Phase 2 Study Design

- Randomization:
  - Placebo (n=2)
  - Placebo (n=6)
  - UTX (n=6)
  - UTX (n=6)

- Treatment Periods:
  - Day 1 Infusion:
    - Placebo: 450 mg in 1h
    - UTX: 450 mg in 1h
  - Week 12 Infusion:
    - Placebo: 450 mg in 1h
    - UTX: 450 mg in 1h
  - Week 48 Infusion:
    - Placebo: 450 mg in 1h
    - UTX: 450 mg in 1h

- OLE Study Design:
  - All subjects enrolled on the OLE, regardless of their cohort assignment in the Phase 2, will receive 450mg of ublituximab administered in one hour infusion every 24 weeks with the first infusion given within 60 days of completing the Phase 2.
  - Each infusion visit is accompanied by routine physical exam, routine blood assessments therefore only 46 patients had received all assessments to be up of 97.5 weeks.
  - For the OLE, subjects must have completed three infusions of ublituximab, have completed the scheduled assessments up to the Week 48 out of TG-1101-RM2021, and be in good health with stable disease since enrollment.

Patient Disposition & Baseline Characteristics

- **Patient Demographics**
  - Gender: 64% Female
  - Age: 45 years
  - Baseline EDSS: 0
  - Disease Duration: 10 years
  - ≥≥T1 lesion: 39% of patients had ≥1 T1 lesion and 36% had ≥1 T1 lesion.
  - No T1 Gd enhancing lesions were detected in any subjects at Week 24.
  - T1 Gd Enhancing Lesions Baseline vs. Week 24 & Week 48

- **Patient Disposition**
  - Disease Duration (Years): During the Phase 2, IRRs were most frequent on Day 1 with 33% of Subjects Placebo / (100% PATIENT DISPOSITION (cont’d) N=48 lesions and 26% had 1.5h Day 1/ (n=6) At the conclusion of the Phase 2 an ARR of 0.07 was observed at Week 48, with 93% of subjects being relapse free and 74% of subjects fulfilling the criteria for NEDA. Additionally, no T1 Gd-enhancing lesions were detected in any subjects at Week 24 or 48 (100% reduction; p<0.003).
  - 7% of subjects showed 24 Week Confirmed Disability Improvement (%)
  - 7% of subjects showed 24 Week Confirmed Disability Progression (%)
  - 57% of subjects showed 24 Week Confirmed Disability Improvement (%)

- **RESULTS**
  - All AEs Deemed at Least Possibly Related to UTX
  - Adverse Event (AE) Summary
    - Phase 2 (n=48)
    - OLE (n=45)
  - Event, n (%)
    - Phase 2 (n=48)
    - Grade 1 Grade 2 Grade 3 Grade 4
    - Total
  - OLE (n=45)
    - Grade 1 Grade 2 Grade 3 Grade 4
    - Total
  - Most frequently reported AEs (n=6)
    - Phase 2
    - Grade 1
    - Grade 2
    - Grade 3
    - Grade 4
  - NEDA
    - Disability/EDSS
    - NEDA
    - Disability Improvement (%)
    - Disability Progression (%)

- **Conclusions**
  - Ublituxim (UTX) was well tolerated with a median duration of follow-up of 97.5 weeks.
  - No drug related discontinuations occurred during the Phase 2 or on the OLE.
  - Infusion Related Reactions (IRRs) were infrequent during the OLE, occurring in 4 patients (9%), all Grade 1 or 2; with no patient experiencing an IRR for the first time on the OLE.
  - The Phase 2, IRRs were more frequent on Day 1 with 33% of patients experiencing an IRR on Day 1 when given 150mg of UTX over 4 hours (the Phase 3 Day 1 dose).
  - Of the 18 infusions administered during the Phase 2 and the OLE, at the Phase 3 dose/infusion time, there were 20 IRR events in 13 patients, representing 12% of the infusions, all Grade 1 or 2.

- **Infusion Related Reactions (IRRs)**
  - All patients on the OLE received 450mg administered in a one hour infusion, with 100% of patients receiving at least one infusion, and 95% of patients receiving 2 or more infusions.
  - IRRs were infrequent during the OLE, occurring in 4 patients (9%), all Grade 1 or 2; with no patient experiencing an IRR for the first time on the OLE.
  - At the conclusion of the Phase 2 an ARR of 0.07 was observed at Week 48, with 93% of subjects being relapse free and 74% of subjects fulfilling the criteria for NEDA. Additionally, no T1 Gd-enhancing lesions were detected in any subjects at Week 24 or 48 (100% reduction; p<0.003).
  - Long term safety data, and Phase 2 efficacy data, support the fully enrolled Phase 3 UBLIMATE trials evaluating a rapid one hour infusion of 450mg of ublituximab in patients with Relapsing Forms of Multiple Sclerosis (RMS).

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

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**Presented at the American Academy of Neurology Annual Conference, Philadelphia, PA, May 7, 2019**