OPAL Clinical Trial

Summary

- A phase 2, open-label, multicohort clinical study (OPAL) is evaluating the safety and efficacy of niraparib novel treatment combinations in participants with recurrent ovarian cancer. Cohort A is evaluating combination treatment with niraparib, dostarlimab (GSK4057190, TSR-042) and bevacizumab in patients with advanced, recurrent, high-grade ovarian, fallopian tube, or primary peritoneal cancer who are poly(ADP-ribose) polymerase (PARP) inhibitor naïve and have received 1 to 2 lines of chemotherapy. OPAL is active, but not recruiting.[1,2]
- Dostarlimab is an investigational humanized anti-programmed death-1 (PD- 1) antibody under development for the treatment of advanced solid tumors in an ongoing Phase 1 dose escalation and cohort expansion study (GARNET).

CLINICAL STUDY

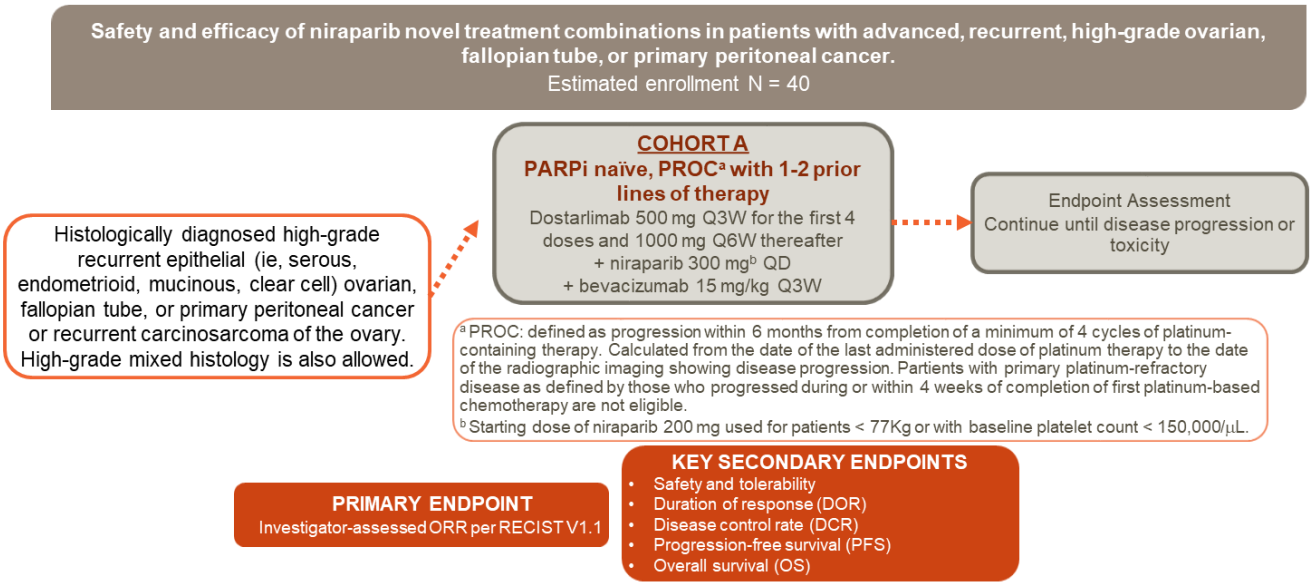
OPAL (NCT03574779) is a phase 2, open-label, multicohort study to evaluate safety and efficacy of novel treatment combinations in patients with advanced, recurrent, high grade ovarian, fallopian tube, or primary peritoneal cancer that have platinum-resistant, but not refractory disease. Cohort A will consist of PARPi naïve patients who have received 1 or 2 prior lines of therapy. Combination regimen includes dostarlimab administered 500 mg every 3 weeks for 4 cycles followed by 1000 mg every 6 weeks thereafter, bevacizumab administered 15 mg/kg every 3 weeks for up to 15 months, and niraparib 300 mg per day. Patients with a baseline body weight < 77 kg and/or a screening platelet count < 150,000/µL will start niraparib at 200 mg daily. The primary efficacy endpoint for each cohort is confirmed objective response rate (ORR), defined as the proportion of patients who have achieved confirmed investigator assessed complete response (CR) or partial response (PR), evaluated using response evaluation criteria in solid tumors (RECIST) v1.1 (Figure 1). [1,2]

REFERENCES

1. ClinicalTrials.gov identifier NCT03574779. Available at: https://clinicaltrials.gov/ct2/show/NCT03574779.
2. Liu JF, Gunderson C, Wahner Hendrickson A, et al. An Open-Label Phase 2 Study of the Combination of Dostarlimab (TSR-042), Bevacizumab, and Niraparib in Patients With Platinum-Resistant Ovarian Cancer: Cohort A of the OPAL Trial. Presented at AACR Annual Meeting, March 29-April 3, 2019, Atlanta, GA, US. Poster CT157.

APPENDIX

Figure 1. OPAL Study Design and Endpoints[1]



ORR = overall response rate; PARP = poly(ADP)ribose polymerase ; Q3W = every 3 weeks; Q6W = every 6 weeks, QD = once daily; RECIST = Response evaluation criteria in solid tumors