Patient were evaluable, including complete response (CR) in one patients, partial response (PR) nine, stable disease six, and progressive disease (PD) zero. The ORR was 62.5% (95% CI, 38.6 to 81.5), the DCR was 100% (95% CI, 80.6 to 100). The median PFS and OS was not reached. The frequent TRAEs were rash (18.3%), gum-pain (11.7%), and decreased white blood cell count (9.9%). four patients experienced grade ≥3 AEs. The commonly reported grade ≥3 AEs were hematologic.

Conclusions Our data showed that anlotinib plus pa-platixane have promising antitumor activity and manageable toxicity profile in patients with recurrent, platinum-resistant ovarian carcinoma.

EP304/#313 Efficacy and safety of niraparib combined with oral etoposide in platinum resistant/ refractory recurrent ovarian cancer: A multicentre, single arm, prospective phase II trial

Huiimei Zhou, Jiaxin Yang*, Qian Liu, Dongyan Cao, Yang Xiang, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, National Clinical Research Center for Obstetric & Gynecologic Diseases, Gynecologic Oncology, Beijing, China; Shandong Cancer Hospital Affiliated to Shandong University, Shandong Academy of Medical Sciences, Gynecologic Oncology, Jinan, China

Objectives Treatment options for platinum resistant or refractory recurrent ovarian cancer (PRR OC) are few and therapeutic efficacy are limited especially for those after 1 prior line of platinum-based chemotherapy. So, we designed a Phase II trial to evaluate the efficacy and safety of niraparib combined with oral etoposide in PRR OC.

Methods Key eligibility criteria include patients with histologically confirmed non-mucinous epithelial ovarian, fallopian tube, or primary peritoneal carcinoma; 1–2 prior lines of platinum-based chemotherapy; platinum resistant or refractory recurrence. Patients will receive niraparib 200 mg and 100 mg on alternate days and oral etoposide 50 mg on day 1–20 of each 30-day treatment cycle. After 6–8 cycles, oral etoposide will be discontinued. Niraparib was given alone until disease progression, intolerable toxicity or withdrawal of informed consent. The primary endpoint is PFS by Response Evaluation Criteria in Solid Tumors (RECIST v1.1).

Results Recruitment began on 22 May 2020. 26 patients were enrolled to date. The mean number of prior lines of chemotherapy was 1.3 which mean almost all of had primary platinum-refractory diseases. Median treatment duration was 4.3 months (1.1–16.1). Notably, one primary platinum resistant patient achieved CR lasting from week 16 to week 64 and is still on treatment. Another patient had clear cell carcinoma and has maintained PR through week 48 assessment; she is also still on treatment.

Conclusions Niraparib combined with oral etoposide show promising antitumor activity in PRR OC patients who received 1–2 prior lines of platinum-based chemotherapies. Study recruitment is ongoing.
Abstract EP305/#335 Figure 1  Study outline

thrombocytopenia (0.00% vs 10%) and with a similar incidence of anemia (11.76% vs 8%).

Conclusions Preliminary results suggested that for advanced epithelial ovarian cancer the short-course Nab-PC regimen as first-line chemotherapy provided equivalent efficacy to that of the PC regimen and there appeared to be a lower incidence of hematologic toxicities.

Conclusions Nab-p plus carboplatin as a NACT regimen was effective and tolerable for unresectable epithelial OC.

Objectives This study aimed to explore the efficacy and safety of nanoparticle albumin-bound paclitaxel (nab-p) combined with carboplatin as a neoadjuvant chemotherapy (NACT) regimen for patients with ovarian cancer (OC).

Methods This is a single-center, open phase Ib/II Clinical Trial (ChiCTR1900026893). We enrolled women with unresectable epithelial OC, FIGO stage III or IV. Patients received 3 cycles of NACT, then interval debulking surgery (IDS), followed by 3–6 cycles of adjuvant chemotherapy. Each 3-week cycle consisted of carboplatin AUC5 plus nab-p 260 mg/m² (Keaili®). In the phase Ib part, the objective was to evaluate the safety and tolerability of the NACT. In the phase II part, the primary objective was R0 resection rate. Secondary objectives were progression-free survival, objective response rate (ORR) and safety.

Results Phase Ib results showed the NACT was safe and tolerable, so the study proceeded to phase II. A total of 22 patients were included in this analysis, 10 patients in the phase Ib and 12 patients in the phase II. The median age was 58.5 years and 13 (59.1%) patients had stage IIIC. After NACT, the ORR was 86.4% (95%CI: 65.1%-97.1%). Among the 20 patients who underwent IDS, all patients achieved optimal debulking and 75% (95%CI: 50.9%-91.3%) achieved R0 resection. During NACT, the most common grade 3/4 adverse events were hematologic toxicities, including neutropenia (81.8%), leucopenia (54.5%), anaemia (22.7%) and thrombocytopenia (22.7%). All adverse events returned to normal or acceptable levels after receiving appropriate treatment.

Abstract EP306/#201  Efficacy and Safety of Nanoparticle Albumin-Bound Paclitaxel Plus Carboplatin as Neoadjuvant Chemotherapy for Women With Unresectable Ovarian Cancer: A Single-Center, Open Phase Ib/II Clinical Trial

Lina Yin*, Wei Jiang, Boer Shan, Huijuan Yang. Fudan University Shanghai Cancer Center, Gynecologic Oncology, Shanghai, China

Objectives This study aimed to explore the efficacy and safety of nanoparticle albumin-bound paclitaxel (nab-p) combined with carboplatin as a neoadjuvant chemotherapy (NACT) regimen for patients with ovarian cancer (OC).

Methods This is a single-center, open phase Ib/II Clinical Trial (ChiCTR1900026893). We enrolled women with unresectable epithelial OC, FIGO stage III or IV. Patients received 3 cycles of NACT, then interval debulking surgery (IDS), followed by 3–6 cycles of adjuvant chemotherapy. Each 3-week cycle consisted of carboplatin AUC5 plus nab-p 260 mg/m² (Keaili®). In the phase Ib part, the objective was to evaluate the safety and tolerability of the NACT. In the phase II part, the primary objective was R0 resection rate. Secondary objectives were progression-free survival, objective response rate (ORR) and safety.

Results Phase Ib results showed the NACT was safe and tolerable, so the study proceeded to phase II. A total of 22 patients were included in this analysis, 10 patients in the phase Ib and 12 patients in the phase II. The median age was 58.5 years and 13 (59.1%) patients had stage IIIC. After NACT, the ORR was 86.4% (95%CI: 65.1%-97.1%). Among the 20 patients who underwent IDS, all patients achieved optimal debulking and 75% (95%CI: 50.9%-91.3%) achieved R0 resection. During NACT, the most common grade 3/4 adverse events were hematologic toxicities, including neutropenia (81.8%), leucopenia (54.5%), anaemia (22.7%) and thrombocytopenia (22.7%). All adverse events returned to normal or acceptable levels after receiving appropriate treatment.

Conclusions Nab-p plus carboplatin as a NACT regimen was effective and tolerable for unresectable epithelial OC.