Background There is a medical need in platinum resistant ovarian cancer patients. Median progression-free survival (PFS) is 3.4 months with chemotherapy and 6.7 months with chemotherapy-bevacizumab combination regimens. RECIST overall response rate (ORR) is 11.8% and 27.3%, respectively. The ORR is 15.9% for bevacizumab as a monotherapy with a median PFS of 4.4 months.

Methods NCT03596281 An open-label phase 1b trial with a modified toxicity probability interval design to evaluate the combination of a flat dose of 400mg bevacizumab for 6 cycles and 200mg pembrolizumab until disease progression, unacceptable toxicity or completed 24 months of treatment in patients with platinum resistant ovarian cancer. The primary evaluation criteria is safety, the secondary endpoint is the efficacy.

Results 19 patients have been enrolled between January 2019 and February 2021 in 6 French centers. Patients’ characteristics are reported (table 1). No dose limiting toxicities were observed. Grade 3 treatment related adverse events occurred in 3 patients (i.e. arterial thromboembolism, bowel perforation, proteinuria and sepsis). No grade 4/5 toxicities were induced. A median of 7 cycles (range 3–14) were administered. Median follow-up of patients was 4.1 months (1.8–23). The RECIST ORR was 26.3% (1 complete response and 4 partial responses) (table 2). The disease control rate was 78.9%. The time to progression was not yet reached in 6 patients. The ORR was equivalent whether patients have been pretreated or not with bevacizumab (27.3 and 25% respectively) (table 3). The ORR according to the combined positive score (CPS) for the evaluation of PD-L1 was 50.0% for CPS≥10% (n=4), 30.0% for a CPS≥1% (n=10) and 25.0% for CPS<1 (n=8) (table 4).

Conclusions A chemotherapy-free regimen combining pembrolizumab and bevacizumab was well tolerated and showed encouraging results in heavily pretreated platinum resistant ovarian cancer patients independent of their previous challenge with antiangiogenic agents.

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Trial Registration NCT03596281

REFERENCES

Ethics Approval This study was approved by CPP Sud Méditerranée V institution’s Ethics Board; approval number 18.020 (EudraCT number 2017-004197-34).