TG Therapeutics Announces Completion of Target Enrollment in the ULTIMATE Phase 3 Trials in Multiple Sclerosis

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NEW YORK, Aug. 07, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced that target enrollment in the ULTIMATE I and II Phase 3 trials has been achieved. ULTIMATE I and II are two independent Phase 3 clinical trials evaluating the safety and efficacy of ublituximab (TG-1101), 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). While target enrollment has been reached, in order to provide an opportunity for patients already identified to participate, enrollment is expected to continue until mid-September.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased to have achieved target enrollment in the ULTIMATE Phase 3 trials approximately 9 months ahead of originally anticipated, which may enable an accelerated readout of the results possibly as early as the middle of 2020." Mr. Weiss continued, "We've presented several early cuts of data from our Phase 2 MS trial of ublituximab at key conferences over the last year and believe the safety and activity demonstrated thus far support our belief that the ULTIMATE Phase 3 studies will be positive. We look forward to presenting the final data from our Phase 2 MS study at a major medical conference before year end. With the Phase 3 MS studies completing enrollment earlier than expected, we now have multiple pivotal data read-outs projected to occur between now and mid-2020 from both our cancer and MS programs."

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 ublituximab (TG-1101) 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. 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. 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, as well as anticipating the timing of the release of additional data from our Phase 2 MS trial and the timing of complete enrollment or anticipation of positive data from our Phase 3 ULTIMATE program in MS 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 from the MS Phase 2 trial will not be reproduced in the final MS Phase 2 data or in the MS Phase 3 ULTIMATE trials; the risk that the clinical results from the MS Phase 3 program, will be not 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; the risk that some of the perceived attributes of ublituximxab in MS, in particular the infusion times and potential pricing advantages may not be incorporated into future plans; the risk that some or all of the pivotal trials expected by mid-2020 will be delayed, will be not be considered pivotal and/or will not be positive or otherwise not support regulatory approval; 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.

CONTACT:

Jenna Bosco
Senior VP, Corporate Communications
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

Primary Logo

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