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

Enrollment expected to continue until mid-October to allow patients already identified an opportunity to participate in the trial

NEW YORK, Sept. 05, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced that target enrollment for the UNITY-CLL Phase 3 trial has been achieved. 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). Per the protocol, the target enrollment was 175 patients in each the U2 arm and the active control arm. While target enrollment has been reached, in order to provide an opportunity for all patients already identified to participate, enrollment is expected to continue until mid-October. The UNITY-CLL Phase 3 trial is being conducted pursuant to a Special Protocol Assessment (SPA) agreement with the Food and Drug Administration (FDA).

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased to announce the completion of target enrollment in the UNITY-CLL clinical trial, nearly 9 months earlier than our original projections. From the beginning, enrollment in this study has exceeded our expectations, putting us in position to deliver top-line data on the ORR endpoint earlier than anticipated, now expected in the second quarter of 2018. If positive, pursuant to our SPA, the ORR data may be used to support a filing for accelerated approval." Mr. Weiss continued, "We want to thank the UNITY-CLL Investigators, research staff, and their patients, for their participation in this important clinical research. Without their commitment and trust, advancing novel medicines would not be possible."

John Gribben, MD, DSc, of the Barts Cancer Institute in London, UK, and Global Study Chair for the UNITY-CLL study stated, "The design of the UNITY-CLL trial is a paradigm shift in the way we approach oncology research, allowing two novel drugs to be evaluated together in a single four-arm study for potential approval. The speed in which target enrollment has completed is even more impressive, considering the size and scope of this innovative study, which also underscores the need for new treatment options despite recent advances. I am eagerly looking forward to presenting results from this study next year."

Ian Flinn, MD, PhD, Director of the Blood Cancer Research Program, Sarah Cannon Research Institute, and a lead US enroller in the UNITY-CLL study stated, "We were pleased at Tennessee Oncology to not only lead enrollment in the first-in-human study of umbralisib, but to now be one of the leading enrollers to the Phase 3 UNITY-CLL trial. The rapid rate of enrollment for both the first-in-human study of umbralisib and the Phase 3 study UNITY study is a testament to the continued need for better, patient-friendly, easy to use, treatment options for both treatment naïve CLL patients and those relapsed or refractory to prior therapy. BTK intolerance and difficulties in delivering anti-bcl2 therapy are challenges for delivering effective chemo-free treatment options for many patients. Approval of the ublituximab + umbralisib regimen would provide new hope to many of those patients.

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 are in clinical development for patients with hematologic malignancies, with TG-1101 also in 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 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 on-time 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 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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