PRIMA/ENGOT-OV26/GOG-3012 STUDY: LONG-TERM CONDITIONAL PFS

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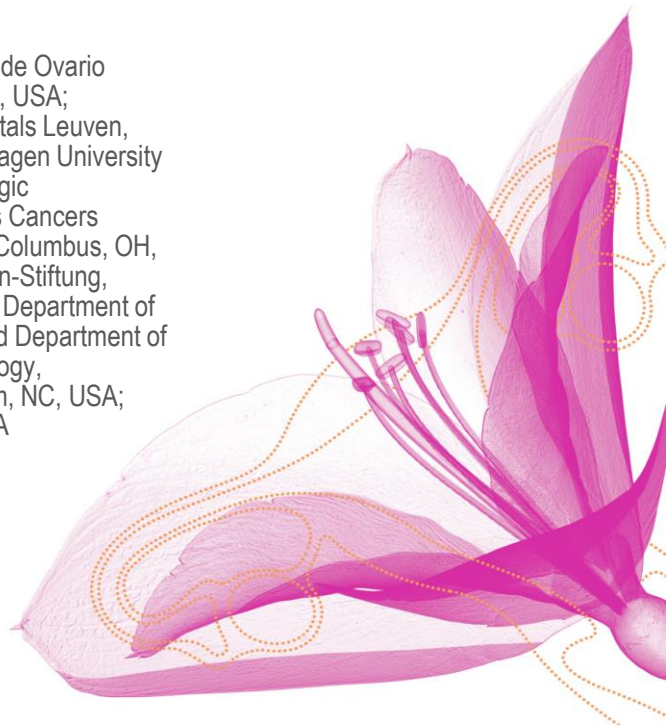

DECLARATION OF INTERESTS

Presenting Author's Conflicts of Interest

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PRIMA: NIRAPARIB 1L MAINTENANCE TREATMENT IN PATIENTS WITH ADVANCED OVARIAN CANCER

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- The phase 3 PRIMA/ENGOT-OV26/GOG-3012 study evaluated niraparib 1L maintenance treatment in patients with newly diagnosed advanced ovarian cancer after a response to 1L platinum-based chemotherapy[1]
  - Study participants were at high risk for disease progression: 35% had stage IV disease, 99.6% with stage III had residual disease post-PDS, 67% received neoadjuvant chemotherapy, and only 31% achieved a partial response to 1L chemotherapy
- In the primary analysis, niraparib maintenance treatment significantly extended PFS (per blinded independent central review) vs placebo, with a hazard ratio (95% CI) of 0.43 (0.31–0.59; *P*<0.001) in patients with HRd tumors and 0.62 (0.50–0.76; *P*<0.001) in the overall population (data cut 17 May 2019)[1]
  - Based on these data, niraparib was approved as maintenance treatment for patients (regardless of molecular profile) who responded to 1L platinum-based chemotherapy
- Updated long-term investigator-assessed PFS and safety (data cut 17 Nov 2021) showed that:
  - Patients administered niraparib were more likely to be free of progression and death at 4 years than those administered placebo in both the HRd (38% vs 17%) and overall (24% vs 14%) populations[2]
  - AEs were manageable and consistent with the primary analysis, and no new safety signals with niraparib were identified[1,2]
  - Long-term niraparib monotherapy was associated with a low rate of discontinuations due to AEs[2]

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1L, first-line; AE, adverse event; HRd, homologous recombination-deficient; PDS, primary debulking surgery; PFS, progression-free survival.

[1]González-Martín A, et al. *N Engl J Med*. 2019;381(25):2391–2402;
[2]González-Martín, et al. *Ann Oncol*. 2022;33(suppl 7):S789.

