



September 16, 2016

TG Therapeutics, Inc. Announces Presentation of Data from a Phase Ib Clinical Trial of TG-1101 in Patients with Neuromyelitis Optica (NMO) at the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis

LONDON, Sept. 16, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX) today announced the presentation of data from a Phase Ib open label study of TG-1101 (ublituximab), the Company's novel, glycoengineered anti-CD20 monoclonal antibody, for the treatment of patients with acute optic neuritis and/or transverse myelitis in neuromyelitis optica (NMO) and neuromyelitis optica spectrum disorder (NMOSD). The data is being presented today, Friday, September 16, 2016, from 15:30 - 17:00 BST, at the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), being held at the ExCel, in London, UK.

The poster, entitled "Phase Ib, open label study of ublituximab in acute relapses of neuromyelitis optica spectrum disorder," (Abstract Number: P1195), is being presented by Michael Levy, MD, PhD, an Associate Professor of Neurology & Director of the Neuromyelitis Optica Clinic at the Johns Hopkins University, and principle investigator of the study, and includes data from patients with acute NMO relapses treated with a combination of ublituximab and corticosteroids. Highlights from the poster include:

- | A single 450 mg infusion of TG-1101 (ublituximab) rapidly and effectively depleted B-cells during acute NMO relapses without significant risks in this patient population
- | TG-1101 was well tolerated, with minimal adverse events and no SAEs or infections observed
- | Timed 25-foot walk and visual acuity, NMO-specific functional measures of recovery, improved along with EDSS scores in patients treated with TG-1101 in combination with corticosteroids

"We are encouraged by the ability of TG-1101 to safely and rapidly deplete B-cells, even with a single low dose, which we believe will be key to the success of TG-1101 in treating patients with autoimmune disorders such as NMO/NMOSD and multiple sclerosis," stated Michael S. Weiss, Executive Chairman and Interim CEO of TG Therapeutics. Mr. Weiss continued, "NMO and NMOSD, disorders which are closely related to multiple sclerosis, represent areas of significant unmet medical need, with no currently approved treatments. We are pleased by the data presented today as well as the orphan drug status that was granted to TG-1101 in NMO and NMOSD just a few weeks ago. We look forward to reviewing additional information from this trial as well as exploring future clinical trial opportunities in NMO and multiple sclerosis."

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 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

Some of the statements included in this press release, particularly those with respect to anticipating benefits from Orphan Drug Designation for TG-1101, future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies 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 pre-clinical and clinical trials for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies will not be reproduced in additional patients or in future studies; the risk that trends observed which underlie certain assumptions of future performance of TGR-1202 will not continue, the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase I study; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303, will not prove to be a safe and efficacious backbone for triple and quad combination therapies; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior pre-clinical and 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.

TGTX - G

CONTACT:

Jenna Bosco

Vice President, Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4351

Email: ir@tgtxinc.com

 [Primary Logo](#)

Source: TG Therapeutics, Inc.

News Provided by Acquire Media