Phase III PAOLA-1/ENGOT-ov25: maintenance olaparib with bevacizumab in patients with newly diagnosed, advanced ovarian cancer treated with platinum-based chemotherapy and bevacizumab as standard of care

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Disclosures

- I Ray-Coquard reports honoraria from AstraZeneca, Clovis, Tesaro and PharmaMar; consulting/advisory board fees from AstraZeneca, Roche, Clovis, Tesaro, Genmab, PharmaMar, MSD and Pfizer; research funding from MSD; and travel expenses from AstraZeneca and Roche
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Background

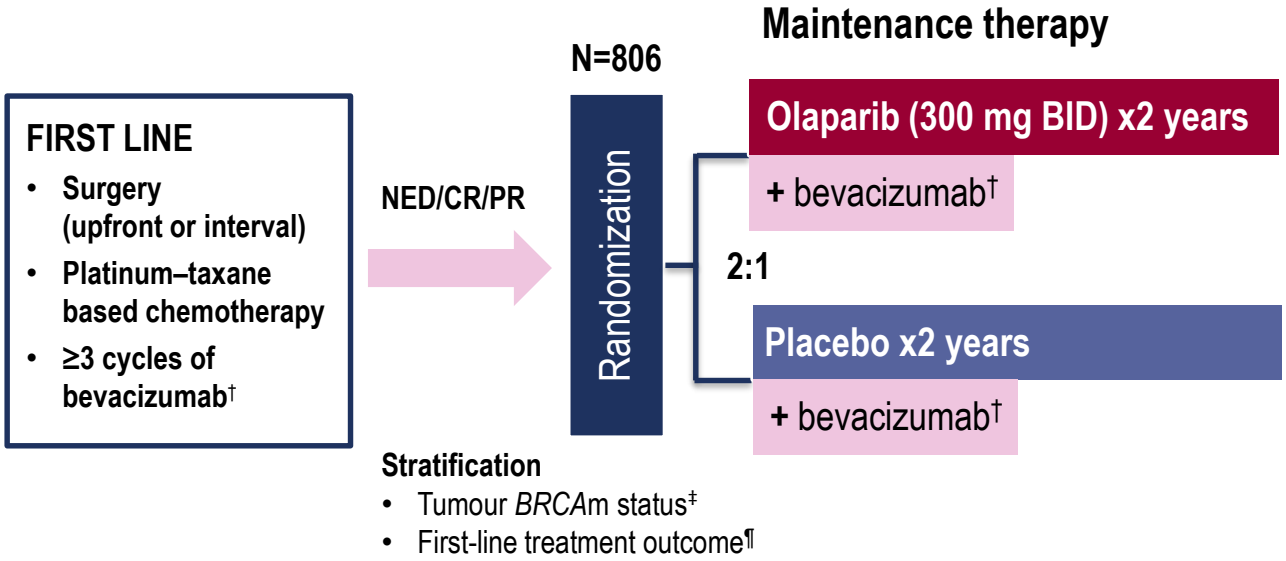
- First-line bevacizumab in combination with chemotherapy and followed by bevacizumab maintenance has been shown to increase response rate,[1] prolong PFS[1,2] and also OS[3,4] in some high-risk subgroups – it is the current standard of care for most patients with newly diagnosed advanced ovarian cancer
- The PARP inhibitor olaparib showed an unprecedented PFS benefit as first-line maintenance monotherapy for patients with a *BRCA* mutation (*BRCA*m)[5]
- Homologous recombination repair deficiency (HRD) is not limited to *BRCA*m and is present in ~50% of high-grade serous ovarian tumours[6]
- In platinum-sensitive relapse, PARP inhibitor activity was observed beyond *BRCA*m[7,8] and was increased when combined with an antiangiogenic agent[9,10]
- PAOLA-1/ENGOT-ov25, an academic-sponsored study, is the first Phase III trial to evaluate the efficacy and safety of maintenance therapy with a PARP inhibitor in patients with advanced ovarian cancer regardless of *BRCA* mutation status who are receiving first-line standard-of-care treatment including bevacizumab

BRCA mutation, *BRCA1* and/or *BRCA2* mutation; PARP, poly(ADP-ribose) polymerase; PFS, progression-free survival; OS, overall survival

1. Perren *et al. N Engl J Med* 2011;365:2484–96; 2. Burger *et al. N Engl J Med* 2011;365:2473–83; 3. Oza *et al. Lancet Oncol* 2015;16:928–36; 4. Tewari *et al. J Clin Oncol* 2019;26:2317–28; 5. Moore *et al. N Engl J Med* 2018;379:2495–505; 6. Cancer Genome Atlas Research Network. *Nature* 2011;474:609–15; 7. Ledermann *et al. Lancet Oncol* 2014;15:852–61; 8. Friedlander *et al. Br J Cancer* 2018;119:1075–85; 9. Mirza *et al. J Clin Oncol* 2019;37 (Suppl:abst 5505); 10. Liu *et al. Ann Oncol* 2019;30:551–7.

Study design

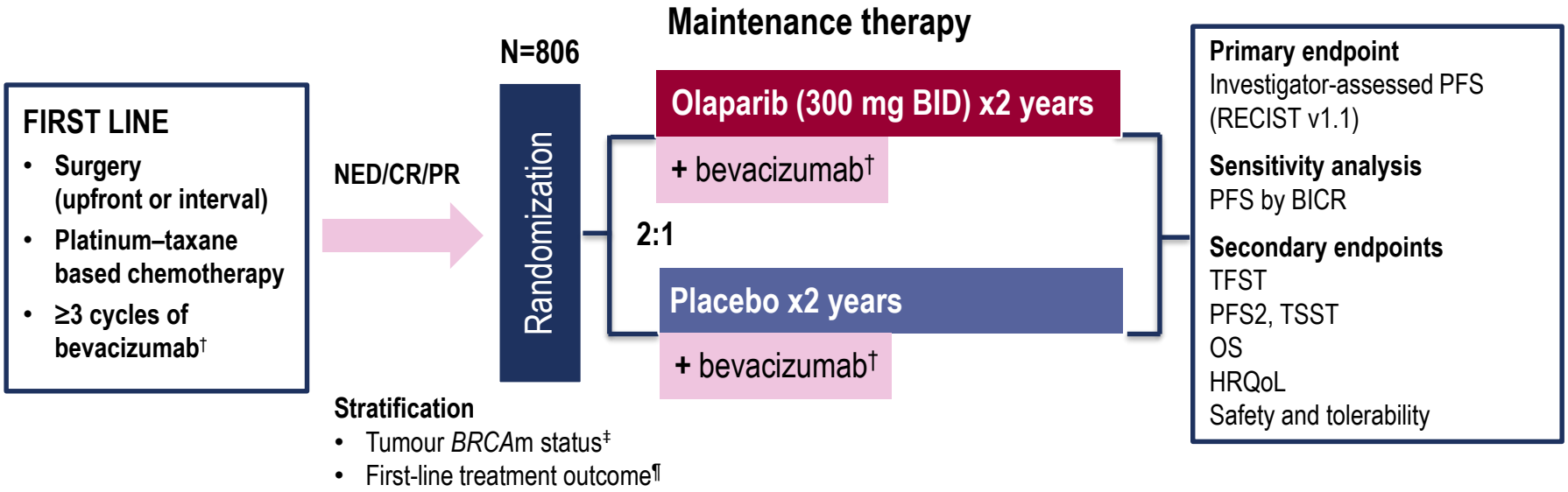
Newly diagnosed FIGO stage III–IV high-grade serous/endometrioid ovarian, fallopian tube or primary peritoneal cancer*



