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LBA33 Maintenance olaparib plus bevacizumab (bev) in patients (pts) with newly diagnosed advanced high-grade ovarian carcinoma (HGOC): Final analysis of second progression-free survival (PFS2) in the phase III PAOLA-1/ENGOT-ov25 trial

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Background: In the primary analysis of PAOLA-1/ENGOT-ov25 (NCT02477644), adding olaparib to maintenance bev after first-line platinum-based chemotherapy with bev led to a significant progression-free survival benefit in advanced HGOC pts (HR 0.59; 95% CI 0.49 -0.72) (Ray-Coquard et al. *NEJM* 2019); PFS2 was immature. Here, we report final PFS2 data from PAOLA-1.

Methods: Pts with newly diagnosed, FIGO stage III -IV HGOC in response after platinum-based chemotherapy plus bev randomized to olaparib tablets (300 mg bid for 24 months) + bev (15 mg/kg q3w for 15 months) or placebo + bev. PFS2 and time to second subsequent therapy or death (TSST) were key secondary endpoints (final PFS2 analysis planned for ≈53% data maturity or 1 year after primary analysis).

Results: 537 pts were randomized to olaparib + bev and 269 to placebo + bev with median PFS2 follow-up of 35.5 and 36.5 months, respectively (data cut-off 22 March 2020). Olaparib + bev provided a statistically significant reduction in the risk of second progression or death vs placebo + bev (ITT analysis; HR 0.78; 95% CI 0.64 -0.95; *P*=0.0125) (Table). HRs for PFS2 by biomarker status with olaparib + bev vs placebo + bev were 0.53 in pts with a tumour BRCA mutation (tBRCAm), 0.56 in HRD-positive pts, 0.60 in HRD-positive pts without a tBRCAm and 1.04 in HRD-negative pts. TSST was longer with olaparib + bev vs placebo + bev (median 38.2 vs 31.5 months) (HR 0.78; 95% CI 0.64 -0.95; *P*=0.0115). 49/537 (9%) olaparib + bev pts and 72/269 (27%) placebo + bev pts received a PARP inhibitor as first subsequent therapy. No new safety signals were seen with longer follow-up.

Conclusions: Adding maintenance olaparib to bev provided a benefit beyond first progression, with a substantial PFS2 benefit in tBRCAm and HRD-positive pts. The statistically significant improvement in PFS2 seen with olaparib + bev vs placebo + bev was supported by a similar TSST benefit.

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LBA34 Single-agent anti-PD-1 balstilimab or in combination with anti-CTLA-4 zalifrelimab for recurrent/metastatic (R/M) cervical cancer (CC): Preliminary results of two independent phase II trials

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Background: Second line treatment for R/M CC continues to be a high unmet clinical need. We present data from 2 ph2 trials, of single-agent balstilimab (bal) and in combination with zalifrelimab (zal) in R/M CC.

Methods: Patients received single-agent bal 3mg/kg q2w (NCT03104699) or in combination with zal 1mg/kg q6w (NCT03495882) up to 2 yrs. The primary endpoint was objective response rates (ORR) assessed per RECIST 1.1 by independent review, secondary endpoints included safety and DOR.

Results: We treated161 & 155 pts in the bal and bal/zal, respectively with 160 & 143 pts had baseline measurable disease (modified ITT population). All pts previously received platinum-based treatment for their first line as per protocol. Squamous-cell cancer (SCC) (63% bal; 74% bal/zal) was the predominant histologic subtype with adenocarcinoma/adenosquamous/other (AC) also represented. PD-L1 positive was defined as CPS $\geq$ 1% (62% bal; 55% bal/zal), negative as CPS $<$1% (26% bal; 25% bal/zal) or unknown (12% bal; 20% bal/zal). Efficacy data are below.
Treatment was well tolerated in both trials. 49 (30%) pts had immune-related AEs in bal & 50 (35%) in bal/zal trial (all grades) and severe (Grade 3+) 13 (8.0%) and 15 (10.5%) respectively. Treatment discontinuation were seen in 22 pts (13.7%) in bal and 15 pts (10%) in bal/zal. There were no treatment related deaths on the bal trial and 2 in the bal/zal trial (nephritis; pneumonitis). No new safety signals were identified.

Table: LBA34

Efficacy	bal (160) N (%)	bal/zal (143) N (%)
ORR	24 (14)	31 (22)
CR	3 (2)	8 (6)
PR	20 (12)	23 (16)
DOR (m)	15.4 [1.1+,15.4]	NR [1.3+,16.6+]
SCC	18/100 (18)	28/106 (27)
AC	5/59 (8)	3/37 (7)
PD-L1 +	19/99 (19)	21/79 (27)
PD-L1 -	4/42 (10)	4/36 (11)
Unknown PD-L1	0/19 (0)	6/28 (21)

Table: LBA33

PFS2	No. of events/no. of pts (%)		Median, months		HR (95% CI); *P*-value
	Olaparib + bev	Placebo + bev	Olaparib + bev	Placebo + bev	
ITT	260/537 (48)	164/269 (61)	36.5	32.6	0.78 (0.64–0.95); *P*=0.0125
tBRCAm	41/157 (26)	36/80 (45)	NR	45.0	0.53 (0.34–0.83)
HRD positive*	85/255 (33)	70/132 (53)	50.3†	35.3	0.56 (0.41–0.77)
HRD positive excluding tBRCAm	41/97 (42)	33/55 (60)	50.3†	30.1	0.60 (0.38–0.96)
HRD negative	127/192 (66)	61/85 (72)	24.4	26.4	1.04 (0.77–1.42)
HRD unknown	48/90 (53)	33/52 (63)	34.0	30.1	0.85 (0.55–1.33)

*tBRCAm and/or genomic instability. †Unstable due to lack of events. CI, confidence interval; ITT, intent to treat; HR, hazard ratio; HRD, homologous recombination deficiency; NR, not reached