop: 35% vs 16%). MDS/AML incidence was <2.5% (nir, 2.3%; PBO, 1.6%); no new safety signals were observed.

Table: LBA29

	Overall		HRd	
	Nir (n=487)	PBO (n=246)	Nir (n=247)	PBO (n=126)
TFST				
Median TFST, mo	17.0	12.0	26.9	13.9
Hazard ratio (95% CI)	0.74 (0.62–0.89)		0.55 (0.43–0.71)	
PFS2				
Median PFS2, mo	30.1	27.6	43.4	39.3
Hazard ratio (95% CI)	0.96 (0.79–1.17)		0.87 (0.66–1.17)	
OS				
Median OS, mo	46.6	48.8	71.9	69.8
Hazard ratio (95% CI)	1.01 (0.84–1.23)		0.95 (0.70–1.29)	
P-value (2-sided)	0.8834		NA[a]	

[a]*P*-value was not generated because testing stopped at the overall population. HRd, homologous recombination-deficient; NA, not applicable; nir, niraparib; OS, overall survival; PBO, placebo; PFS2, progression-free survival 2; TFST, time to first subsequent therapy.

Conclusions: In pts with newly diagnosed aOC at high risk for recurrence, no difference in OS was observed between treatment arms. There was a higher rate of subsequent PARPi use in the PBO arm. In the HRd pop, pts alive at 5 y were twice as likely to be progression free with nir treatment than PBO. Long-term safety data remained consistent with the known safety profile of nir.

Clinical trial identification: NCT02655016.

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LBA30 ATHENA-COMBO, a phase III, randomized trial comparing rucaparib (RUCA) + nivolumab (NIVO) combination therapy vs RUCA monotherapy as maintenance treatment in patients (pts) with newly diagnosed ovarian cancer (OC)

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Background: ATHENA (NCT03522246) consists of 2 studies, MONO and COMBO. In MONO, RUCA monotherapy provided a sustained investigator-assessed progression-free survival (PFS) vs placebo (PBO, median [mdn] 20.2 vs 9.2 months [mo], data cutoff 23 Mar 2022) in pts with newly diagnosed, advanced high-grade OC (AHGOC) after first-line (1L) treatment. COMBO was designed to evaluate if the addition of NIVO to RUCA could further delay time to progression. RUCA + NIVO (COMBO) was compared with RUCA + PBO (MONO) with an additional 2 years (y) of follow up (cutoff 17 May 2024). We report primary efficacy and safety results from COMBO.

Methods: Pts with FIGO stage III–IV AHGOC with response to 1L platinum-based chemotherapy were randomized 1:1 to RUCA 600 mg PO BID + NIVO 480 mg IV Q4W or RUCA + PBO. The primary endpoint was PFS in the intent-to-treat (ITT) population. PFS in homologous recombination deficiency (HRD) subgroups and programmed death-ligand 1 (PD-L1) subgroups were exploratory.

Results: Between 7 Aug 2018 and 26 Oct 2020, 863 pts were randomized. After a mdn follow-up of 48 mo, COMBO was associated with numerically shorter mdn PFS vs MONO in the ITT (15.0 vs 20.2 mo; HR, 1.3; 95% CI, 1.1–1.5), HRD subgroups, and in pts with PD-L1 $\geq$1% and $\geq$5% (table). PFS benefit of 20.2 mo with RUCA MONO was maintained with the additional 2 y follow-up. COMBO had shorter mdn exposure to treatment vs MONO (PO 8.4 vs 14.7 mo, IV 4.6 vs 11.1 mo). Common grade $\geq$3 treatment-related AEs in COMBO vs MONO were anemia/hemoglobin decreased (27.1% vs 28.6%), neutropenia/neutrophil count decreased (25.4% vs 15.4%), and ALT/AST increased (21.2% vs 10.0%).

Table: LBA30

	COMBO vs MONO Data cutoff 17 May 2024			
	RUCA + NIVO (COMBO), n	RUCA + PBO (MONO), n	Median investigator-assessed PFS, mo	HR (95% CI)
ITT	436	427	15.0 vs 20.2	1.3 (1.1–1.5)
HRD	193	185	28.9 vs 31.4	1.1 (0.9–1.5)
BRCA mutation	94	91	48.0 vs NR	1.1 (0.7–1.7)
BRCA wt/LOH^{high}	99	94	17.3 vs 22.3	1.1 (0.7–1.5)
BRCA wt/LOH^{low}	188	189	11.0 vs 12.1	1.3 (1.0–1.7)
BRCA wt/ LOH^{indeterminate}	55	53	9.2 vs 17.5	1.6 (1.0–2.5)
PD-L1 $\geq$ 5%	69	72	22.8 vs 52.2	1.5 (0.9–2.4)
PD-L1 $\geq$ 1%	199	197	18.3 vs 25.8	1.3 (1.0–1.7)

LOH, loss of heterozygosity; NR, not reached; wt, wild-type.

Conclusions: NIVO in combination with RUCA did not add to the PFS benefit of RUCA observed in MONO. The safety profile of RUCA in combination with NIVO was consistent with previously reported studies and their individually known safety profiles.

Clinical trial identification: NCT03522246.

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