CONDITIONAL PFS: PROBABILITY OF BEING ALIVE AND PROGRESSION-FREE AT TIME POINTS BEYOND A PRESPECIFIED LANDMARK

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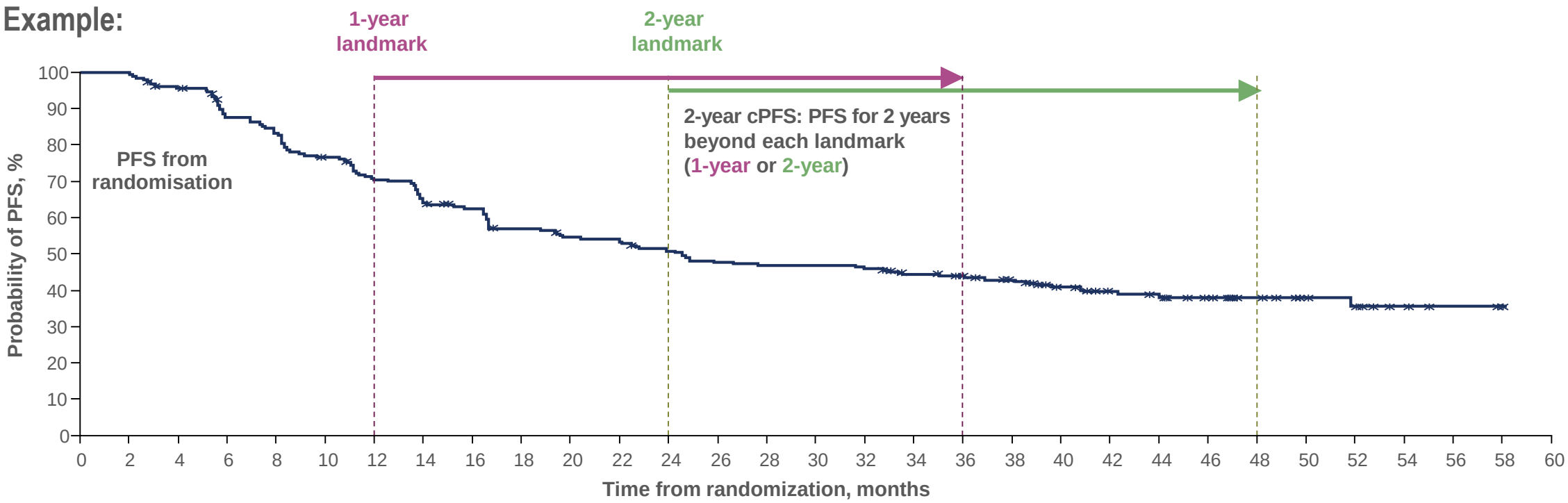

Conditional PFS (cPFS) is an alternative and dynamic estimate of PFS, representing the probability that a patient remains free of progression and death after reaching a predefined survival time point (ie, 1-year or 2-year landmark)[1,2]

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cPFS, conditional progression-free survival; PFS, progression-free survival.

[1]Choi M, et al. *Gynecol Oncol* 2008;109:203-209;
[2]Hieke S, et al. *Clin Cancer Res*. 2015;21(7):1530-6.

CONDITIONAL PFS: PROBABILITY OF BEING ALIVE AND PROGRESSION-FREE AT TIME POINTS BEYOND A PRESPECIFIED LANDMARK

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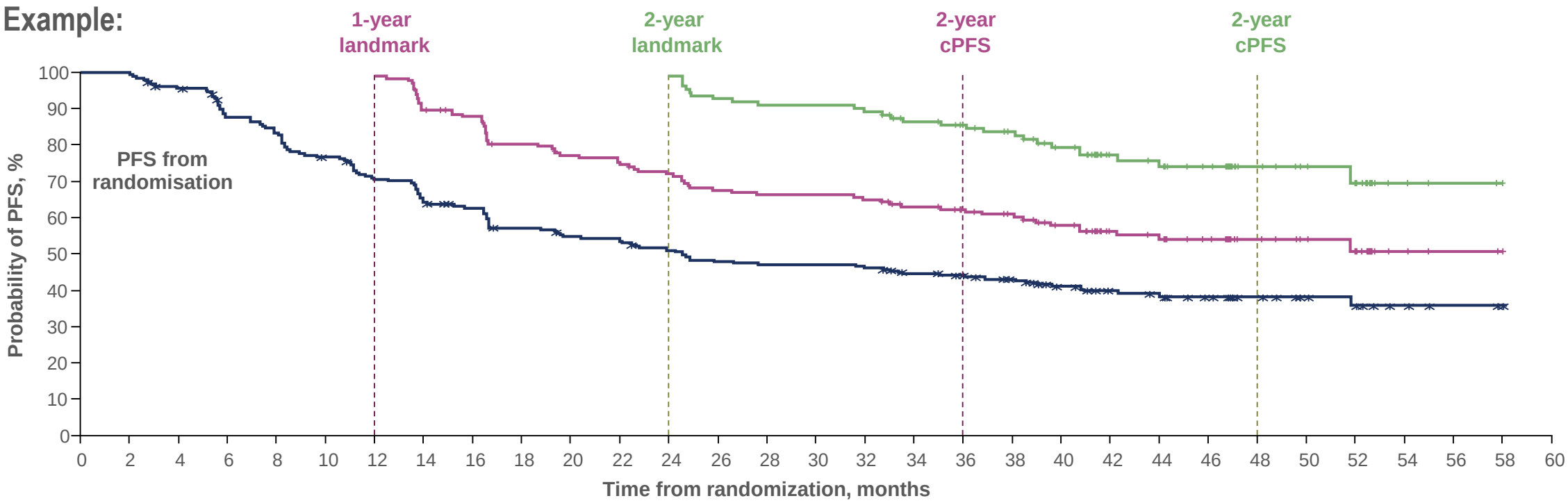

