Ublituximab + TGR-1202 Demonstrates Activity and a Favorable Safety Profile in Relapsed/Refractory B-NHL and High-Risk CLL: Phase I Results


*University of Nebraska Medical Center, Omaha, NE; MD Anderson Cancer Center, Houston, TX; *Cleveland Cancer Institute, Huntsville, AL; City of Hope National Medical Center, Duarte, CA; *Emory University/Winship Cancer Institute, Atlanta, GA; *TGl Therapeutics, Inc., New York, NY; *University of California Irvine, Orange, CA

Background

Ublituximab (TG1101, UTX) is a novel, chimeric monoclonal antibody targeting a unique epitope on the CD20 antigen, and glycoengineered to enhance affinity for all variants of FcγRIIIa receptors, thereby demonstrating greater antibody-dependent cellular cytotoxicity (ADCC) activity than rituximab and ofatumumab.

Phase I trials of single agent ublituximab in patients with relapsed/refractory CLL and NHL reported impressive response rates with rapid and sustained lymphocyte depletion.

Study Design

Study UTX-TGR-1002 (NCT02612311) is a Ph1b/II trial evaluating the combination of ublituximab + TGR-1202 in patients with relapsed or refractory NHL and CLL. The study is divided into two parts:

Part A: 3+3 Dose Escalation evaluating Cycle 1 Doses (CLL & NHL separately)

Part B: Dose Expansion

Objectives

Primary Objective

To determine the Safety and Maximum Tolerated Dose (MTD) of UTX-TGR-Secondary Objectives

To assess efficacy overall response rate, time to response of duration of response, progression-free survival.

Key Eligibility Criteria

- Confirmed cHL or cHL with high-risk cytogenetics, including ≥1% trisomy 900 mg

- For patients with cHL, ≥1% trisomy 900 mg by FISH or ≥2% by CISH.

- Other eligibility criteria included in the clinical trial protocol.

Safety


Duration on Study (Higher Doses)

Patients with DLBCL

- Doses vary based on patients' prior therapy

- Patients treated at the “Higher Doses” of TGR

- Patients not evaluable for Dose

- Patients evaluable for Dose

- Patients evaluable for Dose

- Patients evaluable for Dose

Phases of the UTX-TGR-1202 Study

- Phase I: Dose Escalation

- Phase II: Dose Expansion

- Phase III: Combination

- Phase IV: Maintenance

Conclusions

- Ublituximab in combination with TGR-1202 is well tolerated and highly active in a broad population of heavily pretreated and high-risk patients with NHL and CLL.

- Discontinuations due to adverse events have been limited (8%) and the only Grade 3/4 AE reported in >5% of patients was pneumonitis.

- Safety profile supports multi-drug regimens: triple therapy combinations adding novel agents to ublituximab and TGR-1202 are ongoing (including with ibritumomab, bendamustine, and pembrolizumab) with additional triple therapy studies planned.

- Marked activity observed in CLL, NHL, and DLBCL being explored further in registration directed UNITY-CLL Phase 3 Study and UNITY-DLCL Study, with additional registration studies planned in the UNITY program.

Presented at the 57th American Society of Hematology (ASH) Annual Meeting and Exposition, December 5 – 8, 2015, Orlando, FL