*Patients with other epithelial non-mucinous ovarian cancer were eligible if they had a germline *BRCA1* and/or *BRCA2* mutation
†Bevacizumab: 15 mg/kg, every 3 weeks for a total of 15 months, including when administered with chemotherapy; ‡By central labs; ¶According to timing of surgery and NED/CR/PR
BID, twice daily; *BRCA*m, *BRCA1* and/or *BRCA2* mutation; CR, complete response; NED, no evidence of disease; PR, partial response

Study design

Newly diagnosed FIGO stage III–IV high-grade serous/endometrioid ovarian, fallopian tube or primary peritoneal cancer*



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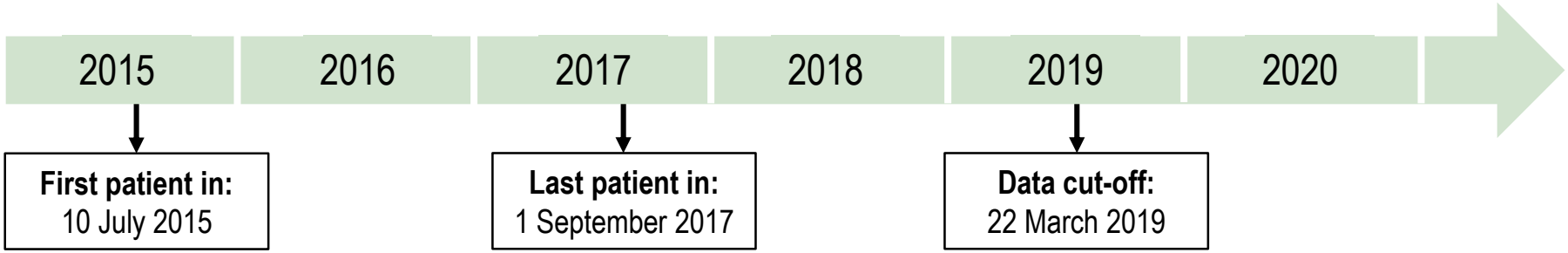
†Bevacizumab: 15 mg/kg, every 3 weeks for a total of 15 months, including when administered with chemotherapy; ‡By central labs; ¶According to timing of surgery and NED/CR/PR
BICR, blinded independent central review; HRQoL, health-related quality of life; PFS2, time to second progression or death; RECIST, Response Evaluation Criteria in Solid Tumours; TFST, time to first subsequent therapy or death; TSST, time to second subsequent therapy or death

Statistical analysis plan

Analysis

- 458 PFS events >80% power at the two-sided 5% level (target HR 0.75), translating to an improvement in median of 15.8 months (placebo) to 21.1 months (olaparib)
- A hierarchical testing strategy will be applied: PFS2 tested only if the null hypothesis for PFS is rejected. OS tested if PFS2 is statistically significant
- Predefined PFS subgroup analyses by tumour *BRCA*m status* and HRD score† will be performed



*By central labs; †By Myriad myChoice® HRD Plus
Predefined subgroup analyses were performed without multiplicity adjustment in order to show the consistency of the treatment effect

Patient characteristics

		Olaparib + bevacizumab (N=537)	Placebo + bevacizumab (N=269)
Age, median, years (range)		61 (32–87)	60 (26–85)
ECOG performance*, n (%)	0 1	378 (70) 153 (28)	189 (70) 76 (28)
Primary tumour location, n (%)	Ovary Fallopian tubes Primary peritoneal	456 (85) 39 (7) 42 (8)	238 (88) 11 (4) 20 (7)
Histology, n (%)	Serous† Endometrioid Other‡	519 (97) 12 (2) 6 (1)	253 (94) 8 (3) 8 (3)
t*BRCA*m status, n (%)	t*BRCA* mutation No t*BRCA* mutation/unknown¶	157 (29) 380 (71)	80 (30) 189 (70)
FIGO stage, n (%)	III IV	378 (70) 159 (30)	186 (69) 83 (31)

*ECOG performance was missing for six patients in the olaparib arm and four patients in the placebo arm
†Two patients had low-grade serous carcinoma with a *BRCA*m; ‡Other includes clear cell, undifferentiated and other histology
¶33 (4%) patients had an unknown t*BRCA*m status; 26 patients in the olaparib arm and 7 patients in the placebo arm
ECOG, Eastern Cooperative Oncology Group; FIGO, Fédération Internationale de Gynécologie et d'Obstétrique; t*BRCA*m, tumour *BRCA* mutation

