Table: LBA36

	Senaparib (n = 271), m	Placebo (n = 133), m	HR (95%CI), P value
PFS (BICR)	NR	13.6	0.43 (0.32-0.58) P < 0.0001
PFS (BICR) BRCA +	NR	15.6	0.43 (0.24-0.76) P = 0.0026
PFS (BICR) BRCA-	NR	12.9	0.43 (0.30-0.61) P < 0.0001
PFS (INVR)	NR	11.1	0.43 (0.32-0.57) P < 0.0001
PFS (INVR) BRCA +	NR	11.1	0.33 (0.20-0.56) P < 0.0001
PFS (INVR) BRCA-	NR	11.1	0.48 (0.34-0.67) P < 0.0001
TFST	NR	14.4	0.44 (0.33-0.59) P < 0.0001

BICR, blinded independent central review; INVR, investigator review; HR, hazard ratio; NR, not reached; PFS, progression-free survival; BRCA +, breast cancer susceptibility gene (BRCA) mutation positive; BRCA -, BRCA mutation negative; TFST, time to first subsequent therapy or death; m, month

analysis showed Sena significantly improved PFS over placebo (HR 0.43, 95% CI 0.32-0.58, P < 0.0001), irrespective of BRCA mutation status (HR 0.43, P < 0.01). Secondary endpoints support the primary analysis (Table). Incidence rates of grade ≥3 adverse events (AEs) were 66.3 % vs 20.3%, AEs leading to dose reduction 63.3 % vs 6.0% and discontinuation 4.4 % vs 0% in Sena and PBO arm. No AE leading to death.

Conclusions: 1L maintenance Senaparib led to an unprecedented reduction in the risk of progression or death versus placebo in OC, regardless of biomarker status. Senaparib was well tolerated, no new safety signals were identified.

Clinical trial identification: NCT04169997.

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LBA37 Atezolizumab (atezo) combined with platinum-based chemotherapy (CT) and maintenance niraparib for recurrent ovarian cancer (rOC) with a platinum-free interval (TFIp) >6 months: Primary analysis of the double-blind placebo (pbo)-controlled ENGOT-Ov41/GEICO 69-O/ANITA phase III trial

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Background: Standard therapy for late-relapsing (TFIp >6 mo) rOC includes PARPi maintenance if disease responds to platinum-based CT. ANITA (NCT03598270) is the first-reported phase 3 trial evaluating atezo with platinum-based CT and maintenance PARPi in late-relapsing rOC.

Methods: Eligible pts had measurable high-grade serous, endometrioid or undifferentiated rOC, ≤2 prior CT lines (most recent including platinum) and TFIp >6 mo. Prior PARPi for rOC and/or prior immune checkpoint inhibitor were prohibited. Pts were stratified by carboplatin (carbo) doublet (paclitaxel, gemcitabine or pegylated liposomal doxorubicin [PLD]), TFIp (6—12 vs >12 mo), *BRCA* status (mutated vs non-mutated) and PD-L1 status (PD-L1-expressing immune cells on <1% vs ≥1% tumour area vs non-informative by SP142). Pts were randomised 1:1 to a carbo doublet + atezo or pbo for 6 cycles followed (in pts without progression on CT) by maintenance niraparib at an individualised starting dose + atezo or pbo until disease progression. The atezo dose was 1200 mg q3w or 840 mg q2w depending on the CT regimen. The primary endpoint was investigator-assessed progression-free survival (PFS) per RECIST v1.1.

Results: Between Nov 2018 and Jan 2022, 417 pts were randomised (14% *BRCA*m, 36% PD-L1+, 66% TFIp >12 mo, 11% prior PARPi after front-line CT, 54% prior bevacizumab); most (71%) received carbo—PLD and 74% began maintenance. At the data cut-off (15 Apr 2023), median follow-up was 36 mo. PFS results (Table) were consistent in key subgroups. Overall response to CT was 43% (95% CI 36—49%) and 45% (95% CI 39—52%) in the pbo and atezo arms, respectively. The safety profile was as expected from prior experience of these drugs.

