TG Therapeutics, Inc. Announces Updated Results from the Ongoing Phase 2 Study of Ublituximab in Patients with Multiple Sclerosis at the 4th Congress of the European Academy of Neurology

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NEW YORK, June 18, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced updated results from the Phase 2 multicenter trial of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS). The data is being presented today at the 4thCongress of the European Academy of Neurology in Lisbon, Portugal, via an oral session titled "MS and related Disorders 2", at 17:00 CET.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased to see that the preliminary Week 48 data presented today from this Phase 2 trial supports the Week 24 data presented earlier this year at the AAN meeting. While only an early look at the Week 48 timepoint, the data continue to be impressive and suggestive of a highly efficacious anti-CD20 monoclonal antibody with a manageable safety profile that can be administered in a convenient one-hour infusion. Mr. Weiss continued, "We look forward to presenting the final results from this Phase 2 trial including Week 48 data on up to 48 patients at a major medical meeting later this year."

Oral Presentation Title:Phase 2 Multicenter Study Results of Ublituximab, a Novel Glycoengineered AntiCD20 Monoclonal Antibody (mAb), in Patients with Relapsing Multiple Sclerosis (RMS)

This Phase 2 trial is a 48-week randomized, placebo controlled, multi-center study evaluating the safety and efficacy of ublituximab at accelerated infusion times as fast as one hour. Today's oral presentation includes Week 24 data from 48 patients with relapsing forms of multiple sclerosis (RMS) that were treated with ublituximab across six dosing cohorts, as well as data from the first 14 patients through Week 48.

Highlights:

- An Annualized Relapse Rate (ARR) of 0.07, calculated cumulatively, based on 48 subjects with a mean follow-up of approximately 11 months
- 99% median B-cell depletion was observed at week 4 and maintained at Week 24 (n=44)
- Ublituximab completely eliminated all (100%) of T1 Gd-enhancing lesions at Week 24 (n=44) (p=0.003) and at Week 48 (n=14)
- 7.67% Reduction in T2 lesion volume at Week 24 from baseline (n=44) and a 10.5% reduction in T2 lesion volume at Week 48 from baseline (n=14)
- Ublituximab was well tolerated across all patients including those receiving rapid infusions, as low as a one hour for the 450mg Phase 3 dose

These data presentations support the international Phase 3 ULTIMATE program evaluating ublituximab for the treatment of relapsing forms 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 are being led by Lawrence Steinman, MD, of Stanford University. The ULTIMATE trials are currently enrolling and complete enrollment is expected by the end of 2018.

POSTER

A copy of the above poster can be found on the Publications page, located within the Pipeline section, of the Company's website at www.tgtxinc.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 two 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 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 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 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 any poster presentation will not 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 ublituximab for MS; the risk that ublituximab 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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