TG Therapeutics, Inc. Announces Final Phase 2 Multiple Sclerosis Data Accepted for Oral Presentation at the Upcoming 34th Congress of ECTRIMS

September 26, 2018

Annualized Relapse Rate (ARR) of 0.07 observed for all patients

Complete (100%) elimination of T1 Gd-enhancing lesions at week 24 and maintained at week 48

NEW YORK, Sept. 26, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that the final Phase 2 data from the multicenter trial of ublituximab (TG-1101), the Company’s novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS) has been selected for oral presentation at the upcoming 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), to be held October 10 – 12, 2018 in Berlin, Germany. Abstracts are now available online and can be accessed on the ECTRIMS meeting website at www.ectrims-congress.eu. Highlights from the abstract and details of the poster presentation are outlined below.

The oral presentation is expected to include final data on all patients enrolled in the study through 48 weeks of treatment.

Abstract Highlights:

- An Annualized Relapse Rate (ARR) of 0.07 was observed for all patients
- Ublituximab completely eliminated all (100%) of T1 Gd-enhancing lesions at week 24 (n=44) and maintained at week 48 (n=22)
- Median B cell depletion was >99% at the primary analysis point of Week 4, and maintained at Week 24 (n=44) and Week 48 (n=22)
- Ublituximab was well tolerated with no study drug related severe adverse events (SAE’s) reported and accelerated infusions times as short as 1 hour for the 450mg Phase 3 dose and regimen did not increase the rate of Infusion Related Reactions (IRR)

Michael S. Weiss, the Company’s Executive Chairman and Chief Executive Officer stated, “We are extremely pleased to announce the final Phase 2 MS data has been accepted for an oral presentation at the annual congress of ECTRIMS taking place next month. The abstract published today includes data from the first 22 patients treated through week 48, and the data continue to demonstrate that ublituximab is an active treatment for patients with MS. The oral presentation will include the final data for the Phase 2 study including all 48 enrolled patients through week 48. We have been impressed with the data presented to date and look forward to presenting the final Phase 2 data, which we believe should be representative of our ongoing ULTIMATE Phase 3 program.”

Oral Presentation Details:

- Title: Final Results of a Placebo Controlled, Phase 2 Multicenter Study of Ublituximab (UTX), a Novel Glycoengineered Anti-CD20 Monoclonal Antibody (mAb), in Patients with Relapsing Forms of Multiple Sclerosis (RMS)
- Presentation Date & Time: Thursday, October 11th, 2018; 16:51-17:03 CEST
- Session Title: Free Communications 4 - Treatment
- Presenter: Edward Fox, MD, PhD, Central Texas Neurology Consultants, Round Rock, Texas

These data support the ongoing international Phase 3 program evaluating ublituximab (TG-1101) 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 are being led by Lawrence Steinman, MD, of Stanford University.

A copy of the above abstract can be found on the ECTRIMS meeting website at www.ectrims-congress.eu. Following the presentation, the data presented will be 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 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 data seen in the Phase 2 MS trial program and performance in 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 or in the MS Phase 3 program; the risk that data included in the abstract submission will not be reproduced in the full data presentation; 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 to treat MS; our ability to successfully and cost-effectively complete the MS Phase 3 trials; 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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