

Abstracts

Abstract 167 Table 1 Baseline geriatric characteristics in older patients (≥ 70 years)

Characteristic	Olaparib arm (n=104)	Placebo arm (n=38)
Median age, years (range)	73 (70–87)	73 (70–85)
ECOG PS		
0	65 (62.5)	22 (57.9)
1	36 (34.6)	16 (42.1)
BMI		
<21 kg/m ²	30 (28.8)	14 (36.8)
21–33 kg/m ²	72 (69.2)	22 (57.9)
>33 kg/m ²	1 (1.0)	2 (5.3)
Albumin <35 g/L	5 (4.8)	1 (2.6)
ADL scores		
ADL <6	15 (14.4)	8 (21.1)
IADL <25	23 (22.1)	12 (31.6)
Age-adjusted CCI ≥ 5	4 (3.8)	3 (7.9)
HADS ≥ 14	16 (15.4)	7 (18.4)
Haemoglobin <10 g/dL	0	0
Lymphocyte count <1 G/L	14 (13.5)	2 (5.3)
Neutrophil count <1.5 G/L	1 (1.0)	0
Platelet count <150 G/L	9 (8.7)	8 (21.1)
Renal function		
Normal	32 (30.8)	13 (34.2)
Mild and moderate insufficiency	71 (68.3)	25 (65.8)

Abstract 167 Table 2 Safety of olaparib plus bevacizumab in older (≥ 70 years) and younger (<70 years) patients

	Older (≥ 70 years) (n=104)	Younger (<70 years) (n=431)
Grade ≥ 3 TRAEs	42 (40.4)	138 (32.0)
Dose reductions due to TRAEs	43 (41.3)	159 (36.9)
Dose interruptions due to TRAEs	51 (49.0)	181 (42.0)
Discontinuations due to TRAEs	25 (24.0)	70 (16.2)
Treatment-related deaths	0	1
Median duration of treatment, months (range)	14.9 (0.0–33.0)	17.9 (0.0–32.1)
Median duration of follow-up, months (IQR)	25.9 (20.0–30.9)	26.0 (22.4–31.3)

Result(s)* Of 806 patients enrolled, 142 (17.6%) were ≥ 70 years old; 104 of these were in the olaparib arm. There was no notable difference in baseline characteristics between olaparib and placebo arms (table 1). In evaluation of safety, moderately increased rates of grade ≥ 3 treatment-related AEs (TRAEs), dose reductions and interruptions, and treatment discontinuation due to TRAEs were reported in older than younger patients (table 2). Grade 3–4 any-cause anaemia (21.2% vs 16.5%) and neutropenia (9.7% vs 5.1%) were more frequent in older patients. The most common grade 3–4 non-haematological AE was hypertension (26.9% vs 16.7%). No acute myeloid leukaemia, myelodysplastic syndrome, or treatment-related death was reported among older patients. Interestingly, GHS during the first 2 years of maintenance was similar between arms. Median PFS was 21.1 months with

olaparib vs 14.3 months with placebo. Analyses by GVS and homologous recombination deficiency subgroups are ongoing and will be presented.

Conclusion* Among older patients in PAOLA-1, olaparib plus bevacizumab maintenance had a manageable safety profile and had no adverse impact on GHS. Median PFS in older patients was similar to the overall population. Analyses stratified by GVS will provide further insight into the safety profile of maintenance olaparib plus bevacizumab in older patients.