Patient characteristics

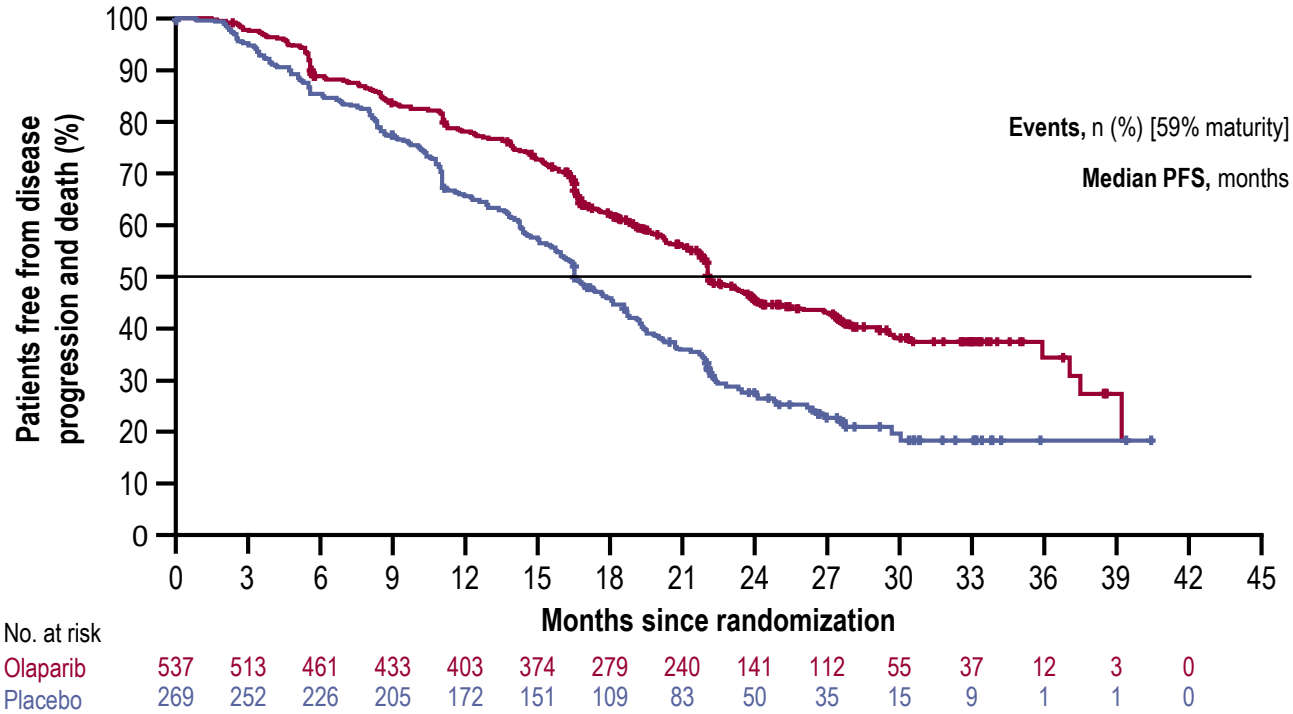
		Olaparib + bevacizumab (N=537)	Placebo + bevacizumab (N=269)
History of cytoreductive surgery, n (%)	Upfront surgery	271 (50)	138 (51)
	• Residual macroscopic disease	111 (41)	53 (38)
	• No residual macroscopic disease	160 (59)	85 (62)
	Interval cytoreductive surgery	228 (42)	110 (41)
	• Residual macroscopic disease	65 (29)	35 (32)
	• No residual macroscopic disease	163 (71)	75 (68)
	No surgery	38 (7)	21 (8)
Response after surgery/platinum-based chemotherapy, n (%)	NED	290 (54)	141 (52)
	CR	106 (20)	53 (20)
	PR	141 (26)	75 (28)

Patient disposition

		Olaparib + bevacizumab	Placebo + bevacizumab
Randomized, n		537	269
Treated, n (%)		535 (99.6)	267 (99.3)
Discontinued study treatment, n (%)		331 (62)	194 (73)
	Disease progression per RECIST	182 (34)	155 (58)
	Disease progression non-RECIST	14 (3)	13 (5)
	TEAE	109 (20)	13 (5)
	Patient decision	17 (3)	10 (4)
	Death	1 (<1)	3 (1)
	Other*	8 (1)	0
Median duration of treatment, months (range)	Olaparib/placebo	17.3 (0.03–33.0)	15.6 (0.07–26.2)
	Bevacizumab	11.0 (0.69–21.4)	10.6 (0.69–17.1)
Median duration of follow-up, months		24.0	22.7

*Other includes lost to follow up, surgery, new comorbidities and other TEAE, treatment-emergent adverse event

PFS by investigator assessment: ITT population



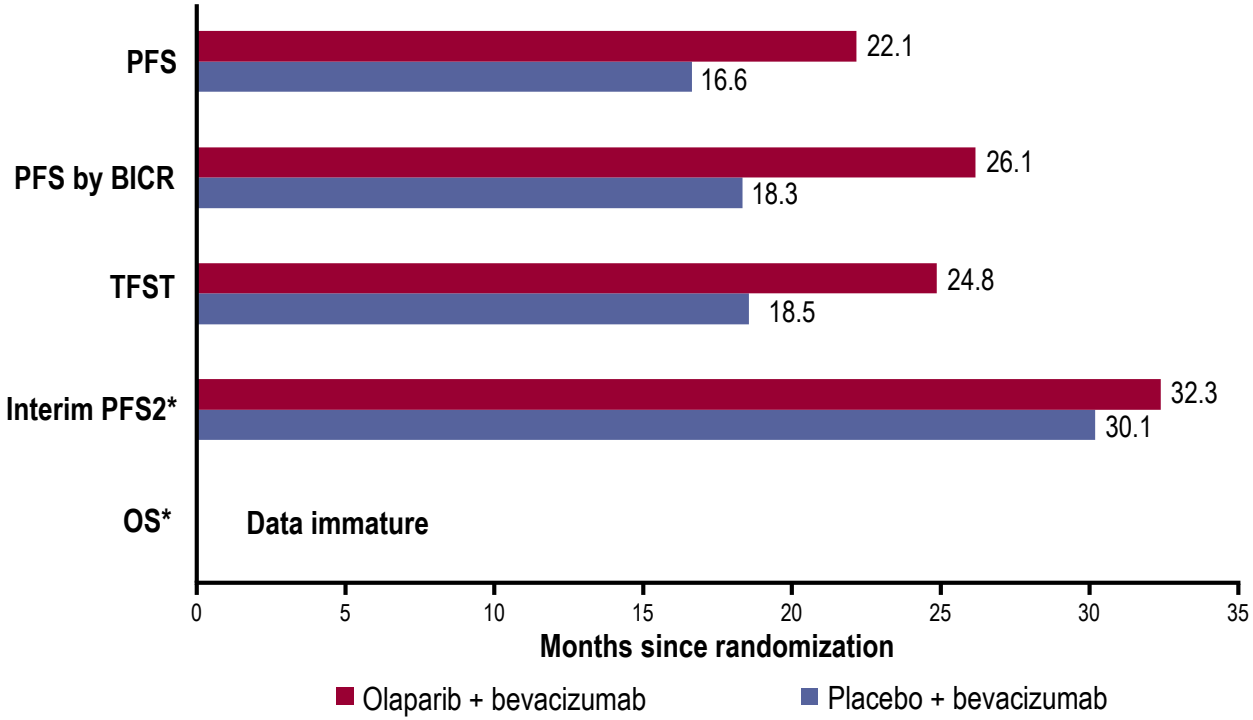
	Olaparib + bevacizumab (N=537)	Placebo + bevacizumab (N=269)
Events, n (%) [59% maturity]	280 (52)	194 (72)
Median PFS, months	**22.1**	**16.6**