Table: LBA37

PFS		Pbo + CT → pbo + niraparib (n = 209)	Atezo + CT → atezo + niraparib (n = 208)
All pts	Events, n (%)	174 (83)	170 (82)
	Hazard ratio (95% CI)	0.89 (0.71—1.10); p=0.28	
	Median, mo (95% CI)	10.1 (9.2—11.2)	11.2 (10.1—12.1)
PD-L1-positive subgroup	Events, n/N (%)	60/73 (82)	61/76 (80)
	Hazard ratio (95% CI)	0.87 (0.61—1.25)[a]	
	Median, mo (95% CI)	11.1 (9.7—12.7)	12.8 (10.2—15.4)
PD-L1-negative subgroup	Events, n/N (%)	92/112 (82)	97/117 (83)
	Hazard ratio (95% CI)	0.93 (0.70—1.24)[a]	
	Median, mo (95% CI)	9.2 (8.3—11.1)	10.5 (9.2—11.8)

[a]Unadjusted estimate.

Conclusions: Combining atezo with CT and maintenance niraparib for late-relapsing rOC did not significantly improve PFS or ORR.

Clinical trial identification: NCT03598270, EudraCT 2018-000366-11.

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LBA38 Pembrolizumab plus chemoradiotherapy for high-risk locally advanced cervical cancer: A randomized, double-blind, phase III ENGOT-cx11/GOG-3047/KEYNOTE-A18 study

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Background: Pembrolizumab (pembro) has shown efficacy in patients (pts) with cervical cancer. The effect of chemoradiotherapy may be enhanced by immunotherapy. ENGOT-cx11/GOG-3047/KEYNOTE-A18(NCT04221945) assessed the efficacy and safety of pembro + concurrent chemoradiotherapy (CCRT) for locally advanced cervical cancer.

Methods: Eligible pts with newly diagnosed, previously untreated, high-risk locally advanced cervical cancer (FIGO 2014 stage IB2-IIB with node-positive disease or stage III-IVA) were randomized 1:1 to receive 5 cycles of pembro 200 mg or pbo Q3W + CCRT, then 15 cycles of pembro 400 mg or pbo Q6W. The CCRT regimen included 5 cycles (with optional 6th dose) of cisplatin 40 mg/m^2 Q1W + EBRT then brachytherapy. Pts were stratified by planned EBRT type (intensity-modulated radiotherapy [IMRT] or volumetric-modulated arc therapy [VMAT] vs non-IMRT or non-VMAT), stage at screening (stage IB2-IIB vs III-IVA) and planned total radiotherapy dose. Primary endpoints were PFS per RECIST version 1.1 by investigator and OS.

Results: 1060 pts were randomized to pembro + CCRT (n=529) or pbo + CCRT (n=531). At the protocol-specified first interim analysis (January 9, 2023, data cutoff), median follow-up was 17.9 mo (range, 0.9-31.0). Pembro + CCRT showed a statistically significant improvement in PFS vs pbo + CCRT. 24-mo PFS was 67.8% with pembro + CCRT vs 57.3% with pbo + CCRT; median PFS was not reached in either group (HR=0.70 [95% CI, 0.55-0.89; P=0.0020]); results were consistent across all prespecified subgroups. With only 103 events (42.9% maturity), the addition of pembro to CCRT showed a favorable trend in OS (HR=0.73 [95% CI, 0.49-1.07]); these data have not crossed the boundary of statistical significance. Grade ≥3 TRAE incidence was 67.0% in the pembro + CCRT group and 60.0% in the pbo + CCRT group.

Conclusions: Pembro + CCRT showed a statistically significant and clinically meaningful improvement in PFS and a favorable trend in OS compared with pbo + CCRT in pts with high-risk locally advanced cervical cancer and had a manageable safety profile. These data suggest pembro + CCRT can be considered as a new standard of care for this population.

Clinical trial identification: NCT04221945.

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