



TG Therapeutics, Inc. Announces Updated Results from the Ongoing Phase 2 Study of Ublituximab (TG-1101) in Patients with Multiple Sclerosis at the American Academy of Neurology 70th Annual Meeting

April 24, 2018

Data on now up to 48 patients through 24 weeks confirms previously reported positive results

NEW YORK, April 24, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced updated results from the Phase 2 multicenter trial of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS). The data is being presented today during Poster Session P3, from 5:30 PM – 7:00 PM PT, at the American Academy of Neurology 70th Annual Meeting in Los Angeles, California.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased by the data presented today which now includes a total of 48 patients across six dosing cohorts for a period of up to 24 weeks. With more patients now through 24 weeks of follow-up, the data continue to confirm the efficacy of ublituximab with sustained B-cell depletion, 100% reduction in T1 Gd-enhancing lesions, and most importantly, an annualized relapse rate (ARR) that remains below the ARR observed with ocrelizumab, the only approved anti-CD20 monoclonal antibody for MS, in its similarly sized Phase 2 study. ARR is the primary endpoint of our Phase 3 trial, which was modeled and powered based on the results from the ocrelizumab pivotal trial. We are excited by the emerging clinical profile of ublituximab that appears to have comparable to better activity than ocrelizumab, with a manageable safety profile and the convenience of a one hour infusion." Mr. Weiss continued, "We look forward to presenting additional data from this Phase 2 trial including 48 week data on up to 48 patients at major medical meetings later this year."

This Phase 2 trial is a 48-week randomized, placebo controlled, multi-center study evaluating the safety and efficacy of ublituximab at accelerated infusion times as fast as one hour. Today's poster includes 6 month (24 week) data from 48 patients with relapsing forms of multiple sclerosis (RMS) that were treated with ublituximab across six dosing cohorts.

Poster Title: Final MRI Results At 6 Months From A Phase 2 Multicenter Study Of Ublituximab, A Novel Glycoengineered Anti-CD20 Monoclonal Antibody (mAb), In Patients With Relapsing Forms Of Multiple Sclerosis (RMS), Demonstrates Complete Elimination Of Gd-Enhancing Lesions (Abstract # 3253)

Poster Highlights:

- An Annualized Relapse Rate (ARR) of 0.05 was observed at Week 24 (n=48)
- 99% median B-cell depletion was observed at week 4 and maintained at Week 24 (n=44)
- Ublituximab completely eliminated all (100%) of T1 Gd-enhancing lesions at Week 24 (n=44) (p=0.003)
- 98% of subjects were relapse free at Week 24
 - One confirmed relapse was reported, in Cohort 1. The patient was initially randomized to the placebo arm. The relapse occurred shortly (12 days) after crossover to active treatment of 150mg of ublituximab. The patient remains on study and has received the second and third infusions of ublituximab and to date has remained relapse free.
- 83% of subjects showed improved or stable EDSS with a mean EDSS improvement from baseline of 0.29
- Ublituximab was well tolerated across all patients including those receiving rapid infusions, as low as a one hour for the 450mg Phase 3 dose

These data presentations support the international Phase 3 ULTIMATE program evaluating ublituximab for the treatment of relapsing forms 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 are being led by Lawrence Steinman, MD, of Stanford University. The ULTIMATE trials are currently enrolling and complete enrollment is expected in the first quarter of 2019.

POSTER

A copy of the above poster can be found on the Publications page, located within the Pipeline section, of the Company's website at www.tgtxinc.com/publications.cfm.

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. Ublituximab (TG-1101) 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 umbralisib (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 ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab 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 any poster presentation will not be reproduced in subsequent data presentations; the risk that the clinical results from the MS Phase 3 program, will not be positive and/or will not support regulatory approval of ublituximab for MS; the risk that ublituximab 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.

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