**Study Design**

- Pre-growth was divided into 2 phases: phase 1A, oversampled for blinding and interval analysis, using time-to-event endpoints (overall survival, disease progression-free survival, and time to progression).
- Phase 1B was designed to evaluate the combination of CX-072 and ipilimumab in patients with advanced solid tumors.

**CX-072**

- CX-072 is a Probody therapeutic directed against PD-L1 for the treatment of patients with cancer.
- Antibodies targeting the PD-1 pathway have demonstrated deep and durable cancer treatment.

**Study Endpoints**

- **Primary objectives**:
  - Time to response and duration of response.
  - Objective response rate.
- **Secondary endpoints**:
  - Safety and tolerability.
  - Duration of response and disease control.
  - Pharmacokinetics and pharmacodynamics.

**Study Populations**

- Patients with advanced solid tumors or lymphoma (excluding thymic carcinoma).
- Patients with a PD-L1 positive tumor have been enrolled.
- Median age: 60 (range 28-70).
- ECOG performance status: 0-1.
- Baseline characteristics are presented in Table 2.
- Of the 16 patients evaluable for response and safety, 9 (56.3%) patients had a best objective response (BOR) of complete response (CR), 5 (31.3%) patients had progressive disease (PD), and 2 (12.5%) patients had stable disease (SD).

**Treatment Cycles**

- Patients received 3 cycles of CX-072 and ipilimumab every 3 weeks, with a washout period of 2 weeks between cycles.
- The combination of CX-072 and ipilimumab was administered concurrently, with the exception of patients who received CX-072 alone for 3 cycles.

**Treatment discontinuations**

- 12 patients discontinued treatment because of disease progression (n = 8), symptomatic deterioration (n = 3), or other reasons (n = 1).
- There were 4 deaths (all from disease progression) within 30 days of last study drug administration.

**Primary Toxicities**

- Grade 3 or 4 treatment-related adverse events (TRAEs) included:
  - Diarrhea
  - Fatigue
  - Anorexia
  - Hematologic toxicities (e.g., neutropenia, anemia, and thrombocytopenia)
  - Other toxicities (e.g., rash, nausea, vomiting, and hypotension).

**Sample Case Studies**

- Patient A has anal cell squamous cell carcinoma with intermediate tumor mutational burden (9 mutations/MB) and was enrolled in the CX-072 0.3 mg/kg + ipilimumab 3.0 mg/kg dose level.
- Patient B has small cell prostate cancer with high tumor mutational burden (275 mutations/MB) and was enrolled in the CX-072 3.0 mg/kg + ipilimumab 3.0 mg/kg dose level.

**Interim Results of the First-in-Human, Dose-Finding PROCLAIM-CX-072 Trial of the PD-L1 Probody Therapeutic in Combination With Ipilimumab in Patients With Advanced Solid Tumors**

- The preliminary interim results of the first-in-human, dose-finding PROCLAIM-CX-072 trial of the PD-L1 Probody therapeutic in combination with ipilimumab have been presented.
- Of the 16 evaluable patients, 9 (56.3%) patients had a best objective response (BOR) of complete response (CR), 5 (31.3%) patients had progressive disease (PD), and 2 (12.5%) patients had stable disease (SD).
- The primary toxicities included:
  - Diarrhea
  - Fatigue
  - Anorexia
  - Hematologic toxicities (e.g., neutropenia, anemia, and thrombocytopenia)
  - Other toxicities (e.g., rash, nausea, vomiting, and hypotension).

**CONCLUSIONS AND END POINTS**

- The primary objectives of Part 1 of the study are to assess the safety and tolerability of the combination of CX-072 and ipilimumab in patients with advanced solid tumors.
- Of the 16 evaluable patients, 9 (56.3%) patients had a best objective response (BOR) of complete response (CR), 5 (31.3%) patients had progressive disease (PD), and 2 (12.5%) patients had stable disease (SD).

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- No new safety signals were observed with the combination of the anti–PD-L1 Probody CX-072 and ipilimumab.

**REFERENCES**

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