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TG Therapeutics, Inc. Announces Publication of Clinical Data from the Phase 2 Trial of TG-1101 (ublituximab) in Combination with Ibrutinib in the British Journal of Haematology

Combination treatment resulted in 95% ORR in patients with High-Risk CLL, the patient population being evaluated in the Phase 3 GENUINE Trial

NEW YORK, Dec. 16, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) announced the publication of clinical data from a Phase 2 study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with ibrutinib, the oral BTK inhibitor, in patients with Chronic Lymphocytic Leukemia (CLL). The data, which was presented at the 2015 International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland, demonstrates the combination to be well tolerated with limited grade 3/4 adverse events observed. An 88% overall response rate (ORR) was reported at month 6 for all patients treated, with a 95% ORR observed in patients with high risk CLL (presence of a 17p or 11q deletion or a TP53 mutation). These data are described further in the manuscript titled, "Ublituximab (TG-1101), a novel, glycoengineered anti-CD20 antibody, in combination with ibrutinib is safe and highly active in patients with relapsed and/or refractory chronic lymphocytic leukemia: results of a phase 2 trial," which was published online today in the *British Journal of Haematology*. The online version of the article can be accessed at http://onlinelibrary.wiley.com/.

"We want to thank Dr. Jeff Sharman and the team at the US Oncology Network for their work on this important Phase 2 study and congratulate them on this peer-reviewed publication. We believe the chemo-free combination of TG-1101 and ibrutinib is an effective and much needed treatment option for patients with high-risk CLL who continue to exhibit a poor prognosis, and the data in this publication underscores our belief. The results from this study support the GENUINE Phase 3 study, and given the dramatic and rapid responses seen in this Phase 2, we are confident in the success of GENUINE. We recently announced the completion of enrollment in the revised GENUINE trial and look forward to announcing top line data in the first half of 2017," stated Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer.

"While ibrutinib is effective in patients with CLL, it is not the only answer. In this study, the addition of ublituximab to ibrutinib not only produced high response rates, but also allowed patients to achieve deeper responses with complete responses and minimal residual disease (MRD) negativity seen, which is rare with ibrutinib alone. We look forward to exploring how the increased depth of response may affect the sequence of treatments given to patients," stated Dr. Jeff Sharman, Medical Director of Hematology Research for the US Oncology Network.

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 preclinical 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 topline data for the GENUINE study, the usability of the results from GENUINE for accelerated approval, timing of initial data from the UNITY-DLBCL study, timing of the release of data and commencement of our MS pivotal 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 GENUINE, the UNITY-CLL or the UNITY-DLBCL trials; the risk that the clinical results from the GENUINE, UNITY-CLL and/or UNITY-DLBCL 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, the UNITY-CLL and/or the UNITY-DLBCL 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 or the UNITY-DLBCL 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 or the UNITY-DLBCL studies, 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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