In the subset of patients who survived either 1 or 2 years post-randomisation in PRIMA, we evaluated the probability of their being alive and progression-free for an additional 2 years (ie, 2-year investigator-assessed cPFS)

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cPFS, conditional progression-free survival; PFS, progression-free survival.

CONDITIONAL PFS IN THE PRIMA HRd POPULATION

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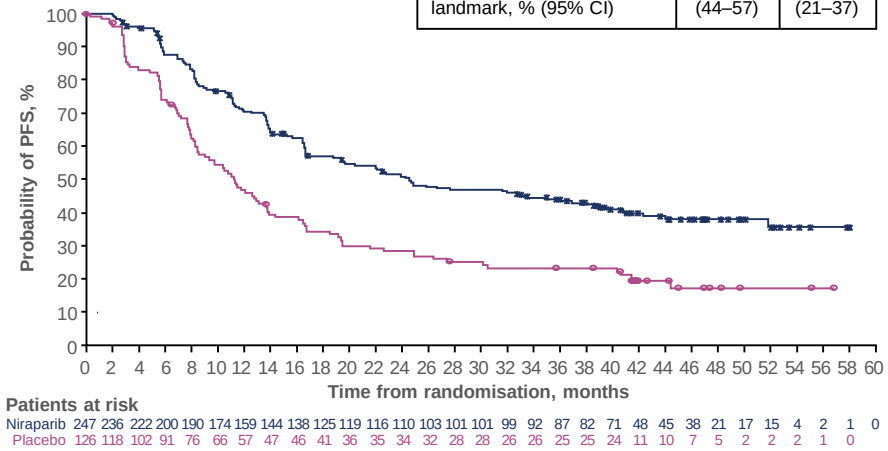
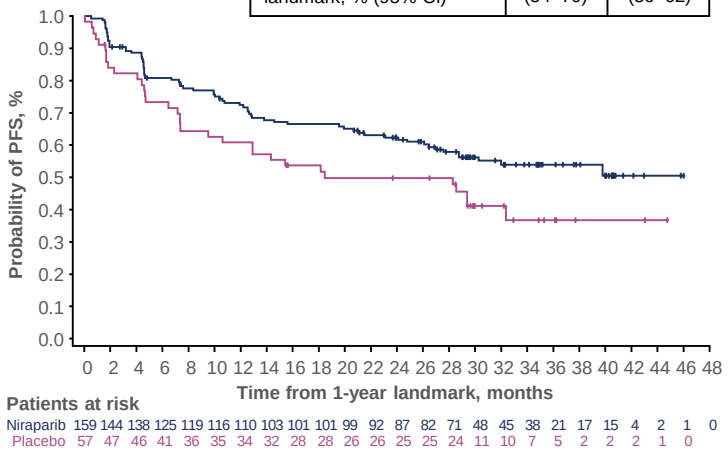
Standard PFS

	Niraparib	Placebo
Events/total patients	137/247	98/126
2-yr survival probability from landmark, % (95% CI)	51 (44–57)	29 (21–37)



