Time to Next Treatment (TTNT) of First-Line Maintenance (1Lm) Niraparib Monotherapy in Epithelial Ovarian Cancer (EOC) Patients in the CHARZMA Study

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The clinical development of poly (ADP-ribose) polymerase (PARP) inhibitors has provided new treatment options for patients with platinum-resistant ovarian cancer, following failure of primary platinum-sensitive (collectively, EOC) groups who typically have a poor prognosis.

Niraparib was approved on 29 April 2020 in the United States (US) as a once-daily oral monotherapy in the frontline setting for patients with platinum-sensitive advanced EOC regardless of breast cancer germline (BRCA) mutation status and homologous recombination deficiency (HRD) status, based on the findings of the PRIMA cancer trial.1

Given the observed benefits of niraparib 1Lm therapy for patients with EOC shown in clinical trials, there is a critical need for clinical outcomes data in the real-world setting.

Aim

To characterize the real-world-time to next treatment (TTNT) of patients with EOC who received niraparib 1Lm monotherapy overall and across key subgroups.

Methods

Study design

CHARZMA was a real-world, longitudinal, retrospective cohort study based on the US flatiron Health electronic health record database, which assessed the outcomes of patients who received niraparib monotherapy.

The flatiron Health electronic health record database contains de-identified patient-level structured and unstructured data, curated via technology-enabled abstraction.2 Data originated from ~300 cancer centers (>3,000 sites of care); note, the majority (~40%) of patients in the database originate from community oncology practices.

The index date was defined as the end date of first-line platinum-based chemotherapy.

Patients were followed from the index date to the earliest occurrence of date of death, and of follow-up, or end of study period (31 May 2022).

Patients included in the study met the eligibility criteria shown in Figure 1.

Results

Study population

- A total of 414 patients met the eligibility criteria and had baseline demographic characteristics shown in Table 1.
- Most patients were White (65.4%), and were <75 years old (74.9% with a median age of 67 years).
- Clinical characteristics are shown in Table 2; most patients had an Eastern Cooperative Oncology Group (ECOG) performance status score of 0–1 (38.7%) and either Stage III or Stage IV EOC at diagnosis (43.8% and 34.1% respectively).
- Median patient follow-up from index date was 13.8 (quartile 3.8–28.6) months.
- Of note, patients with BRCA mutations were added to the HRD-deficient subgroup to improve the completeness of HRD status information in the study population.

TNT

- The Kaplan-Meier curve for observed TTNT is shown in Figure 2.
- Survival rates (95% CI) at 12, 24, and 36 months were 33.1% (25.8%, 40.5%), 23.9% (17.9%, 30.9%), and 20.2% (15.3%, 25.8%), respectively.

Conclusions

- The CHARZMA study is the first to describe the TNT of a demographically diverse cohort of patients with advanced EOC who received niraparib 1Lm therapy in a real-world setting.
- Despite this, more than one quarter of patients had an electronic health record (EHR) value for race other than White and were aged 75 years or older; these patients are not typically well-represented in US (geographical) cancer clinical trials.
- The real-world trend in PFS observed in this study was demonstrated across all biomarkers, with longer observed benefit in patients with known HRD-defined STATUS* (than HRD-unknown), and both BRCA mutations (than no BRCA mutations), supporting findings shown in the PRIMA cancer trial.
- Within patients with no visible RD were not included in the PRIMA clinical trial, as the results from this current study population revealed that patients with known HRD-deficient 1Lm treatment who did not have visible RD or who did not receive treatment with niraparib in the real-world setting was also evident.
- The results shown here also suggest that patient characteristics can impact clinical outcomes for patients with EOC who receive niraparib monotherapy and highlight the importance of biomarker testing the HRD status testing in the real-world was also evident.
- Given the relatively small size of some subgroups, these results should be interpreted with caution. Future research should aim to contextualize these results to further inform clinical management of patients with EOC.

Disclosures

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References


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