Niraparib Maintenance Treatment with Individualised Dosing was Efficacious with Dose Modification in Chinese Patients with Platinum-sensitive Recurrent Ovarian Cancer: a Post Hoc Analysis

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INTRODUCTION

• In the global phase 3 NOVA study of niraparib maintenance therapy (MT) in platinum-sensitive recurrent ovarian cancer (PSROC), niraparib was initiated at 300 mg.1 Post hoc analysis then showed that for patients with baseline weight <77 kg or platelet count <150×103/microL, the usual average daily dose was 300 mg/day but due to dose interruption and reduction for managing treatment-emergent adverse events (TEAEs), especially haematologic TEAEs.2

METHOD

• Key eligibility criteria: 1) ≥18 years old; 2) having received ≥2 prior lines of platinum-based chemotherapy; 3) having complete/partial response to most recent platinum-containing chemotherapy. In NORA, patients were randomised 2:1 to niraparib or placebo MT of 28-day cycles. Dose modification (i.e., dose interruption 28 days or dose reduction) were allowed (Figure 1).

• Safety and efficacy parameters examined in this post hoc analysis are shown in Figure 1.

AIM

This post hoc analysis of NORA aims to further inform the management of Chinese patients receiving niraparib with ISD, specifically by understanding:

• The major haematologic TEAEs necessitating niraparib dose modification, and the temporal pattern of their occurrence
• The efficacy of niraparib at individualised, optimised stable doses

RESULTS

Niraparib Dose Modification

• Safety set: a total of 177 patients received ≥1 dose of niraparib treatment.

• In Months 1–2, dose modification occurred in 22.0%–36.2% of patients due to platelet count decrease and in 8.5%–12.1% of patients due to neutrophil count decrease (Figure 2).

• These percentages decreased from Month 3 onward and remained low through Months 4–6 (Figure 2).

• PFS curves were similar between the 100-mg and 200-mg subgroup, regardless of germline BRCA mutation status (Figure 3).

• The 300-mg subgroup PFS data were not interpretable due to small sample size and are thus not presented here.

CONCLUSIONS

In Chinese patients from the NORA study

• Compared to fixed starting dose in NOVA, niraparib with ISD in NORA showed improved safety and comparable efficacy in the overall study population.1,3

• Platelet count decrease and neutrophil count decrease were the major haematologic TEAEs necessitating niraparib dose modification, the frequency of which decreased substantially three months after niraparib initiation.

• Upon achieving stable, optimised doses in majority of patients, the PFS was comparable between subgroups receiving niraparib MT at 200 mg and 100 mg dose levels.

Figure 1. Study overview

Figure 2. Haematologic TEAEs leading to niraparib dose modification by month (safety set)

Figure 3. Kaplan-Meier curves for PFS by niraparib dose level at the beginning of Cycle 4 (ITT set)

References


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Author Disclosure

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