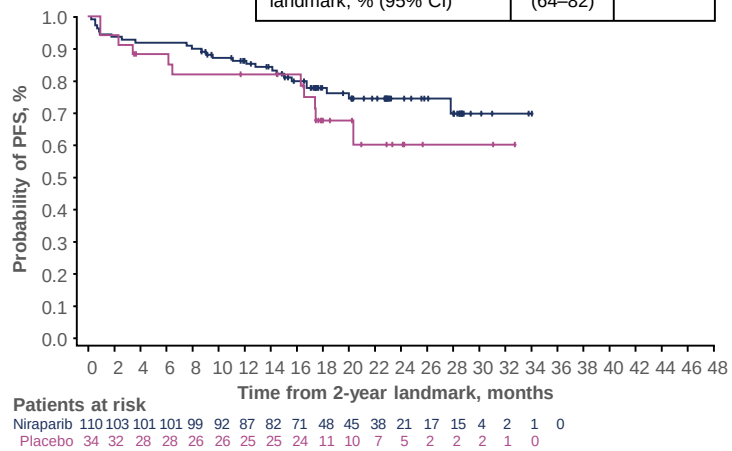
cPFS from 1-year landmark

	Niraparib	Placebo
Events/total patients	69/159	33/57
2-yr survival probability from landmark, % (95% CI)	62 (54–70)	50 (36–62)



cPFS from 2-year landmark

	Niraparib	Placebo
Events/total patients	26/110	11/34
2-yr survival probability from landmark, % (95% CI)	74 (64–82)	60[a]



In the HRd population:

- Standard PFS rate at:
  - 3 years was 44% for niraparib and 23% for placebo
  - 4 years was 38% for niraparib and 17% for placebo
- Estimates for 2-year cPFS rates were higher at each additional year of PFS

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[a]95% CI were not calculated at time points with <10 patients.
cPFS, conditional progression-free survival; HRd, homologous recombination-deficient; PFS, progression-free survival.

CONDITIONAL PFS IN THE PRIMA OVERALL POPULATION

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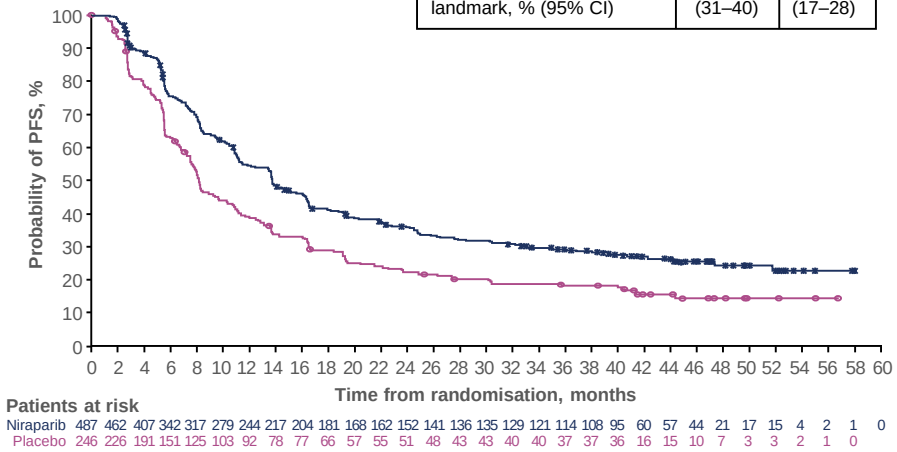
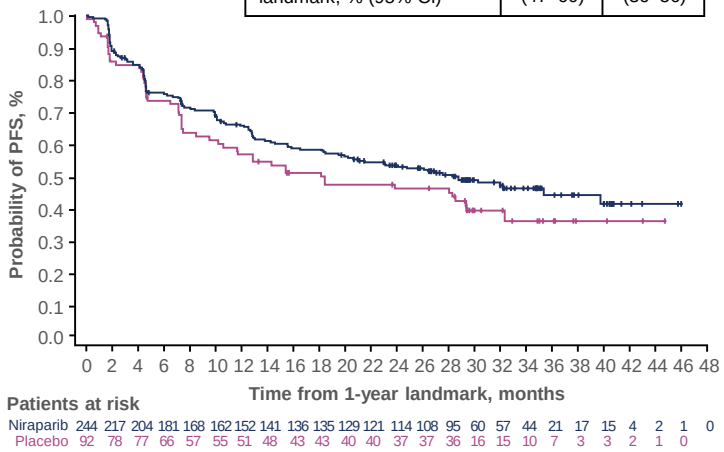
Standard PFS

	Niraparib	Placebo
Events/total patients	332/487	199/246
2-yr survival probability from landmark, % (95% CI)	36 (31–40)	22 (17–28)



