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811MO Maintenance olaparib for patients (pts) with newly diagnosed, advanced ovarian cancer (OC) and a BRCA mutation (BRCAm): 5-year (y) follow-up (f/u) from SOLO1

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Background: Newly diagnosed advanced OC pts are at high risk of relapse and 5-y survival is 30–50%. Delay of recurrence, prolonged survival and, for some patients, increased chance of cure are goals of treatment in this setting. In SOLO1 (NCT01844986; GOG-3004) pts with OC and a BRCAm who were in response after first-line platinum-based chemotherapy derived significant progression-free survival (PFS) benefit from maintenance olaparib vs placebo (pbo; median 41 months [m] f/u; median not reached vs 13.8 m; HR 0.30; $P<0.001$; Moore *et al. NEJM* 2018). We report data from 5-y f/u (data cut-off 5 March 2020).

Methods: Pts received maintenance olaparib (tablets; 300 mg bid) or pbo for up to 2 y or until progression. PFS and recurrence-free survival (RFS) were investigator-assessed by modified RECIST v1.1. For pts in complete response (CR) at baseline, RFS was defined *post hoc* as time from randomization to disease recurrence (new lesions by imaging) or death.

Results: 260 pts were randomized to olaparib; 131 to pbo (median treatment duration 24.6 vs 13.9 m, respectively). After a median of 4.8 and 5.0 y of f/u, median PFS was 56 vs 14 m (Table). Among pts in CR at baseline, risk of disease recurrence or death was reduced by 63%. Additional secondary endpoints will be reported.

Table: 811MO

	PFS		RFS*	
	Olaparib N=260	Pbo N=131	Olaparib N=189	Pbo N=101
Events, n (%)	118 (45)	100 (76)	79 (42)	74 (73)
Median, m	56.0	13.8	NR	15.3
HR (95% CI)	0.33 (0.25–0.43)		0.37 (0.27–0.52)	
Pts progression or recurrence free at timepoint,† %				
1 y	87.7	51.4	91.0	58.0
2 y	73.6	34.6	77.2	39.0
3 y	60.1	26.9	64.0	28.9
4 y	52.3	21.5	55.2	23.0
5 y	48.3	20.5	51.9	21.8

*Pts had CR at baseline based on electronic case report form data.
†Kaplan–Meier estimates. CI, confidence interval; HR, hazard ratio; NR, not reached

The safety profile of olaparib was consistent with previous observations. No new cases of myelodysplastic syndrome or acute myeloid leukaemia were reported and incidence of new primary malignancies remained balanced between arms (olaparib, 7/260 [3%]; pbo, 5/130 [4%]).

Conclusions: For pts with a BRCAm and newly diagnosed advanced OC the benefit derived from 2 y of maintenance olaparib was sustained beyond the end of treatment and after 5 y almost half of pts were progression-free vs 20% with pbo. Over 50% of pts in CR after first-line platinum-based chemotherapy remained free from relapse 5 y later. 5-y f/u is the longest for any PARP inhibitor in this setting and no new safety signals were observed.

Clinical trial identification: NCT01844986.

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