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EFFICACY AND SAFETY OF MAINTENANCE OLAPARIB BY PATIENT AGE IN NON-GERMLINE BRCA-MUTATED PLATINUM-SENSITIVE RELAPSED OVARIAN CANCER IN OPINION

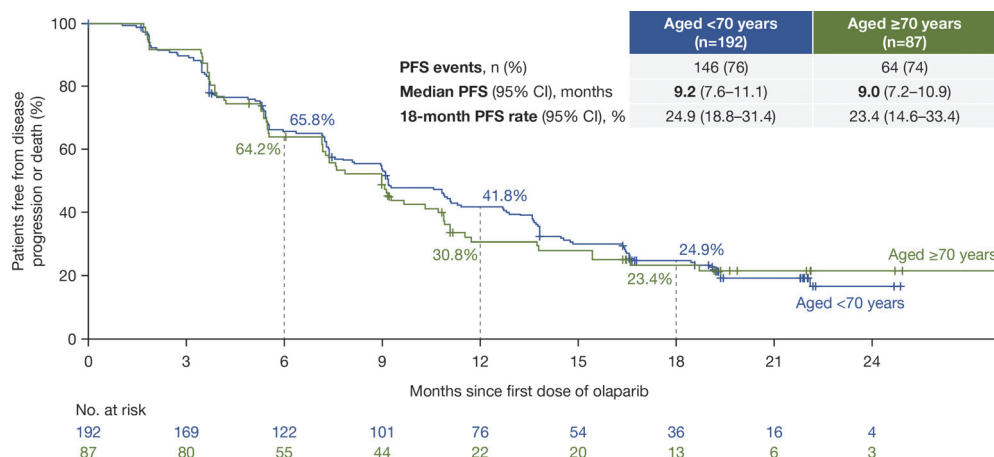
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Introduction/Background* The Phase IIIb single-arm OPINION study was the first study to prospectively evaluate maintenance olaparib in patients with non-germline *BRCA1* and/or *BRCA2*-mutated (non-gBRCAm) platinum-sensitive relapsed ovarian cancer (PSR OC). Median progression-free survival (PFS) in OPINION was 9.2 months (95% confidence interval [CI] 7.6–10.9) (Poveda *et al.* ASCO 2021), showing clinical benefit vs historical controls. Limited data are available focussing on older patients with OC receiving olaparib. We evaluated the efficacy and safety of maintenance olaparib in OPINION patients aged <70 and ≥ 70 years.

Methodology Patients with high-grade serous or endometrioid non-gBRCAm OC who had received ≥ 2 prior lines of platinum-based chemotherapy and were in response to their most recent platinum regimen received olaparib tablets (300 mg bid) until disease progression or unacceptable toxicity. This *post hoc* subgroup analysis evaluated investigator-assessed PFS (modified RECIST v1.1; primary endpoint), time to first subsequent therapy or death (TFST) and safety in patients aged <70 and ≥ 70 years.

Result(s)* At enrolment, median patient age was 65.0 years (range 40–85); 192 patients were aged <70 years (median 60.0 years; range 40–69) and 87 were aged ≥ 70 years

**Abstract 172 Figure 1**

Abstract 172 Table 1 Summary of TEAEs in patients aged, <70 and ≥70 years

n (%)	Aged <70 years (n=192)		Aged ≥70 years (n=87)	
	All grades	Grade ≥3	All grades	Grade ≥3
Any TEAE*	183 (95)	53 (28)	84 (97)	28 (32)
Nausea	93 (48)	0	42 (48)	1 (1)
Fatigue/asthenia†	82 (43)	4 (2)	41 (47)	5 (6)
Anaemia†	73 (38)	26 (14)	36 (41)	12 (14)
Dysgeusia	32 (17)	0	7 (8)	0
Vomiting	28 (15)	2 (1)	17 (20)	1 (1)
Neutropenia†	29 (15)	2 (1)	15 (17)	3 (3)
Abdominal pain	26 (14)	0	10 (11)	0
Diarrhoea	25 (13)	0	15 (17)	0
Thrombocytopenia†	23 (12)	2 (1)	12 (14)	4 (5)
Cough	22 (11)	0	7 (8)	0
Decreased appetite	18 (9)	0	14 (16)	0
Arthralgia	16 (8)	0	10 (11)	0
Urinary tract infection	13 (7)	0	14 (16)	0
Back pain	10 (5)	0	15 (17)	0
Serious TEAE	37 (19)	–	18 (21)	–
Dose interruption due to TEAE	83 (43)	–	48 (55)	–
Dose reduction due to TEAE	38 (20)	–	25 (29)	–
Treatment discontinuation due to TEAE	12 (6)	–	9 (10)	–

*Data are shown for TEAEs occurring in >10% of patients aged <70 or ≥70 years.

