OLAPARIB MONOTHERAPY VERSUS (VS) CHEMOTHERAPY FOR GERMLINE BRCA-MUTATED (GBRCAM) PLATINUM-SENSITIVE RELAPSED OVARIAN CANCER (PSR OC) PATIENTS (PTS): PHASE III SOLO3 TRIAL

Results

Pts were randomized (2:1) to olaparib tablets (300 mg bid) or chemotherapy treatment of physician’s choice (TPC) (paclitaxel [P; 80 mg/m² on day 1 (D1), D8, D15, D22 every 4 weeks (q4w)], gemcitabine [G; 1000 mg/m² D1, D8, D15 q4w] or PLD [50 mg/m² D1 q4w]) until progression, stratified by: TPC, prior lines of chemotherapy (2–3 vs ≥4) and platinum-free interval (6–12 vs >12 months). Primary endpoint: ORR (blinded independent central review [BICR]). Secondary endpoints included PFS and safety.

Results

266 gBRCAm PSR OC pts were randomized (olaparib, n=178; TPC, n=88 [PLD, n=47; P, n=20; G, n=13; T, n=8]); 12 in the TPC arm withdrew before receiving study treatment. 223 pts (84%) had baseline BICR measurable disease (olaparib, n=151; TPC, n=72). ORR was 72% with olaparib vs 51% with TPC (OR 2.53, 95% CI 1.40–4.58; P=0.002). HR for PFS by BICR was 0.62 (95% CI 0.43–0.91; P=0.013; median 13.4 vs 9.2 months [olaparib vs TPC]) and by investigator assessment was 0.49 (95% CI 0.35–0.70; P<0.001; median 13.2 vs 8.5 months, respectively). Most common adverse events (AEs) with olaparib were nausea (65% vs 34% [TPC]) and anemia (50% vs 25%) and with TPC were palmar-plantar erythrodysesthesia (PPE; 36% vs 1% [olaparib]) and nausea. Most common grade ≥3 AEs in either arm were anemia (21% [olaparib]) vs 0 [TPC]), PPE (0 vs 12%) and neutropenia (6% vs 11%). For olaparib vs TPC, serious AEs were reported by 24% vs 18% and AEs led to treatment discontinuation in 7% vs 20%.

Conclusions

Pts with gBRCAm PSR OC receiving olaparib monotherapy had a significant, clinically relevant improvement in ORR and PFS vs TPC, with no new safety signals.