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TG Therapeutics Provides Update on FDA Meeting for GENUINE Phase 3 Trial

Follow-up meeting with FDA expected before year end

NEW YORK, Oct. 16, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics (NASDAQ:TGTX) announced today that it has met with the U.S. Food and Drug Administration (FDA) regarding the use of the results from the GENUINE Phase 3 trial to support a Biologics License Application (BLA) filing for approval of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with ibrutinib. During the meeting, the FDA confirmed that accelerated approval based on Overall Response Rate (ORR) would be a review issue. As part of the discussion, the FDA encouraged the Company to consider future available therapy in its risk/benefit analysis as part of any potential future BLA filing that may impact accelerated approval.

The Company and the FDA also discussed the potential use of Progression Free Survival (PFS) results from the GENUINE trial to support the full approval of TG-1101. The Company plans to have a follow-up meeting with the FDA to discuss the use of the PFS endpoint in more detail before the end of the year and also plans to monitor the regulatory landscape for new approvals of agents for previously treated high-risk Chronic Lymphocytic Leukemia (CLL) while continuing to make preparations for a BLA filing as early as 2Q18.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We had a very productive meeting with the FDA regarding the GENUINE study and its use for approval of TG-1101 in combination with ibrutinib. We look forward to our follow-up meeting and working with the FDA in an effort to reach an agreement on the potential use of PFS for full approval in a similar timeframe as accelerated approval." Mr. Weiss continued, "We were also pleased to announce today the early completion of UNITY-CLL, which makes the potential filing timelines for GENUINE and UNITY-CLL now nearly overlapping, setting the stage for an exciting 2018."

ABOUT THE PHASE 3 GENUINE TRIAL

The Phase 3 GENUINE study is a randomized, open label, multicenter clinical trial to evaluate the safety and efficacy of TG-1101 (ublituximab) plus ibrutinib compared to ibrutinib alone in adult patients with high risk Chronic Lymphocytic Leukemia (CLL) who received at least one prior therapy for their disease. The study was conducted at 160 clinical trial sites in the US and Israel and randomized 126 patients. Patients received ibrutinib orally at 420 mg once daily in both arms and in the treatment arm those patients also received intravenous infusions of TG-1101 at 900 mg dosed on days 1, 8 and 15 of cycle 1 and day 1 of cycles 2-6. Patients in the treatment arm who had not progressed received quarterly infusions of TG-1101 maintenance at 900 mg.

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

Some of the statements included in this press release 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. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, factors that could cause our actual results to differ materially are the following: the risk that the clinical results from the GENUINE trial or the UNITY-CLL trial may not be sufficient or may not

support regulatory approval of TG-1101 or TGR-1202; the risk that the company will not be able to deliver data or updates on schedule as planned; the risk that a filing based on UNITY-CLL, GENUINE or any other registration-direct trials cannot be made on schedule as targeted or at all; the risk that the filing timelines for GENUINE and UNITY-CLL do not overlap or do not occur at all; the risk that the company will not file a BLA for TG-1101 based on the GENUINE trial; the risk that the regulatory landscape for available therapies changes prior to a potential approval of TG-1101 based on GENUINE in a way that prevents an accelerated approval; the risk that the Company and FDA are not able to reach an agreement on the use of the PFS endpoint for full approval or, if an agreement is reached, that the PFS results are not positive and supportive of approval; the risk that safety issues or trends will be observed in the GENUINE or UNITY-CLL studies that prevent approval; the risk that the company decides not to use the GENUINE trial results to seek accelerated approval of TG-1101; the risk that early clinical trial results, that may have influenced our decision to proceed with additional clinical trials, will not be reproduced in the final data. 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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