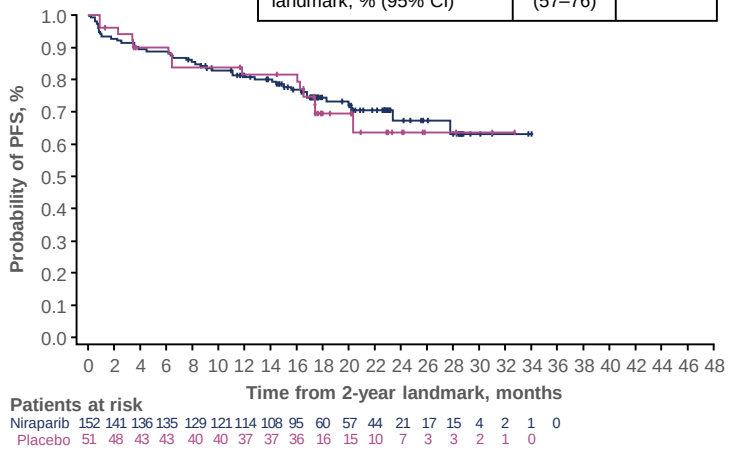
cPFS from 1-year landmark

	Niraparib	Placebo
Events/total patients	124/244	54/92
2-yr survival probability from landmark, % (95% CI)	54 (47–60)	46 (36–56)



cPFS from 2-year landmark

	Niraparib	Placebo
Events/total patients	42/152	15/51
2-yr survival probability from landmark, % (95% CI)	67 (57–76)	64[a]



In the overall population:

- Standard PFS rate at:
  - 3 years was 29% for niraparib and 18% for placebo
  - 4 years was 24% for niraparib and 14% for placebo
- Estimates for 2-year cPFS rates were higher at each additional year of PFS

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[a]95% CI were not calculated at time points with <10 patients.
cPFS, conditional progression-free survival; PFS, progression-free survival.

CONCLUSIONS

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- Patients in the HRd and overall populations treated with niraparib in PRIMA experienced durable PFS compared with placebo up to 4 years post-randomisation
- cPFS is a clinically relevant measure that describes the probability of being alive and progression-free after a specific landmark timepoint
  - cPFS may be particularly useful for advanced ovarian cancer, which is characterised by high rates of progression in the first 1–2 years post-diagnosis
- In our study, patients free from death and progression at the 1- and 2-year landmarks had a high probability of being alive and progression-free 2 years later, illustrating the long-term effect of niraparib and supporting its use as 1L maintenance therapy
- cPFS analyses demonstrate how the patient-risk profile (ie, prognosis) changes over time and may provide useful information to help guide patient counseling and treatment decision-making

1L, first-line; cPFS, conditional progression-free survival; HRd, homologous recombination-deficient; PFS, progression-free survival.

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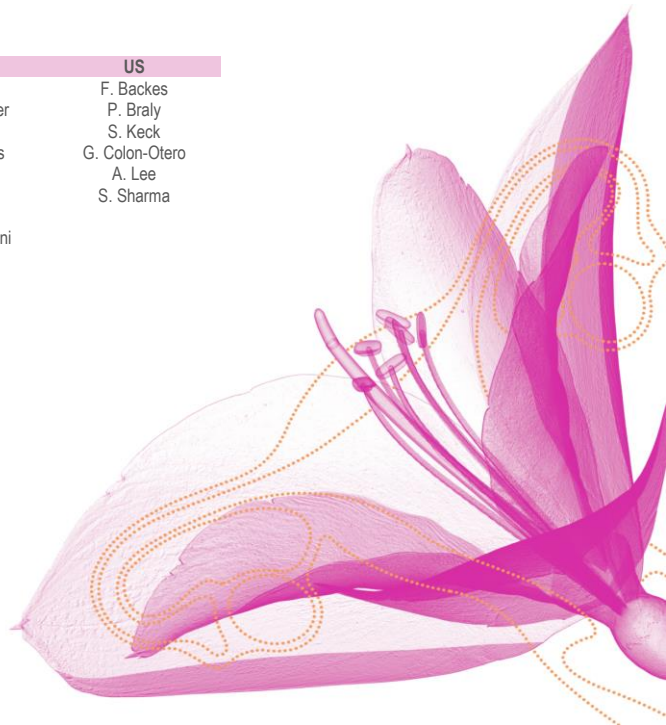

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