October 16, 2017

TG Therapeutics, Inc. Recaps Clinical Data Presentations at the Upcoming 7th Joint ECTRIMS - ACTRIMS Meeting

B-cell depletion data and MRI data at 24 weeks (6 months) to be presented

Abstract data shows complete (100%) elimination of T1 Gd-enhancing lesions at week 24

NEW YORK, Oct. 16, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced that clinical abstracts featuring data from the Phase 2 multicenter trial of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS) have been selected for presentation at the upcoming 7th Joint ECTRIMS - ACTRIMS meeting, to be held next week, October 25 - 28, 2017, at the Le Palais de Congrès de Paris, in Paris, France. Abstracts are now available online and can be accessed on the ECTRIMS meeting website at www.ectrims-congress.eu. Details of the poster presentations are outlined below.

Abstract Highlights:

- *TG-1101 completely eliminated all (100%) of T1 Gd-enhancing lesions at week 24 (n=16)*
- *At week 4, median 99% B-cell depletion was observed and maintained at week 24 (6 months) (n=24)*
- *TG-1101 was well tolerated with no study drug related SAE's reported and accelerated infusions times as short as 1 hour for the 450mg Phase 3 dose and regimen did not increase the rate of Infusion Related Reactions (IRR) (n=24)*

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are excited to release the first clinical MRI data of TG-1101 in patients with RMS as we believe the abstract data presents an extremely compelling case for the use of TG-1101 in the treatment of patients with MS. While still early, the data thus far is setting the stage for a best-in-class profile for TG-1101 in treating MS. We are looking forward to presenting the full data on the first three cohorts (n=24) through 24 weeks (6 months) of treatment at the ECTRIMS-ACTRIMS meeting next week." Mr. Weiss continued, "We will continue to update these data at multiple conferences over the next year as we treat and follow the full 48 patients (from the 6 cohorts) for up to 1 year. With our Phase 3 program now underway pursuant to a Special Protocol Assessment (SPA), we believe MS represents the next level of growth for the Company."

Poster Presentation Details:

• Title: Patient characteristics, safety, and preliminary results of a placebo controlled, phase 2a multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis

- Presentation Date & Time: Thursday, October 26th, 2017; 15:30-17:00 CEST
- Session Title: Poster Session 1
- Presenter: Edward Fox, MD, PhD, Central Texas Neurology Consultants, Round Rock, Texas

• Title: 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) demonstrates rapid Gd-enhancing lesions decrease

- Presentation Date & Time: Thursday, October 26th, 2017; 15:30-17:00 CEST
- Session Title: Poster Session 1
- Presenter: Matilde Inglese, MD, PhD, Icahn School of Medicine at Mount Sinai, New York, NY

• Placebo controlled, phase 2a multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis (RMS): 6 months analysis of B cell subsets

- Presentation Date & Time: Friday, October 27 th, 2017; 15:30-17:00 CEST
- Session Title: Poster Session 2

- Presenter: Amy E. Lovett-Racke, PhD, The Ohio State University, Columbus, OH

These data presentations support the recently announced international Phase 3 program evaluating TG-1101 (ublituximab) for the treatment of relapsing form 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 will be led by Lawrence Steinman, MD, of Stanford University.

A copy of the above abstracts can be found on the ECTRIMS meeting website at www.ectrims-congress.eu. Following each poster presentation, the data presented will be available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com.

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 (umbralisib), 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, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 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 early data seen in the Phase 2 MS trial and anticipating the timing 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 and Phase 3 trials; 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 TG-1101 for MS; the risk that TG-1101 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.

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.