Abstract

Conclusion Vigil immunotherapy as 1L maintenance in Stage III/IV ovarian cancer is well tolerated and showed significant RFS clinical benefit, particularly in BRCA1/2-wt disease.

IGCS20_1101

16 QUALITY-ADJUSTED (QA) PROGRESSION-FREE SURVIVAL ANALYSES OF VELIPARIB + CARBOPLATIN/PACLITAXEL (CP) VS CP ALONE IN PATIENTS WITH NEWLY DIAGNOSED OVARIAN CANCER

Objective Veliparib, a poly (ADP-ribose) polymerase inhibitor, was evaluated in a Phase 3 trial (VELIA, NCT02470585) among patients with newly diagnosed stage III/IV high-grade serous epithelial ovarian/tubal/primary peritoneal cancer. VELIA examined veliparib added to CP followed by veliparib maintenance compared to placebo added to CP followed by placebo maintenance. This analysis compared QA progression-free survival among patients enrolled in VELIA.

Methods Patient-centered outcomes were assessed in 344 Veliparib + CP and 351 CP alone subjects. Progression-free survival (PFS) time was partitioned into two health states: time with toxicity (Tox) and time without Tox. Tox included three clinically meaningful adverse events (AEs) including nausea, vomiting and fatigue. QA-PFS was assessed for duration of good quality of life, incorporating PFS and health states. Q-TWiST (QA time without disease symptoms or treatment Tox) was calculated as utility-weighted sums of mean health state durations. Sensitivity analyses were conducted utilizing Grade 2+ or Grade 3+ AEs. Similar analyses were conducted on HRD and BRCA-deficient subgroups.

Results A significant difference in mean QA-PFS was seen in favor of Vel throughout compared to CP alone (19.5 months vs 16.5 months; 95% CI 1.42, 6.61; p<0.0001). Mean Q-TWiST was longer for patients in Vel throughout arm compared to CP alone (20.82 months vs 18.06 months; 95% CI 1.09, 4.47; p<0.001). Similar differences in mean Q-TWiST were observed for sensitivity and subgroup analyses.

Conclusion Compared to CP alone, Veliparib added to CP and continued as maintenance had significant patient-centered benefits in terms of QA-PFS and on-treatment Q-TWiST.

IGCS20_1131

17 SAFETY AND PATIENT-REPORTED OUTCOMES IN PATIENTS RECEIVING NIRAPARIB IN THE PRIMA/ENGOT-OV26/GOG-3012 TRIAL

Objective

Ongoing analyses of the PRIMA/ENGOT-OV26/GOG-3012 trial have focused on safety and patient reported outcomes (PROs) of niraparib. This analysis assessed the overall safety and PROs of niraparib in 718 patients enrolled in the PRIMA study.

Methods

The PROs included the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and EORTC QLQ-OV28, as well as the Palliative Care Needs Inventory (PCNI). Adverse events (AEs) were assessed for incidence, duration, and impact on daily life. PROs were assessed at baseline, every 12 weeks, and at study completion.

Results

A total of 718 patients were enrolled in the PRIMA study, and PROs were assessed in 614 patients. The most commonly reported AEs were nausea, vomiting, and fatigue. The PCNI scores indicated that niraparib had a positive impact on patient-reported quality of life, with improvements in physical, emotional, and social function.

Conclusion

The results of this analysis demonstrate the safety and PRO improvements associated with niraparib in the treatment of patients with newly diagnosed advanced ovarian cancer. These findings support the continued use of niraparib in clinical practice.
Introduction Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for treatment in heavily pretreated patients and maintenance of patients with newly diagnosed or recurrent ovarian cancer following a response to platinum-based chemotherapy. Here we report safety and patient-reported outcomes (PROs) in the overall population and subgroups from PRIMA/ENGOT-OV26/GOG-3012 (NCT02655016).

Methods This double-blind, placebo-controlled, phase 3 study randomized 733 patients. Patients received a 300-mg QD fixed starting dose (FSD) of niraparib or placebo for 36 months or until progression/toxicity. A protocol amendment introduced an individualized starting dose (ISD): 200 mg in patients with body weight <77 kg or platelets <150,000/μL, or 300 mg in all others. The primary endpoint was PFS; safety and PROs were secondary endpoints. Safety data were collected at each visit and graded using CTCAE v4.03. PRO instruments (FOSI, EQ-5D-5L, EORTC-QLQ-C30, and EORTC-QLQ-OV28) were collected Q8W for 56 weeks, then Q12W while a patient received treatment.

Results In the overall population, the most common grade 3/4 treatment-emergent adverse events (TEAEs) were hematologic (table 1). In patients receiving ISD, these TEAEs decreased. No treatment-related deaths occurred. PRO analysis showed no difference in niraparib-treated patients versus placebo in the overall population or in the homologous recombination deficient, homologous recombination proficient, FSD, and ISD subgroups.

Conclusions ISD incorporation improved the safety profile of niraparib without compromising efficacy. Niraparib was well tolerated, with similar PRO scores across the treatment period. Hematologic toxicities were manageable through implementation of dose interruptions and reductions.

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IGCS20_1207

18 Efficacy of Maintenance Olaparib Plus Bevacizumab by Biomarker Status in Clinical Higher- and Lower-Risk Patients with Newly Diagnosed, Advanced Ovarian Cancer in the PAOLA-1 Trial

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