



December 6, 2016

TG Therapeutics, Inc. Announces that the GENUINE Phase 3 Study has Reached Target Enrollment

Top-line data expected first half 2017

NEW YORK, Dec. 06, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced that the target enrollment of 120 patients in the GENUINE Phase 3 study has been met and enrollment will be closed shortly. The GENUINE Phase 3 study is a randomized study of TG-1101, the Company's novel, glycoengineered anti-CD20 monoclonal antibody in combination with ibrutinib, the oral Bruton's tyrosine kinase (BTK), versus ibrutinib alone in approximately 120 patients with high-risk relapsed or refractory Chronic Lymphocytic Leukemia (CLL). In October, the study was modified to convert the primary endpoint solely to Overall Response Rate (ORR). If the study results are positive, and subject to a positive outcome of pre-BLA meeting with the FDA, the Company plans to utilize the results to file for accelerated approval. The Company expects to release top-line data from the GENUINE Phase 3 study in the first half of 2017.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commenting on the announcement stated, "Today's news puts us on a clear path toward our first pivotal data for TG-1101. As demonstrated in our Phase 2 study evaluating TG-1101 plus ibrutinib, we believe the addition of an anti-CD20 monoclonal antibody can enhance the clinical response of single agent ibrutinib by more rapidly reducing tumor burden, increasing the rate of response, deepening responses and, ideally, leading to better long-term outcomes. Overall response rate has been utilized as an acceptable surrogate endpoint for improved progression free survival and overall survival for a number of recent approvals in high-risk CLL and we believe the results, if positive, may support an accelerated approvable for the combination. We want to thank our clinical collaborators and their patients for their participation in this study."

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 (ublrituximab) 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 the timing of the completion of the GENUINE study, timing of the completion of the UNITY-CLL study, timing of filing of a BLA for TGR-1101, and projected cost savings from amending the GENUINE study 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 GENUINE or the UNITY-CLL trials; the risk that the clinical results from the GENUINE or UNITY-CLL studies will be not positive and/or will not support regulatory approval of TG-1101 or TGR-1202; the risk that the FDA will not grant us a pre-BLA meeting to discuss the results of the GENUINE study; the risk that we will not file a BLA for TG-1101 or an NDA for TGR-1202 based on either the GENUINE or the UNITY-CLL; the risk that despite early positive trends in enrollment in the UNITY-CLL study that enrollment will be delayed beyond our projections; the risk that the planned interim analysis will not allow early closure of the single agent arms in the UNITY-CLL study, necessitating enrollment beyond the projected 450 patients, which would extend enrollment beyond our projections; the risk that safety issues or trends will be observed in the GENUINE study or the UNITY-CLL study that prevent approval of either TG-1101 and/or TGR-1202 or require us to terminate either the GENUINE study or the UNITY-CLL study prior to completion; 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 the GENUINE study, as amended or the UNITY-CLL study, or any of our other registration-directed clinical trials as designed or amended may not be sufficient or acceptable to support regulatory approval; the risk that trials will take longer to enroll than expected; the risk that the

projected cost savings to be realized by amending the GENUINE trial will not be realized; 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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