TG Therapeutics, Inc. Announces Final Phase 2 Multiple Sclerosis Data Presentation at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Annual Meeting

March 1, 2019

Annualized Relapse Rate (ARR) of 0.07 observed for all patients on Phase 2 MS trial

NEW YORK, March 01, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company dedicated to developing medicines for patients with B-cell mediated diseases, today announced the final 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 were presented yesterday at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) annual meeting held in Dallas, TX. The data was previously presented at the 34thCongress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting held in October of 2018.

Highlights from the presentation are outlined below.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased by the final Phase 2 MS data presented last night at ACTRIMS. We believe our Phase 2 data present a compelling profile of best-in-class activity coupled with a convenient one-hour infusion. With our Phase 3 ULTIMATE program fully enrolled, we are looking forward to the results next year."

The presentation includes final data on all patients enrolled in the study through 48 weeks of treatment.

Presentation Highlights:

- An Annualized Relapse Rate (ARR) of 0.07 was observed with 93% of subjects relapse free at Week 48
- Median B cell depletion was >99% at the primary analysis point of Week 4 (n=48), and maintained at Week 24 and Week 48
- Ublituximab completely eliminated all (100%) of T1 Gd-enhancing lesions at Week 24 and maintained complete elimination at Week 48 (n=46)
- 10.6% reduction in T2 lesion volume from baseline to Week 48 (n=46)
- Ublituximab was well tolerated across all patients including those receiving rapid infusions, as low as a one hour for the 450mg dose currently being studied in the Phase 3 ULTIMATE program and no study drug related discontinuations occurred

These data support the ongoing, fully enrolled, international Phase 3 program evaluating ublituximab for the treatment of 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 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 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 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 its anti-PD-L1 monoclonal antibody, TG-1501, as well as its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801, 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.

CONTACT:

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



Source: TG Therapeutics, Inc.