Open Label Extension (OLE) of Phase 2 Multicenter Study of Ublituximab (UTX), a Novel Glycoengineered Anti-CD20 Monoclonal Antibody (mAb), in Patients with Relapsing Forms of Multiple Sclerosis (RMS)

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Objective: To evaluate the safety/tolerability and long-term disability outcomes of ublituximab (UTX) treatment in RMS patients enrolled in the OLE.

Background:
UTX is a novel mAb targeting a unique epitope on the CD20 antigen and glyco-engineered for enhanced B cell targeting through antibody-dependent cellular cytotoxicity (ADCC). The greater ADCC potency may offer a benefit over currently available anti-CD20s in terms of lower doses and shorter infusion times.
Design/Methods: TG1101-RMS201 was a 52-week, phase 2, placebo-controlled, multicenter study designed to assess the optimal dose and infusion time of UTX in RMS subjects. Subjects who completed the RMS201 study were eligible to continue treatment in an OLE, receiving one-hour 450mg UTX infusions every 24 weeks for an additional 96 weeks. Safety is monitored throughout the OLE with EDSS assessments performed every 48 weeks.

Results:
48 subjects were enrolled in the Phase 2 study. Median B cell depletion of >99% was observed at Week 4 and maintained at Week 48. At Week 48, T1-Gd enhancing lesions decreased from a baseline mean of 3.63 to zero; mean T2 lesion volume decreased 10.6% from baseline; 93% of subjects were relapse free and an ARR of 0.07 was observed. Most common adverse events (AEs) were infusion related reactions (all grade 1-2). No discontinuations due to severe AEs were reported. 37 subjects from the Phase 2 trial enrolled in the OLE. As of October 2018, approximately 30% of patients completed 48 weeks in the OLE. UTX continues to be well tolerated, with no discontinuations due to AEs. At the time of presentation, it is anticipated that additional patient follow-up from the OLE study will be available.
Conclusions: The Phase 2 OLE supports that one-hour infusions of UTX continue to be safe and well tolerated. These results support the ongoing Phase 3 ULTIMATE program in RMS.