†Grouped term.

TEAE, treatment-emergent adverse event.

(median 74.0 years; range 70–85). Among patients aged <70 vs ≥70 years, 73% vs 59% were Eastern Cooperative Oncology Group (ECOG) performance status 0, 27% vs 41% were ECOG performance status 1, 64% vs 49% had received only two prior platinum regimens, 36% vs 51% had received ≥3 prior platinum regimens, and 35% vs 28% had a complete response and 64% vs 70% had a partial response to their latest platinum regimen. At data cut-off (2 Oct 2020), median PFS and 18-month PFS rates were similar in both age groups (figure 1). Median TFST was 15.6 months (95% CI 12.2–18.1) in patients aged <70 years and 11.4 months (95% CI 9.7–15.6) in patients ≥70 years. The safety profile of maintenance olaparib (median treatment duration 9 months) was generally similar in both age groups (table 1).

Conclusion* Efficacy and safety data support the use of maintenance olaparib in non-gBRCAm PSR OC patients irrespective of age.

175 COST-EFFICIENT ANALYSIS OF BRCANESS STATUS IN HIGH-GRADE SEROUS OVARIAN CARCINOMAS

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Introduction/Background* Paclitaxel/carboplatin (TCbP) is a standard therapy for high-grade serous ovarian cancer (HGSOC), however many patients do not benefit from this combination. **Methodology** Genetic profiling was performed for 71 HGSOC consecutive patients, who received neoadjuvant chemotherapy (NACT).

Result(s)* BRCA1/2 germline mutation carriers (n = 22) had longer treatment-free interval (TFI) than non-carriers (n = 49) (9.5 vs. 3.8 months; P = 0.007). 51 HGSOCs with sufficient quality of tumor DNA were examined by the SeqCap EZ CNV/LOH Backbone Design NGS panel, which systematically

spans the entire genome at 50 kb intervals. All 13 tumors obtained from BRCA1/2 germline mutation carriers and 12 sporadic HGSOCs had high number of evenly spread chromosomal breaks, that was defined as a BRCAness phenotype; median TFI for this combined group approached 9.5 months. The remaining 26 HGSOCs had similarly high global LOH score (above 20%); however, in contrast to BRCAness tumors, LOH involved large chromosomal segments; these patients had significantly lower TFI (3.7 months; P = 0.006). Comparison between this newly developed BRCAness test, which discriminated tumors simply by the number of affected genomic segments, and the commonly accepted HRD scoring system, revealed high concordance of the results and at least non-inferior clinical performance of our assay. Virtually all tumors with BRCAness (23/25 [92%]) demonstrated gain at MYC locus, while this event was less common in non-BRCAness HGSOCs (12/26 [46%]; P = 0.0006). All patients with CCNE1 amplification (n = 7), TP53 R175H substitution (n = 6), and RB1 mutation (n = 4) had poor response to TCbP. **Conclusion*** BRCA1/2 germ-line testing has superior performance in identifying responders to TCbP. Simple and rapid PCR-based tests for MYC and CCNE1 amplification allow to classify patients for potential responders and non-responders with a reasonable level of accuracy. BRCAness phenotype can be reliably detected by a laboratory-scale NGS assay, which evaluates the total number of chromosomal breaks. It is of concern that TCbP is being routinely administered both to potential responders and to potential non-responders to this scheme. Novel treatment options for the latter category of HGSOC patients need to be searched within preclinical and clinical studies.

177 EFFICACY OF NIRAPARIB BY TIMING OF SURGERY AND RESIDUAL DISEASE: A POST-HOC ANALYSIS OF PATIENTS IN THE PRIMA/ENGOT-OV26/GOG-3012 STUDY

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