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TG Therapeutics Announces Completion of Full Enrollment in the UNITY-CLL Phase 3 Trial

Top-Line ORR data from the UNITY-CLL trial expected in 2Q18

Targeting an NDA/BLA filing for combination of TGR-1202 + TG-1101 in 2H18

NEW YORK, Oct. 16, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics (NASDAQ:TGTX) announced today that it has completed full enrollment in the UNITY-CLL Phase 3 clinical trial. The UNITY-CLL Phase 3 trial is a randomized study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with TGR-1202 (umbralisib), the Company's PI3K delta inhibitor (together referred to as the U2 regimen), compared to an active control arm of obinutuzumab plus chlorambucil, in patients with both treatment naïve and relapsed or refractory Chronic Lymphocytic Leukemia (CLL). The UNITY-CLL trial is being conducted under Special Protocol Assessment (SPA) agreement with the Food and Drug Administration (FDA).

Last month, the Company announced that target enrollment of 175 patients in each of the TG-1101 plus TGR-1202 and obinutuzumab plus chlorambucil arms was achieved, however, enrollment was extended to allow eligible patients who were already identified or in screening the ability to participate in the study. Completion of full enrollment has now been achieved with more than 200 patients in each of the two combination arms. Approximately 60% of patients enrolled in the combination arms were front-line and 40% were previously-treated. As per the SPA, the primary and secondary endpoint analyses will include all patients. Top-line Overall Response Rate (ORR) data from the UNITY-CLL trial is expected in the second quarter of 2018 and the company is targeting a New Drug Application (NDA)/ Biologics License Application (BLA) filing for the combination of TGR-1202 and TG-1101 in the second half of 2018.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We are pleased to report that UNITY-CLL has now completed full enrollment, far exceeding the original targeted enrollment and doing so much faster than anticipated. We believe the tremendous demand for this study underscores the need for new treatment options for CLL patients as well as the enthusiasm specifically for the U2 regimen. Additionally, with the early completion of UNITY-CLL, the potential filing timelines for GENUINE and UNITY-CLL are now nearly overlapping, with a UNITY-CLL filing based on ORR possible as early as 3Q18." Mr. Weiss continued, "Our goal is to extend quality life for patients with CLL by developing efficacious treatments that are well-tolerated, easy to use and don't require harsh chemotherapy or hospital admission to receive therapy. We believe U2 possesses these attributes and has the potential to become one of the leading treatment options for first and second line CLL."

ABOUT UNITY-CLL PHASE 3 TRIAL

UNITY-CLL is a global Phase 3 randomized controlled clinical trial in patients with Chronic Lymphocytic Leukemia (CLL) that includes two key objectives: first, was to demonstrate contribution of each agent in the TG-1101 (ublituximab) + TGR-1202 (umbralisib) or U2 regimen, and second, to demonstrate superiority in Progression Free Survival (PFS) over the standard of care to support the submission for full approval of the combination. In addition, upon completion of enrollment, this trial will evaluate Overall Response Rate (ORR) for accelerated approval. The study initially randomized patients into four treatment arms: TG-1101 plus TGR-1202, TG-1101 single agent, TGR-1202 agent, and an active control arm of obinutuzumab plus chlorambucil. Pursuant to the Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA), an early interim analysis was conducted to assess contribution of each single agent which allowed for early termination of both single agent arms.

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: our ability to successfully and cost effectively complete the UNITY-CLL trial or deliver data on schedule as planned; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 or "U2," and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination treatment option for any indication; the risk that UNITY-CLL does not demonstrate an ORR advantage or that even if an ORR advantage is shown that the results do not support accelerated approval; the risk that Unity-CLL will not demonstrate a PFS advantage; the risk that safety issues or trends will be observed in the UNITY-CLL study or any other on-going studies that prevent approval of either TG-1101 and/or TGR-1202; the risk that 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 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 early clinical trial results, that may have influenced our decision to proceed with additional clinical trials, will not be reproduced in the final data presented; the risk that the final data will not support regulatory approval. 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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