**INTRODUCTION**

CD52 (5L-2R)-o is expressed on the cell surface of many lymphomas, including Hodgkin lymphoma (HL), peripheral T-cell lymphoma, cutaneous T-cell lymphoma, and diffuse large B-cell lymphoma. ADCT-301 (cami-tansumab tesirine [Cami-T]) is an antibody drug conjugate comprising a human monoclonal antibody against CD52 stochastically conjugated via a cleavable valine-alanine linker to tansumab, a potent pyrrolobenzodiazepine (PBD) dimer toxin (Figure 1). Cami-T binds to the CD52 antigen on tumor cells and is internalized via endocytosis.

- The protease-sensitive linker is cleaved in the lysosome and the free PBD dimers migrate into the nucleus
- PBD dimers sequence-selectively bind to the DNA minor groove, blocking cell division and resulting in cell death
- Cami-T has demonstrated potent antitumor activity against CD52-expressing mouse xenograft lymphoma models

**OBJECTIVES**

Part 2 will further evaluate safety, tolerability, PK and clinical activity at the dose recommended from part 1.

- In this Phase 1, open-label, multicenter study, eligible patients (Table 1) received 1-hour intravenous infusions of Cami-T every 3 weeks (1 cycle).
- ADCT-301 (cami-tansumab tesirine [Cami-T]) is an antibody drug conjugate comprising a human monoclonal antibody against CD52 stochastically conjugated via a cleavable valine-alanine linker to tansumab, a potent pyrrolobenzodiazepine (PBD) dimer toxin.
- Cami-T has demonstrated potent antitumor activity against CD52-expressing mouse xenograft lymphoma models.

**RESULTS**

- As of November 1, 2017, 86 patients have been treated with Cami-T
  - Median number of cycles: 2 (min, max: 1, 15)
  - Median treatment duration of 43 days (IQR, 37, 79)
- 71 patients have been treated with doses ranging from 3 to 150 μg/kg during part 1
  - 15 patients have been treated with doses ≥45 μg/kg in part 2

**Cami-T safety data**

- Doses have been reported in 4 patients:
  - Oral mucositis and small bowel enteritis at 20 μg/kg
  - Elevated creatine phosphokinase at 30 μg/kg
  - Maculopapular rash and pruritus at 30 μg/kg
  - Lip ulceration and skin infection at 45 μg/kg
- The most common treatment-emergent adverse events (TEAEs) were fatigue, rash, elevated gamma-glutamyltransferase and pyrexia (Table 3). The most common treatment-emergent adverse events (TEAEs) were fatigue, rash, elevated gamma-glutamyltransferase and pyrexia (Table 3). The most common treatment-emergent adverse events (TEAEs) were fatigue, rash, elevated gamma-glutamyltransferase and pyrexia (Table 3). The most common treatment-emergent adverse events (TEAEs) were fatigue, rash, elevated gamma-glutamyltransferase and pyrexia (Table 3). The most common treatment-emergent adverse events (TEAEs) were fatigue, rash, elevated gamma-glutamyltransferase and pyrexia (Table 3).
  - Of the 12 patients with HL who have been treated with dose ≥45 μg/kg, 21/27 patients (77.8%) with prior brentuximab vedotin
  - Of the 13/18 patients (72.2%) with prior checkpoint inhibitor therapy
  - Two cases of Guillain-Barré syndrome (GBS)

**CONCLUSIONS**

- In patients with R/R HL, Cami-T was active with the safety profile as described during the dose escalation and expansion.
- The ORR in this heavily pretreated population is very promising and HL expansion cohorts are underway.
- Cami-T has shown high levels of activity in HL, T- and B-cell lymphomas.
- Characterization of the dosing regimen is ongoing to maximize the therapeutic window for Phase 2 of HL.

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**REFERENCES**