OLAPARIB MAINTENANCE MONOTHERAPY FOR PATIENTS WITH NON-GERMLINE BRCA1/2-MUTATED PLATINUM-SENSITIVE RELAPSED OVARIAN CANCER: PHASE IIIIB OPINION INTERIM ANALYSIS

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Introduction and Methods
- Maintenance olaparib significantly improved progression-free survival (PFS), versus placebo, in both the Phase II Study 19 trial (NCT01735415) in patients with platinum-sensitive relapsed ovarian cancer (PSR-OC) with or without a BRCA mutation (BRCAm), and the Phase II SOLO2 trial (NCT01747533) in patients with PSR-OC and a BRCAm.
- In Study 19, a significant prolongation of PFS with maintenance olaparib (33.6 vs 20.1 months; hazard ratio 0.54; 95% CI 0.34–0.85), as well as clinically meaningful benefit, was observed in patients with or without a BRCAm.
- In Study SOLO2, patients with and without a BRCAm achieved similar PFS improvements with olaparib versus placebo (10.2 vs 3.8 months; hazard ratio 0.54; 95% CI 0.34–0.85).
- We present an updated analysis of the Phase IIIB, single-arm, international OPINION study (NCT03240041) investigating olaparib tablet formulation maintenance non-gemcitabine BRCAm (BRCAm) PSR-OC patients who had received p2 previous lines of platinum-based chemotherapy.
- Detailed study methods can be found in the Supplementary Material (accessed via Q1 cascade).

Results

- Patient dispositions and characteristics are summarized in Table 1. At the time of the interim analysis data cut-off (January 2019), 664 patients were enrolled from 17 countries (February 2018 to April 2019).

Conclusions

- In this interim analysis of the OPINION study, maintenance olaparib tablets demonstrated relevant activity in patients with non-gBRCAm PSR-OC, with a median PFS of 9.2 months.
- The PFS outcome was supported by a median TST of 13.4 months.
- Activity was seen across all patient subgroups, regardless of HRD and BRCAm status, objective response to latest platinum chemotherapy, or number of prior platinum chemotherapy regimens.
- In HRD-positive patients (excluding sBRCAm), median PFS was 9.7 months.
- The safety profile was consistent with that known for olaparib, with no new safety signals observed.
- Only 15.1% of patients required dose reduction and 7.2% discontinued treatment due to AEs.
- Additional follow-up will provide further information on the efficacy of olaparib in patients with non-gBRCAm PSR-OC.

Table 1. Patient characteristics at baseline

- **Table 2. Myriad biomarker analyses: tBRCA and sBRCA mutation status and tHRD status**

Figure 1. Study design

- **Figure 2. Kaplan-Meier plot of PFS**

- **Figure 3. Kaplan-Meier plot of PFS by HRD/BRCAm status**

- **Figure 4. Summary of most common TEAs reported (incidence ≥10%)**

Table 3. PFS outcomes by key subgroups

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Safety

- 263 patients (94.3%) experienced at least one treatment-emergent adverse event (AE) at data cut-off (Figure 4).
- Most TEAs were Grade 1 or 2 (≥-grade 3 AEs occurred in 72 patients [25.8%; Grade 3, 67 patients [24.0%]; Grade 4, 5 patients [1.8%]; no patients had a Grade 5 TEAE).
- Serious TEAEs were reported in 52 patients (18.6%), though only two serious TEAEs occurred in >1 patient (seizure due to olaparib treatment  due to a TEAE).
- The most common Grade ≥3 TEAEs reported were anemia (12.9%) and fatigue/asthenia (3.2%).

Table A. Detailed information on the efficacy and safety of olaparib maintenance monotherapy

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**References**


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