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TG Therapeutics Recaps Preliminary Results from Ongoing Phase 2 Study of TG-1101 (ublituximab) in Patients with Multiple Sclerosis at the 3rd Congress of the European Academy of Neurology

MS patients treated with TG-1101 exhibited median B-cell depletion of 99% at week 4

TG-1101 was well tolerated with no grade 3/4 adverse events reported, with median time on study of 5 months

NEW YORK, June 26, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) recapped preliminary results from 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 data was presented this past weekend at the 3rd Congress of the European Academy of Neurology (EAN), taking place in Amsterdam, by Dr. Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas, Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX, and the Principal Investigator for this Phase 2 study. This data was presented previously at the 69th American Academy of Neurology (AAN) annual meeting, which took place in Boston, MA.

Poster Presentation Title: Rapid and Robust B Cell Depletion in Preliminary Results of Phase 2 Multicenter Study of Ublituximab (UTX), a Novel Glycoengineered Anti-CD20 Monoclonal Antibody (mAb), in Patients with Relapsing forms of Multiple Sclerosis (RMS)

This presentation includes data from 24 patients with RMS treated with TG-1101. Three dosing cohorts of up to 8 patients each were evaluated to assess the safety and tolerability of TG-1101 at accelerated infusion times.

Highlights from the poster include:

- TG-1101 was well tolerated with no Grade 3/4 adverse events observed and the most commonly reported AE being infusion related reactions, with median time on study of 5 months
- All scheduled doses were fully delivered to all subjects to date
- The independent DSMB reviewed safety data for each cohort periodically and approved continuation of the study at each review based on acceptable safety measures
- All patients met the primary end-point of > 95% B-cell depletion by 4 weeks
- The median B-cell depletion at week 4 was 99% after two infusions (Day 1 and 15) with a cumulative dose of 600mg, which compares favorably with other anti-CD20 monoclonal antibodies

POSTER PRESENTATION DETAILS

A copy of the poster presentation is available on the Company's website at www.tgtherapeutics.com, located on the Publications Page, within the Pipeline section.

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 TG-1101 will not have a differentiated profile from the other drugs in the class 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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