HR 0.59 (95% CI 0.49–0.72; *P*<0.0001)

Median time from first cycle of chemotherapy to randomization = 7 months

ITT, intent-to-treat population

Key sensitivity analysis on primary endpoint and secondary efficacy endpoints



HR 0.59 (95% CI 0.49–0.72, *P*<0.0001)

HR 0.63 (95% CI 0.51–0.77, *P*<0.0001)

HR 0.59 (95% CI 0.49–0.71, *P*<0.0001)

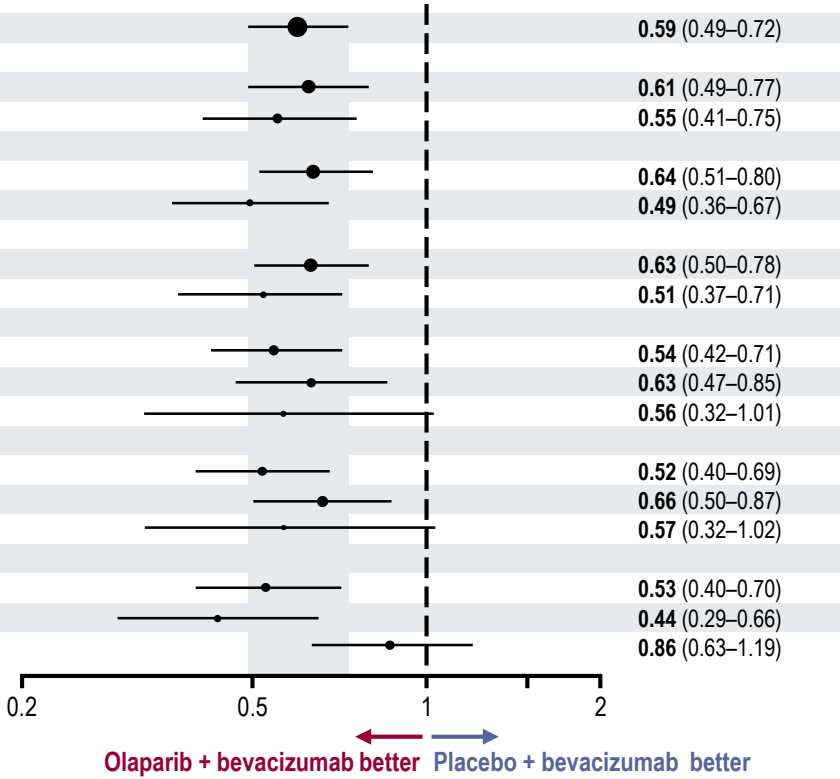
HR 0.86 (95% CI 0.69–1.09)

In the second line, 30/537 (6%) patients in the olaparib arm and 55/269 (20%) patients in the placebo arm received treatment with a PARP inhibitor

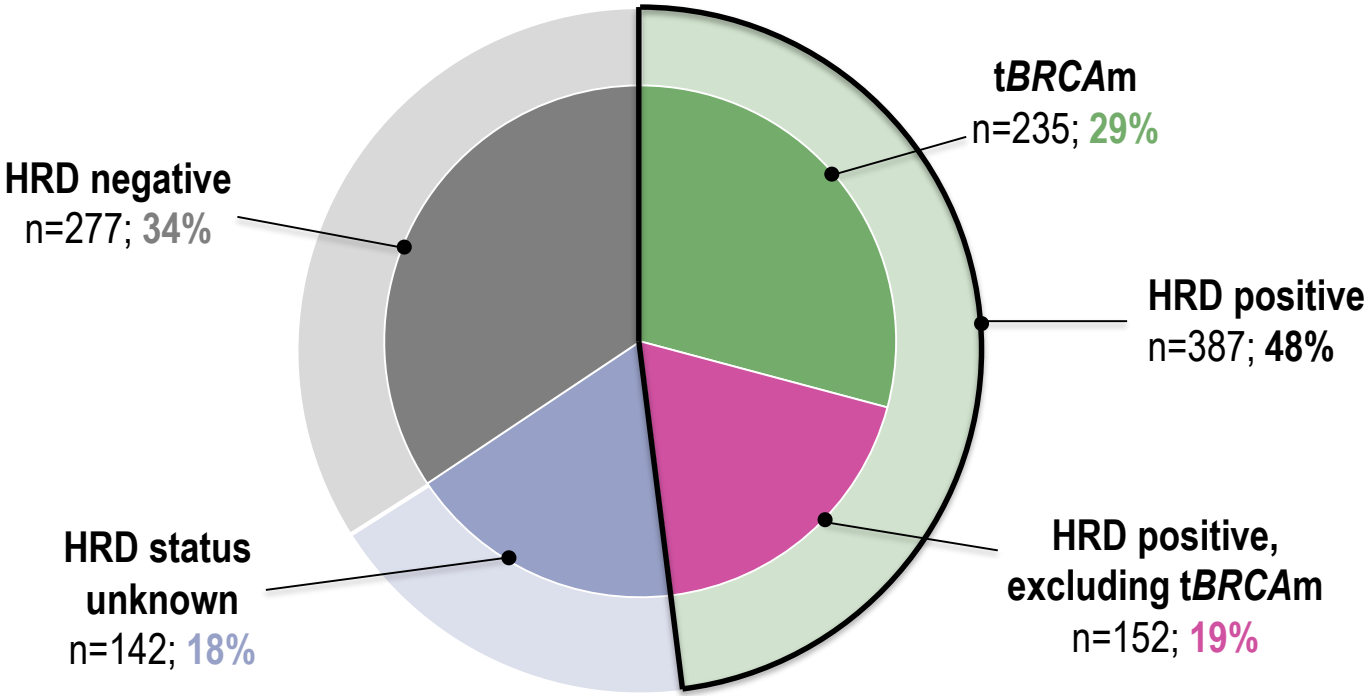
*These results are immature: PFS2 39% mature and OS 26% mature

