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

October 11, 2018

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

ECTRIMS data review conference call to be held today, October 11, 2018, 19:30 CEST/1:30pm ET

NEW YORK, Oct. 11, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), 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 is being presented today during an oral session at the 34thCongress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), in Berlin, Germany. 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 today during the annual congress of ECTRIMS. We believe this complete dataset, which now includes all patients through 48 weeks, confirms the efficacy and safety profile of ublituximab and provides a compelling rationale for its use to treat patients with MS. This final data compare very favorably with previously presented data for ocrelizumab, the only approved anti-CD20 for the treatment of MS. With more than 1 million patients currently living in the United States with MS, we believe ublituximab will become an important treatment option, representing a major market opportunity for us." Mr. Weiss continued, "These data support our fully enrolled global Phase 3 ULTIMATE program, being conducted under SPA agreement with the FDA, which if successful would support the full approval of ublituximab in relapsing forms of MS."

"The final Phase 2 ublituximab data presented today is highly encouraging and further confirms the safety and efficacy seen in Multiple Sclerosis patients treated with ublituximab. It was especially interesting to see that the one hour infusion was well tolerated by patients. The approval of ocrelizumab confirmed anti- CD20's as an important part of the MS treatment paradigm and ublituximab's shorter infusion time and tolerable safety profile offer a real advantage to our patients. We look forward to the results of the ublituximab Phase 3 ULTIMATE program and advancing this important treatment option forward," 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.

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

Oral 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)
- 17% of patients met the criteria for 24 Week Confirmed Disability Improvement (CDI) at Week 48
- 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

Conference Call Details:

- **Title:** TG Therapeutics ECTRIMS Data Review Call
  - **Date & Time:**Thursday, October 11th, 2018; 19:30 CEST/ 1:30pm ET
  - **Dial in:** 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.)
  - **Webcast:**http://ir.tgtherapeutics.com/events
  - **Presenter:**Edward Fox, MD, PhD, Director, MS Clinic of Central Texas, Central Texas Neurology Consultants, PA and Clinical Associate Professor at the University of Texas Dell Medical School

An audio recording of the conference call will also be available for replay at www.tgtherapeutics.com, for a period of 30 days after the call.

These data support the ongoing international Phase 3 program evaluating ublituximab (TG-1101) 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 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 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.

CONTACT:

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

TG Therapeutics Logo

Source: TG Therapeutics, Inc.