BACKGROUND

- Preclinical evidence suggests chemotherapy can induce sensitivity to immunotherapy.
- Patients with advanced gastrointestinal cancer may benefit from immunotherapy, but currently there are no approved therapeutic options.
- The study aimed to evaluate the safety and preliminary efficacy of a novel combination therapy in patients with advanced solid tumors.

OBJECTIVES

- To determine the recommended phase 2 dose (RP2D) of the combination therapy.
- To evaluate the safety, tolerability, and preliminary efficacy of the combination therapy.

METHODS

- IOLite is a novel combination therapy under investigation.
- Patients were enrolled in a phase 1 study following predefined dose escalation and expansion protocols.
- The study included patients with different types of advanced solid tumors.
- Treatment was administered in a 3-week cycle (Part A) or 4 weeks (Parts B and D).
- Dosing: Dostarlimab 30 min before niraparib.
- Primary endpoints: safety, tolerability, and clinical activity.
- Secondary endpoints: pharmacokinetics and biomarker analysis.

RESULTS

- 55 patients were enrolled in the study.
- No dose-limiting toxicities were observed.
- The most common adverse events were fatigue, neutropenia, and dyspnea.
- Confirmed responses among response-evaluable patients were observed in various cancer types.

CONCLUSIONS

- The RP2D was confirmed for the combination therapy.
- The dose was well-tolerated, with manageable adverse events.
- Preliminary efficacy data show responses in various cancer types.

REFERENCES