**Phase 1b Study of TRU-016, an Anti-CD37 SMIP™ Protein, in Combination with Bendamustine in Relapsed Chronic Lymphocytic Leukemia**

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Introduction

- CD37 is a transmembrane phosphoprotein that is widely expressed on the surface of normal and transformed B-cells across a wide range of normal B-cell stages and demonstrates death signaling via Fas (CD95).
- TRU-016 is novel humanized CD37 SMIP™ (specific macrophage-activated) antibody fragment.
- It is in clinical trials in combination with bendamustine in patients with relapsed or refractory CLL and MCL.

METHODS

- The primary endpoint was to evaluate the safety and tolerability of TRU-016 in combination with bendamustine.
- Secondary endpoints included: overall response rate (ORR), complete response rate (CR), and duration of response (TDR).

RESULTS

- **TRU-016 15 mg/kg and Bendamustine 70 mg/m²**
  - **ORR**: 100% (33% CR)
  - **TDR**: 14.3 months
  - **Median Time to Progression**: 10.28 (3.0)

- **TRU-016 20 mg/kg and Bendamustine 70 mg/m²**
  - **ORR**: 75%
  - **TDR**: 14.3 months
  - **Median Time to Progression**: 10.28 (3.0)

- The combination produced a response in the majority of patients.

Adverse Events

- Most events were grade 1-2.
- Grade 4 events included: neutropenia (2 patients), hypokalemia (1 patient), increased AST (1 patient), pyrexia (1 patient), fever (2 patients), dehydration (1 patient), decreased appetite (1 patient), and vomiting (1 patient).

Safety

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  - **ORR**: 75%
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- There is no apparent dose-response relationship.

Conclusions

- **TRU-016 in combination with bendamustine was well tolerated.**
- **The combination produced a response in the majority of patients.**
- **The Phase 1 trial comparing TRU-016 with bendamustine was successful.**