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Real-world (rw) outcomes in patients (pts) with advanced ovarian cancer (aOC) receiving niraparib (nir) as first-line maintenance (1LM) in the EUROPA study

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Background

Nir was approved for 1LM treatment of pts with aOC based on results from the PRIMA trial (NCT02655016). PRIMA enrolled pts at high risk for progression, having excluded pts with stage III aOC who had no visible residual disease (NVRD) after primary cytoreductive surgery (PCS). The objective of this study was to assess rw outcomes in 1LM nir pts and pts with stage III aOC and NVRD post-PCS.

Methods

EUROPA was a noninterventional, multicenter, retrospective cohort study in France, Germany, and Italy that included pts with epithelial aOC who initiated 1LM nir monotherapy (index date [ID]) from 01Oct2018 to 31Mar2023. Pts were followed from ID to the earliest of death, loss to follow-up, or end of the study period (30Sep2023). Demographic and clinical characteristics were described for the overall 1LM nir cohort and the subgroup of pts with stage III disease and NVRD status post-PCS. Rw time to treatment discontinuation (rwTTD), time to next treatment or death (rwTTNTD), and progression-free survival (rwPFS) were assessed using Kaplan-Meier methods.

Results

Overall, EUROPA included 186 pts who received nir as 1LM. Demographic and clinical characteristics of pts receiving nir 1LM in the stage III NVRD subgroup (n=48) were similar to those in the overall 1LM nir cohort. Median (95% CI) rwTTD was longer in stage III NVRD pts (26.2 [8.9–not reached] mo) than in the overall 1LM nir cohort (10.6 [7.8–18.6] mo). Median rwTTNTD and rwPFS were 20.3 (13.2–31.2) and 14.7 (10.1–29.3) mo, respectively, in the overall nir cohort but not reached in the stage III NVRD subgroup (Table). rwTTNTD and rwPFS probabilities were consistently higher for the stage III NRVD subgroup at 12, 24, and 36 mo post-ID.Table: 1104P

Parameter	Overall 1LM nir (n=186)	Stage III NVRD subgroup (n=48)
rwTTNTD		
Events, n (%)	94 (50.5)	17 (35.4)
Median (95% CI), mo	20.3 (13.2–31.2)	NR (NR–NR)
Probability (95% CI) at		
12 mo	0.58 (0.51–0.66)	0.75 (0.63–0.88)
24 mo	0.46 (0.38–0.54)	0.66 (0.53–0.81)
36 mo	0.39 (0.31–0.50)	0.63 (0.50–0.79)
rwPFS		
Events, n (%)	99 (53.2)	19 (39.6)
Median (95% CI), mo	14.7 (10.1–29.3)	NR (23.3–NR)
Probability (95% CI) at		
12 mo	0.52 (0.45–0.60)	0.70 (0.59–0.85)
24 mo	0.43 (0.36–0.52)	0.62 (0.49–0.77)
36 mo	0.40 (0.33–0.49)	0.59 (0.47–0.75)
Follow-up time from ID, median (IQR), mo	19.1 (11.3–28.7)	29.8 (24.2–33.6)

NR, not reached.

Conclusions

Pts with stage III disease and NVRD post-PCS receiving 1LM nir had better clinical outcomes than the overall 1LM nir cohort. The exclusion of pts with stage III aOC with NVRD post-PCS may have underestimated the clinical benefit of nir in PRIMA.

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