PFS subgroup analysis

Subgroup	Olaparib + bevacizumab	Placebo + bevacizumab	HR (95% CI)
	No. of events/no. of patients (%)		
All	280/537 (52)	194/269 (72)	**0.59** (0.49–0.72)
Age group			
<65 years old	171/332 (52)	126/182 (69)	**0.61** (0.49–0.77)
≥65 years old	109/205 (53)	68/87 (78)	**0.55** (0.41–0.75)
FIGO stage			
III	184/378 (49)	125/186 (67)	**0.64** (0.51–0.80)
IV	96/159 (60)	69/83 (83)	**0.49** (0.36–0.67)
ECOG baseline			
0	193/378 (51)	132/189 (70)	**0.63** (0.50–0.78)
1	85/153 (56)	61/76 (80)	**0.51** (0.37–0.71)
Cytoreductive surgery outcome			
Debulking surgery with no residual macroscopic disease	135/323 (42)	104/160 (65)	**0.54** (0.42–0.71)
Debulking surgery with residual macroscopic disease	113/176 (64)	71/88 (81)	**0.63** (0.47–0.85)
No debulking surgery	32/38 (84)	19/21 (90)	**0.56** (0.32–1.01)
Timing of cytoreductive surgery			
Upfront	116/271 (43)	92/138 (67)	**0.52** (0.40–0.69)
Interval debulking	132/228 (58)	83/110 (75)	**0.66** (0.50–0.87)
No debulking surgery	32/38 (84)	19/21 (90)	**0.57** (0.32–1.02)
Response to first line CT			
NED	119/290 (41)	92/141 (65)	**0.53** (0.40–0.70)
CR	54/106 (51)	42/53 (79)	**0.44** (0.29–0.66)
PR	107/141 (76)	60/75 (80)	**0.86** (0.63–1.19)



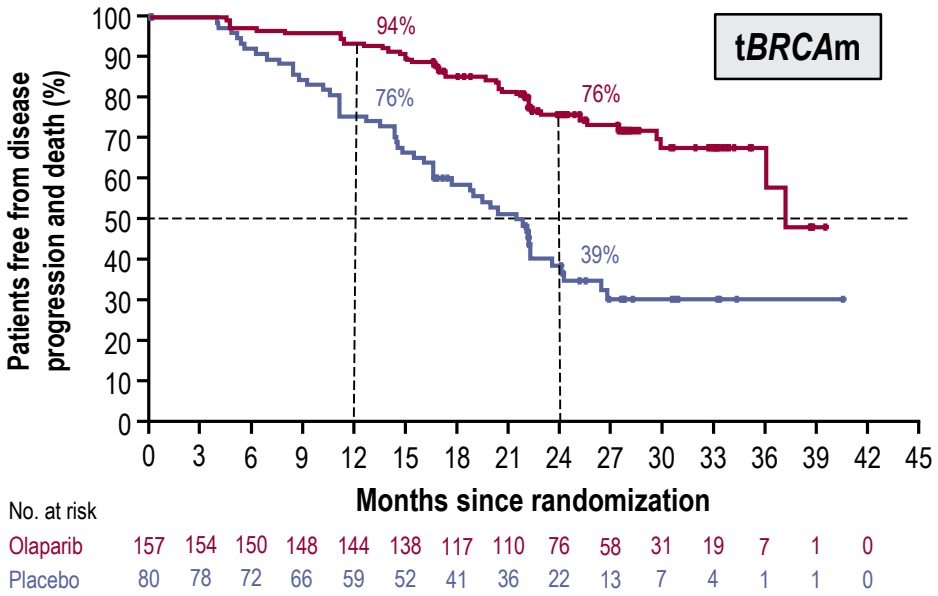
Biomarker subgroups in PAOLA-1/ENGOT-ov25



HRD positive is either tumour *BRCA* mutation and/or HRD score ≥42 by Myriad MyChoice® HRD Plus
Reasons for HRD status unknown: 4.2% missing; 2.1% fail; 11.3% inconclusive

PFS by t*BRCA* mutation status

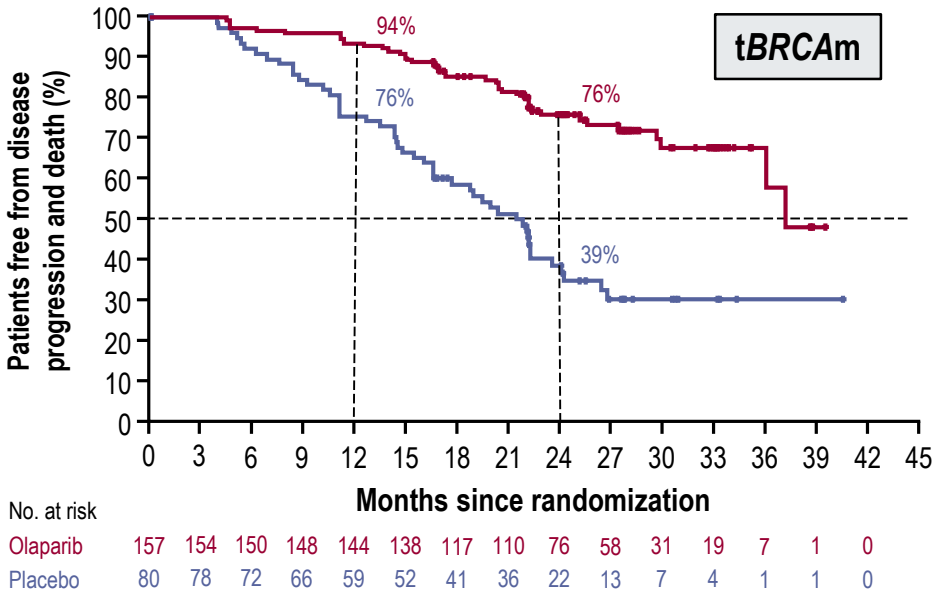
PFS by t*BRCA* mutation status

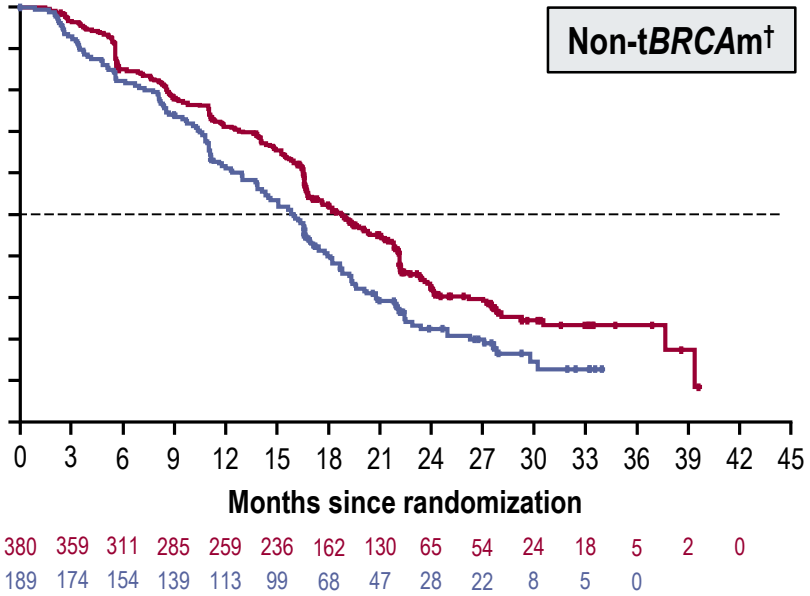


	Olaparib + bevacizumab (N=157)	Placebo + bevacizumab (N=80)
Events, n (%)	41 (26)	49 (61)
Median PFS, months	**37.2***	**21.7**
	HR 0.31 (95% CI 0.20–0.47)	

