

October 26, 2017

# TG Therapeutics, Inc. Announces Updated Results from the Ongoing Phase 2 Study of TG-1101 (ublituximab) in Patients with Multiple Sclerosis at the 7th Joint ECTRIMS - ACTRIMS Meeting

100% reduction of T1 Gd-enhancing lesions at week 24 (n=20)

99% median B-cell depletion was observed at week 4 and maintained at week 24 (n=24)

TG-1101 was well tolerated across all patients including those receiving 1 hour infusions of the Phase 3 450mg dose

NEW YORK, Oct. 26, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced results from the Phase 2 multicenter trial of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS). The data is being presented today in two posters during Poster Session 1, from 15:30 - 17:00 CEST, at the 7<sup>th</sup> Joint ECTRIMS - ACTRIMS meeting in Paris, France.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased with the data presented today demonstrating not only sustained B-cell depletion by week 24, but even more importantly, complete elimination of T1 Gd-enhancing lesions, as well as a well-tolerated safety profile at our Phase 3 dose. We believe these data, although early, compare very favorably to the results seen with other anti-CD20s in the class, with TG-1101 exhibiting what could be a best-in-class profile. These data support our currently enrolling Phase 3 program in MS, which is being launched globally." Mr. Weiss continued, "We look forward to presenting additional B-cell data tomorrow during the second poster session as well as presenting updated data, including additional patients, from this trial at conferences over the next year."

"The clinical and MRI data presented today is highly encouraging and further confirms the compelling efficacy seen in Multiple Sclerosis patients treated with ublituximab. While still early, it appears ublituxmab can be a highly competitive anti-CD20 with a shorter infusion time, which is a great benefit to our patients. We look forward to additional data from this Phase 2 trial and to participating in the Phase 3 ULTIMATE trials and advancing this important treatment option," stated Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Associate Professor at the University of Texas Dell Medical School in Austin, TX and the Principal Investigator for this Phase 2 study.

This Phase 2 trial is a 52-week randomized, placebo controlled, multi-center study evaluating the safety and efficacy of TG-1101 (ublituximab) at accelerated infusion times. Today's posters include data from 24 patients with RMS that were treated with TG-1101 across three dosing cohorts.

Poster Presentation Title: Patient characteristics, safety, and preliminary results of a placebo controlled, phase 2a multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis

# Poster Highlights:

- 99% median B-cell depletion was observed at week 4 and maintained at week 24 (6 months) (n=24)
- 96% of subjects (23/24) were relapse free at week 24
  - -- One confirmed relapse was reported in a patient initially randomized to the placebo arm. The relapse occurred 12 days after the patients first infusion of 150mg of TG-1101. The patient remains on study and has received the second and third infusions of TG-1101 and to date has remained relapse free.
- Mean EDSS improvement from baseline of 0.35 with 79% of subjects showing improved or stable EDSS
- TG-1101 was well tolerated across all patients including those receiving rapid infusions, as low as a one hour for the 450mg Phase 3 dose, and produced similar levels of B-cell depletion with no identified change in IRR or overall safety profile.

Poster Presentation Title: Preliminary results 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) demonstrates rapid Gd-enhancing lesions decrease

- TG-1101 completely eliminated all (100%) of T1 Gd-enhancing lesions at week 24 (n=20) (p=0.005)
- 7% Reduction in the T2 lesion volume at Week 24 from baseline (p=0.02), suggestive of a decrease in burden of disease
- 6.5% Reduction in T1 hypointense lesion volume at Week 24 from baseline (p=0.03)

These data presentations support the recently announced international Phase 3 program evaluating TG-1101 (ublituximab) for the treatment of relapsing form of Multiple Sclerosis (RMS). The Phase 3 trials, entitled ULTIMATE I and ULTIMATE II, are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and will be led by Lawrence Steinman, MD, of Stanford University.

### **POSTERS**

A copy of the above posters can be found on the Publications page, located within the Pipeline section, of the Company's website at <a href="https://www.tgtxinc.com/publications.cfm">www.tgtxinc.com/publications.cfm</a>.

## 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 two therapies targeting hematological malignancies and autoimmune diseases. TG-1101 (ublituximab) 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 TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination of which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for multiple sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. 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 early data seen in the Phase 2 MS trial and anticipating the timing of our MS Phase 3 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: our ability to successfully and cost-effectively complete the MS Phase 2 and Phase 3 trials; the risk that early clinical results that supported our decision to move forward will not be reproduced in additional patients in expansion cohorts or in the MS Phase 3 program; the risk that data included in the posters presented will be reproduced in subsequent data presentations; the risk that the clinical results from the MS Phase 3 program, will not be positive and/or will not support regulatory approval of TG-1101 for MS; the risk that TG-1101 will not have a differentiated profile from the other drugs in the class and that early signs of best-in-class attributes will not be supported by future results; the risk that trials will take longer to enroll than expected; 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.

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