Background: Niraparib, a potent inhibitor of PARP 1/2, maintenance therapy significantly improved the outcome of platinum-sensitive recurrent ovarian cancer (PSROC) in Caucasian and Chinese patients in NOVA and NORA studies. An individualized starting dose according to the baseline body weight and platelet count was utilized in the majority of patients in NORA trial aiming to decrease incidence of AE while maintaining efficacy.

Methods: NORA was conducted in 32 hospitals in China. Eligible patients were women aged ≥18 years with PSROC who had either germline BRCA mutation or high-grade serous histologic features, and a complete or partial response after completion of the last round of platinum therapy. Patients were randomly allocated (2:1) to receive oral niraparib or placebo at 300mg once daily. After a protocol amendment in June 2016, patients were also divided into high (≥60 kg) and low (<60 kg) body weight groups. The primary endpoint was progression-free survival (PFS) assessed by blinded independent central review.

Results: In total, 265 patients were randomized and included in the intent-to-treat (ITT) efficacy population. Of these, 249 patients (median body weight 61 kg) received the individualized dosing of niraparib/placebo. Patients in the niraparib group had a significantly longer median PFS than those in the placebo group, 18.3 vs. 5.4 months (HR 0.30; 95% CI 0.21–0.49). The incidences of grade ≥3 treatment emergent AEs and ≥3 grade hematological AEs of neutrophil count decreased, platelet count decreased and anemia were 48.8% vs 20.5%, 19.9% vs 8.4%, 8.4% vs 1.3%, 13.9% vs 2.4% in niraparib group and placebo arm, respectively.

Conclusions: This is the first study to demonstrate the efficacy and safety of niraparib in Chinese patients with PSROC. Individualized starting dosing of niraparib is effective and safe and should be considered standard clinical practice in this patient population, especially in Asian patients with low body weight.

Clinical trial identification: NCT03705156.

Legal entity responsible for the study: Zai Lab.

Funding: This study was funded by Zai Lab (Shanghai) Co., Ltd., Shanghai, China. The study was also partially supported by the National Major Scientific and Technological Special Project for “Significant New Drugs Development” in 2018 (No. 2018ZX09736019), China, and Shanghai Municipal Commission of Economy and Informatization (No. 18XK24).

Disclosure: All authors have declared no conflicts of interest.
E每个人都安排了不同</p>