The percentages of patients progression-free at 12 months and 24 months have been calculated based on Kaplan-Meier estimates. *This median is unstable due to a lack of events – less than 50% maturity

PFS by t*BRCA* mutation status





No. at risk

Olaparib	157	154	150	148	144	138	117	110	76	58	31	19	7	1	0
Placebo	80	78	72	66	59	52	41	36	22	13	7	4	1	1	0

Olaparib	380	359	311	285	259	236	162	130	65	54	24	18	5	2	0
Placebo	189	174	154	139	113	99	68	47	28	22	8	5	0		

	Olaparib + bevacizumab (N=157)	Placebo + bevacizumab (N=80)
Events, n (%)	41 (26)	49 (61)
Median PFS, months	**37.2***	**21.7**
	HR 0.31 (95% CI 0.20–0.47)	

	Olaparib + bevacizumab (N=380)	Placebo + bevacizumab (N=189)
	239 (63)	145 (77)
	18.9	**16.0**
	HR 0.71 (95% CI 0.58–0.88)	

The percentages of patients progression-free at 12 months and 24 months have been calculated based on Kaplan-Meier estimates. *This median is unstable due to a lack of events – less than 50% maturity; †Includes t*BRCA* unknown

PFS by HRD status

ARCAGY - GINECO
ENGOT European Network of Gynaecological Oncological Trial groups
GYNECOLOGIC CANCER INTERGROUP An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers
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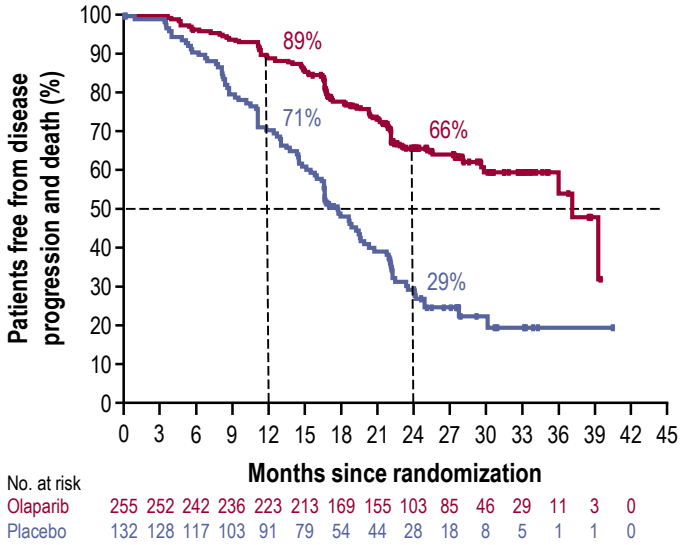
PFS by HRD status

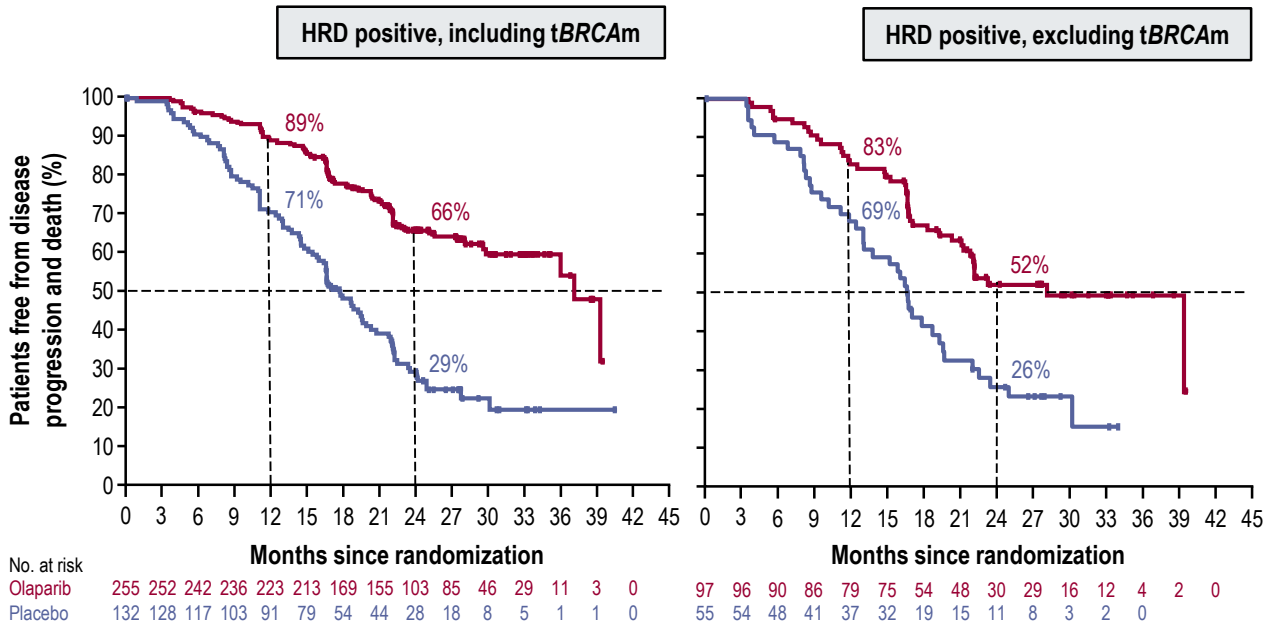
HRD positive, including t*BRCA*m



	Olaparib + bevacizumab (N=255)	Placebo + bevacizumab (N=132)
Events, n (%)	87 (34)	92 (70)
Median PFS, months	**37.2***	**17.7**
HR 0.33 (95% CI 0.25–0.45)		

The percentages of patients progression-free at 12 months and 24 months have been calculated based on Kaplan-Meier estimates. HRD positive is an HRD score ≥42. *This median is unstable due to a lack of events – less than 50% maturity

