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TG Therapeutics, Inc. Announces the Phase 3 ULTIMATE Trials Evaluating TG-1101 in Patients with Multiple Sclerosis Are Now Open for Enrollment

NEW YORK, Sept. 15, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced that enrollment is now open for the Phase 3 ULTIMATE I and II trials. ULTIMATE I and II are two independent Phase 3 clinical trials evaluating the safety and efficacy of TG-1101 (ublituximab), the Company's glycoengineered anti-CD20 monoclonal antibody, as compared to teriflunomide, in patients with relapsing forms of Multiple Sclerosis (RMS). These studies are being led by Dr. Lawrence Steinman, of Stanford University and are being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics, stated, "Thanks to the hard work of our clinical team, we are excited to open enrollment into our ULTIMATE Phase 3 clinical program. The speed at which our team was able to bring TG-1101 into Phase 3 for Multiple Sclerosis under a Special Protocol Assessment is truly unprecedented and represents an important milestone for us." Mr. Weiss continued, "We believe B-cell targeted therapy has the potential to become the leading treatment option for MS and that TG-1101 has the potential to differentiate itself amongst the other B-cell targeted therapies by offering a rapid, convenient one hour infusion at an attractive price. We are highly encouraged by the early data seen in our Phase 2 trial and look forward to presenting additional data from that study at the ECTRIMS-ACTRIMS meeting next month."

Lawrence Steinman, MD, George A. Zimmermann Professor and Professor of Pediatrics, Neurology and Neurological Sciences at Stanford University, and global study chair for both ULTIMATE I and ULTIMATE II trials commented, "The approval of Ocrelizumab as a B-cell targeted therapy for the treatment of Multiple Sclerosis has truly changed the treatment landscape by offering a new method to treat this disease. We are excited to lead this Phase 3 trial and evaluate the unique attributes of ublituximab which may provide a more convenient and possibly less costly treatment option for our patients. At our recently concluded investigator meeting, there was much enthusiasm for this trial and the potential benefits this novel agent may provide our patients."

ABOUT THE ULTIMATE TRIALS

ULTIMATE I and ULTIMATE II are two independent Phase 3 trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing TG-1101 (ublituximab) to teriflunomide in subjects with relapsing forms of Multiple Sclerosis (RMS). The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment. Each trial will enroll approximately 440 subjects, randomized in a 1:1 ratio, with approximately 880 patients to be enrolled across both trials. Additional information on these clinical trials can be found at www.clinicaltrials.gov.

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 pre-clinical 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 the timing of the first patient enrolled into 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, will be not positive and/or will not support regulatory approval of TG-1101 for MS; the risk that TG-1101 will not have a differentiated profile from the other drugs in the class; the risk that some of the perceived attributes of TG-1101, in particular the infusion times and potential pricing advantages may not be incorporated into future plans 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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