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TG Therapeutics Announces Completion of Enrollment and B-cell Depletion Data from Part 1 of Ongoing Phase 2 Multiple Sclerosis Study

Early data demonstrates rapid and profound B-cell reductions in MS patients treated with TG-1101 with median B-cell reduction of 99%

TG-1101 was well tolerated with no grade 3/4 adverse events reported, including at the target Phase 3 dose given in a 1-hour infusion

Data from this study to be submitted for presentation at a neurology conference in 2017

Phase 3 MS program planned to initiate in 1H 2017

NEW YORK, Jan. 11, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced the completion of enrollment into Part 1 of its ongoing Phase 2 study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in patients with relapsing forms of multiple sclerosis (RMS). The study, led by Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX, evaluated three dosing cohorts, each with 8 patients. The primary objective of the study was to assess the safety and tolerability of TG-1101 in patients with RMS as well as to determine the optimal dosing regimen for TG-1101 by examining the level of B-cell depletion and the tolerability of accelerated infusion times. Established MS clinical efficacy endpoints are also being evaluated, which require longer-term follow-up and are anticipated to be reported on later this year or next year at a medical conference.

Part 1 of the study is exploring TG-1101 at an initial dose of 600 mg administered as a 150 mg infusion on day 1 and 450 mg infusion on day 15, followed by either 450 mg or 600 mg at week 24. The day 15 and week 24 doses were subject to accelerated infusion times by cohort, down to a 1-hour infusion by cohort 3. The median B-cell depletion for all patients in Part 1 was 99% and TG-1101 was well-tolerated with no grade 3/4 adverse events reported, including in patients receiving the one-hour infusion at the target Phase 3 dose and infusion rate. As Part 2 of the trial, the Company has added expansion cohorts and will explore accelerated dosing of the initial 150mg dose.

"Multiple sclerosis remains a debilitating disease and an area of unmet need. Recent data shows that B-cell depletion therapy may be amongst the most efficacious new weapons to fight MS. The speed at which we were able to rapidly enroll into this study demonstrates the on-going need for new treatment options for patients. We were extremely pleased to see rapid and robust B-cell depletion and excited to see that a one-hour infusion was well tolerated, possibly providing an important convenience advantage over first generation anti-CD20 monoclonal antibodies. We look forward to continuing enrollment into one or more expansion cohorts and to launching a Phase 3 program in the first half of this year," stated Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer.

"B-cell depletion therapy has proven to be highly efficacious in the treatment of both relapsing and progressive forms of MS and we are highly encouraged by the rapid b-cell depletion that we have seen with TG-1101. Given the favorable safety profile, and unique ability for TG-1101 to be dosed in a rapid 1-hour infusion, we are excited to continue to enroll into this study and participate in the Phase 3 program," stated Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX.

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, 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 are in clinical development for patients with hematologic malignancies, with TG-1101 recently entering clinical development for autoimmune disorders. The Company also has preclinical programs to develop IRAK4 inhibitors, BET inhibitors, and anti-PD-L1 and anti-GITR antibodies. 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, as well as anticipating the timing of the release of additional data from our Phase 2 MS trial and commencement 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 trial; 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 the clinical results from the MS Phase 3 program, if conducted, will be not positive and/or will not support regulatory approval of TG-1101 for MS; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior clinical trials; 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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