PFS by HRD status

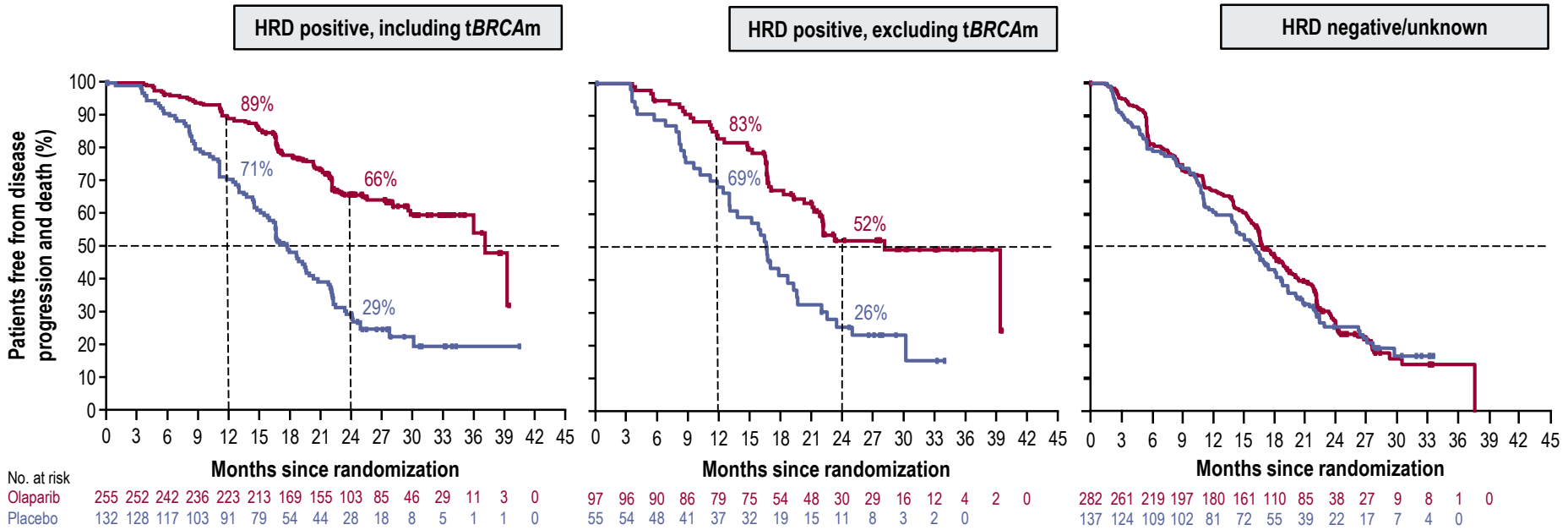


	Olaparib + bevacizumab (N=255)	Placebo + bevacizumab (N=132)
Events, n (%)	87 (34)	92 (70)
Median PFS, months	**37.2***	**17.7**
	HR 0.33 (95% CI 0.25–0.45)	

	Olaparib + bevacizumab (N=97)	Placebo + bevacizumab (N=55)
	43 (44)	40 (73)
	28.1*	**16.6**
	HR 0.43 (95% CI 0.28–0.66)	

The percentages of patients progression-free at 12 months and 24 months have been calculated based on Kaplan-Meier estimates. HRD positive is an HRD score ≥42. *This median is unstable due to a lack of events – less than 50% maturity

PFS by HRD status



	Olaparib + bevacizumab (N=255)	Placebo + bevacizumab (N=132)
Events, n (%)	87 (34)	92 (70)
Median PFS, months	**37.2***	**17.7**
	HR 0.33 (95% CI 0.25–0.45)	

	Olaparib + bevacizumab (N=97)	Placebo + bevacizumab (N=55)
	43 (44)	40 (73)
	28.1*	**16.6**
	HR 0.43 (95% CI 0.28–0.66)	

	Olaparib + bevacizumab (N=282)	Placebo + bevacizumab (N=137)
	193 (68)	102 (74)
	16.9	**16.0**
	HR 0.92 (95% CI 0.72–1.17)	

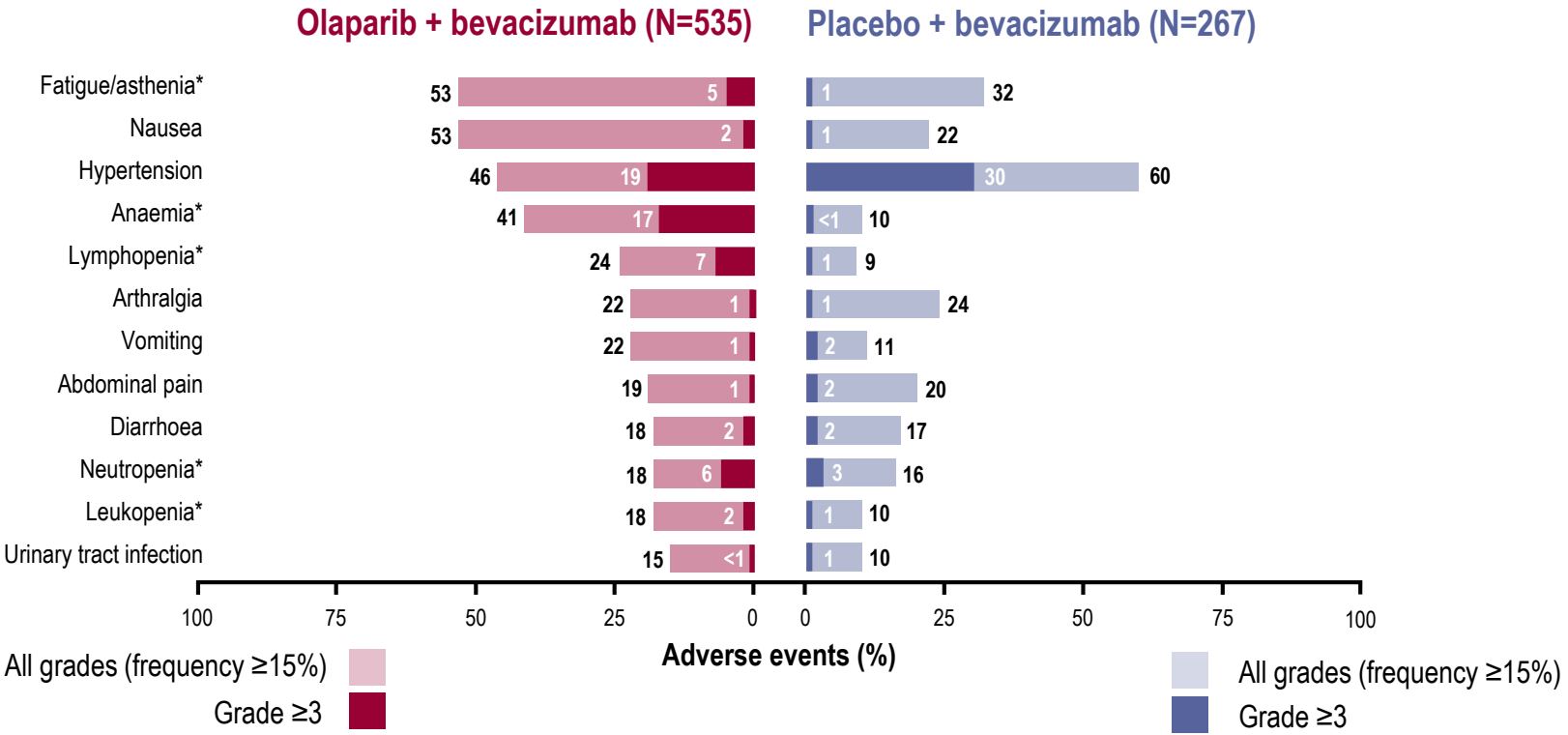
The percentages of patients progression-free at 12 months and 24 months have been calculated based on Kaplan-Meier estimates. HRD positive is an HRD score ≥42. *This median is unstable due to a lack of events – less than 50% maturity

