



TG Therapeutics Presents Data for Ublituximab at the 35th Annual Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)

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NEW YORK, Sept. 12, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today presented the first look at the ULTIMATE I & II Phase 3 trial design and demographic data and updated Phase 2 extension trial data for ublituximab, the Company's novel, glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of multiple sclerosis (RMS) at the 35th Annual Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), being held in Stockholm, Sweden.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are pleased to present the first look at the study design and patient demographics data from our Phase 3 ULTIMATE program. Importantly, the population enrolled appears consistent with a typical RMS population and similar to the patient populations enrolled in other CD20 Phase 3 trials." Mr. Weiss continued, "We are also highly encouraged by the Phase 2 long-term safety data demonstrating ublituximab continues to be very well tolerated with a median duration of follow-up of 124.7 weeks and no discontinuations due to AEs reported. We look forward to continuing to follow our Phase 2 patients and to topline results from our Phase 3 trial in the middle to second half of 2020. If successful, we believe ublituximab will represent an important anti-CD20 treatment option for patients with RMS that can be delivered in a convenient one-hour infusion every six months."

The following summarizes the highlights from each presentation during the 35th ECTRIMS meeting:

Title: [Study Design and Patient Demographics of the ULTIMATE Phase III Trials Evaluating Ublituximab \(UTX\), a Novel Glycoengineered Anti-CD20 Monoclonal Antibody \(mAb\), in Patients with Relapsing Multiple Sclerosis \(RMS\)](#)

This presentation includes the study design and demographic data from ULTIMATE I & II, two identical, randomized, international, multi-center, double-blinded, double dummy, active controlled Phase 3 trials, evaluating a twice per year one-hour 450mg infusion of ublituximab in RMS. These trials are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and are being led by Lawrence Steinman, MD, of Stanford University.

Presentation Highlights:

- Patient recruitment for ULTIMATE I & II was successfully completed in the second half of 2018.
- Baseline characteristics of patients enrolled in ULTIMATE I & II are consistent with a typical RMS population.
- The ULTIMATE I & II trials are expected to elucidate the therapeutic potential of a one hour, 450mg infusion of ublituximab in patients with RMS. Topline results are expected in the second half of 2020.

Title: [Long-term Follow-up Results from the Phase 2 Multicenter Study of Ublituximab \(UTX\), a Novel Glycoengineered Anti-CD20 Monoclonal Antibody \(mAb\), in Patients with Relapsing Multiple Sclerosis \(RMS\)](#)

This presentation includes long-term follow-up data for 45 patients from the Phase 2 trial that enrolled into the Open Label Extension (OLE) trial and recaps the final efficacy data on patients enrolled in the Phase 2 study through 48 weeks of treatment.

Presentation Highlights:

- Ublituximab continues to be well tolerated, with a median duration of follow-up of 124.7 weeks.
- No subjects discontinued due to an Adverse Event (AE) related to ublituximab on the Phase 2 or during the OLE.
- AEs deemed at least possibly related to ublituximab were infrequent during the OLE with all patients dosed at 450mg of ublituximab administered in a one-hour infusion (Phase 3 dose).
- Infusion Related Reactions (IRRs) were rare during the OLE, occurring in only 5 patients (11%), all Grade 1 or 2.
- An Annualized Relapse Rate (ARR) of 0.07 was observed with 93% of subjects relapse free at Week 48.

The above referenced data presented are available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing multiple therapies targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing umbralisib (TGR-1202), an oral, once-daily inhibitor of PI3K-delta. Umbralisib uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K-delta inhibitors. Both ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought into Phase 1 clinical development, TG-1501, its anti-PD-L1 monoclonal antibody, TG-1701, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor and TG-1801, its anti-CD47/CD19 bispecific antibody. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Statements included in this press release, particularly those with respect to anticipating the benefit of the data seen in the Phase 2 and OLE MS program and performance of ublituximab in the Phase 3 ULTIMATE clinical program may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Among the factors that could cause our actual results to differ materially are the following: the risk that early clinical results that supported our decision to move forward will not be reproduced in additional patients in expansion cohorts, with longer term follow-up, or in the Phase 3 ULTIMATE program; the risk that ublituximab will not have a differentiated safety or efficacy profile from the other drugs in the class; the risk that the long-term safety profile presented thus far will not be replicated in the Phase 3 ULTIMATE program; the risk that the clinical results from the Phase 3 ULTIMATE program will not be positive and/or will not support regulatory approval of ublituximab to treat MS; the risk that the results from the Phase 3 ULTIMATE program will not be available within the guided timelines; our ability to successfully and cost-effectively complete the Phase 3 ULTIMATE program; our ability to achieve the milestones we project over the next year; our ability to manage our cash in line with our projections, and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.tgtherapeutics.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

CONTACT:

Jenna Bosco
Senior Vice President,
Corporate Communications
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com



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