



## The Lancet Oncology Publishes Results from Phase 2 QUADRA Clinical Trial of Niraparib

April 10, 2019

Recently, the Lancet Oncology published results from phase 2 QUADRA clinical trial of niraparib. The study results showed that in patients with ovarian cancer who had received multiple lines of treatment, niraparib had clinical efficacy beyond BRCA mutations, especially for those with homologous recombination deficiency (HRD)-positive tumors.

QUADRA was a multicentre, open-label, single-arm, phase 2 study that evaluated the safety and activity of niraparib in adult patients ( $\geq 18$  years) with relapsed, high-grade serous (grade 2 or 3) epithelial ovarian, fallopian tube, or primary peritoneal cancer who had been treated with three or more previous chemotherapy regimens. The study was done in the USA and Canada, and 56 sites screened patients. 463 patients were enrolled.

The study results showed:

- Niraparib monotherapy provides a new treatment option for advanced ovarian cancer patients who are refractory to clinical therapy and have few effective treatment options. In the study, the patients had received a median of four previous lines of therapy and 27% of the patients were treated in the sixth or later line. 68% were platinum-resistant or platinum-refractory. 19% had BRCA mutations and 48% were HRD-positive.
- Niraparib showed significant clinical efficacy in patients with ovarian cancer who had received four or later previous anticancer therapies, regardless of BRCA mutational status. In the primary efficacy population (HRD-positive, platinum-sensitive, fourth or fifth line,  $n=47$ ), the overall response rate was 28% (95% CI 15.6-42.6; one-sided  $P = 0.00053$ ), the clinical benefit rate was 68% and median duration of response was 9.2 months (95% CI 5.9-NE).
- Long-term efficacy benefits were shown in all populations. About 44% of the total population ( $n = 456$ ) achieved a response, with a duration of response more than 12 months and median overall survival of 17.2 months (95% CI 14.9, 19.8). Compared with the previous clinical trial data of 10.6 months, the overall survival of patients was significantly prolonged.
- No new adverse reactions were found, and the safety profile of niraparib in the QUADRA treatment study was consistent with the safety profile observed in the NOVA trial maintenance population.

Click [here](#) to view the original paper published online in the Lancet Oncology.

### About Niraparib

Niraparib (ZEJULA®, ZL2306) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor. It was approved in March 2017 in the United States and in November 2017 in Europe as a maintenance treatment for women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Based on the approval status in the United States and Europe, Zai Lab has obtained the approval for marketing ZEJULA in Hong Kong in October 2018. The New Drug Application (NDA) for niraparib was submitted in December 2018 and was included in the priority review list in January 2019.