Summary of AEs

	Olaparib + bevacizumab (N=535)	Placebo + bevacizumab (N=267)
All grade TEAEs, n (%)	531 (99)	256 (96)
Grade ≥3 TEAEs, n (%)	303 (57)	136 (51)
SAEs, n (%)	167 (31)	83 (31)
Deaths, n (%)	1 (<1)	4 (1)
Dose interruptions due to AEs, n (%)	291 (54)	65 (24)
Dose reductions due to AEs, n (%)	220 (41)	20 (7)
Discontinuations due to AEs, n (%)	109 (20)	15 (6)

Dose interruptions, reductions and discontinuations reported are for olaparib and placebo
SAE, serious adverse event

Most common AEs



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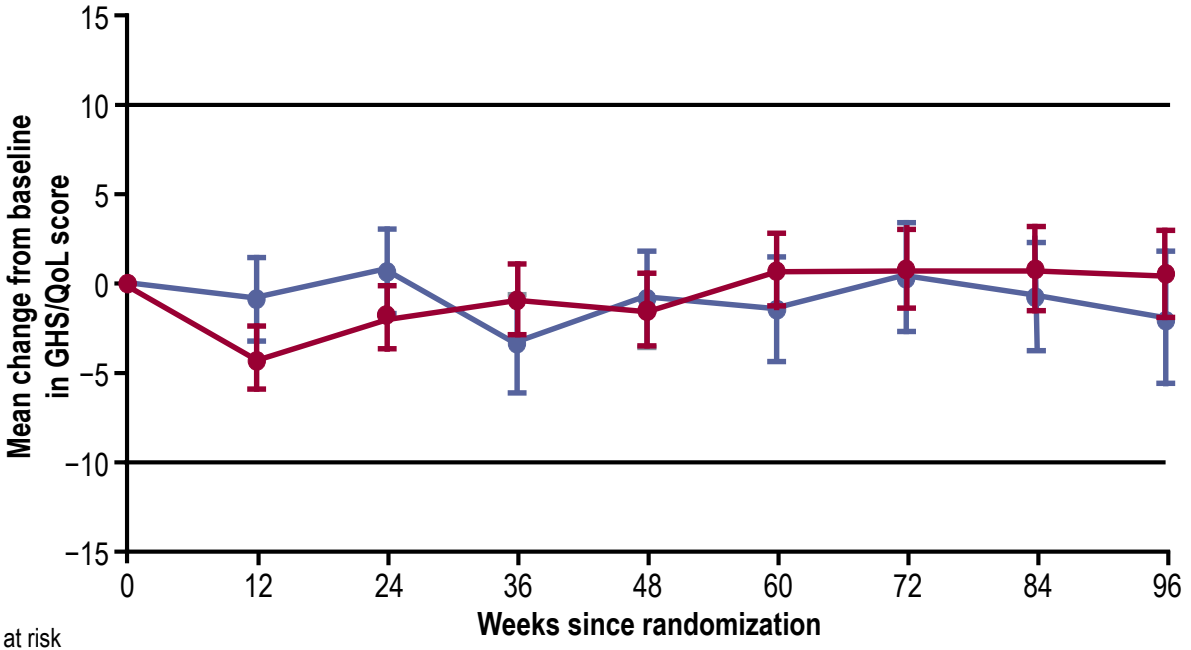
*Grouped terms. All-grade thrombocytopenia (grouped term) occurred in 8% of patients in the olaparib group and 3% of patients in the placebo group, grade ≥3 thrombocytopenia occurred in 2% of patients in the olaparib group and <1% of patients in the placebo group

AEs of special interest for olaparib

	Olaparib + bevacizumab (N=535)	Placebo + bevacizumab (N=267)
MDS/AML/AA, n (%)	6 (1.1)	1 (0.4)
New primary malignancies, n (%)	7 (1.3)	3 (1.1)
Acute lymphocytic leukaemia	1	0
Breast cancer	2	2
Lung cancer	1	0
Myeloma	1	0
Pancreatic cancer	1	0
Squamous skin cancer	1	0
Thyroid cancer	0	1
Pneumonitis/ILD, n (%)	6 (1.1)	0

AA, aplastic anaemia; AML, acute myeloid leukaemia; ILD, interstitial lung disease; MDS, myelodysplastic syndrome

Health-related quality of life



No. at risk									
Olaparib	508	458	432	396	393	352	342	308	252
Placebo	249	228	207	199	185	171	166	151	123

	Olaparib + bevacizumab	Placebo + bevacizumab
n	498	246
Adjusted mean	−1.33	−2.89
95% CI, *P*	−2.47 to −0.19, *P*=0.022	−4.52 to −1.26, *P*=0.0005
Estimated difference	1.56	
95% CI, *P*	−0.42 to 3.55, *P*=0.123	

A minimal clinically important difference is defined as ±10 points (Cocks *et al. Eur J Cancer* 2012;48:1713–21)
GHS, global health score; QoL, Quality of life

Conclusions

- PAOLA-1/ENGOT-ov25 included a broad, front-line population of advanced ovarian cancer patients which was not restricted by surgical outcome or *BRCA* mutation status
- PAOLA-1/ENGOT-ov25 met its primary objective, demonstrating a statistically significant improvement in PFS in the ITT population when olaparib compared with placebo was added to first-line standard-of-care bevacizumab maintenance treatment
- Prespecified subgroup analyses showed that patients with t*BRCA* mutations and patients with a positive HRD status had the greatest PFS benefits
  - The results reveal a patient population beyond t*BRCA*m patients, who are HRD positive, that experiences substantial benefit from maintenance treatment with olaparib and bevacizumab
- The safety profile of olaparib in combination with bevacizumab was generally consistent with previous trials of each drug and the addition of olaparib did not impact on bevacizumab tolerability and HRQoL

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