# TG Therapeutics Announces Update Regarding UNITY-CLL Phase 3 Trial

September 25, 2018

**Conference call to be held today, Tuesday, September 25, 2018 at 8:30 am ET**

NEW YORK, Sept. 25, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics (NASDAQ: TGTX) today announced that the independent Data Safety Monitoring Board (DSMB) for the UNITY-CLL Phase 3 trial met to review ongoing data from the study and advised the Company that the interim analysis of Overall Response Rate (ORR) could not be conducted at this time as the data were not sufficiently mature to conduct the analysis. The DSMB did not provide any further guidance but plans to meet quarterly over the next year to continue to monitor the ongoing progress of the trial. Given the uncertainty surrounding the timing and the outcome of the ORR analysis, as well as the significant regulatory hurdles associated with accelerated approval for CLL, the Company is now guiding that it will focus on the primary endpoint of Progression Free Survival (PFS) to support full approval of the ublituximab plus umbralisib (U2) combination. At this time the Company is not planning to seek accelerated approval based on ORR. The Company remains blinded to all efficacy data.

Additionally, the DSMB reviewed safety data from over 600 patients, including over 300 patients treated with umbralisib either alone or in combination with ublituximab, of which approximately 60% were treatment naïve. While no evaluation of PFS was conducted, the DSMB had PFS information available to them solely for purposes of assessing the overall benefit-risk. After review of the data, the DSMB identified no safety concerns and recommended the trial continue without modification. The UNITY-CLL Phase 3 trial continues to be conducted under Special Protocol Assessment (SPA) agreement with the Food and Drug Administration (FDA).

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "While we are disappointed that we were not able to report positive ORR today, we feel that making the decision to focus on PFS, the primary endpoint for the study, is an important step to getting everyone aligned on the endpoint of this study that matters most to the Company and its long-term shareholders. From a timing standpoint, we could have a PFS read out in 2019, and we remain extremely optimistic about the prospects for a successful PFS result. Other B-Cell Receptor antagonists have shown dramatic improvements in PFS in similarly designed studies and we believe the umbralisib early clinical data supports our confidence in a positive PFS outcome from UNITY-CLL."

Mr. Weiss continued, "We now have 5 fully enrolled registration-directed programs, including UNITY-CLL, UNITY- NHL (including Follicular Lymphoma, Marginal Zone Lymphoma and Diffuse Large B-cell Lymphoma cohorts) and the ULTIMATE Phase 3 MS program and are awaiting pivotal data from all of them. With all of these exciting data read-outs to come, we believe we remain well positioned to deliver significant value for our shareholders."

**ABOUT UNITY-CLL PHASE 3 TRIAL**

UNITY-CLL is a global Phase 3 randomized controlled clinical trial comparing the combination of ublituximab plus umbralisib, or U2, to an active control arm of obinutuzumab plus chlorambucil in patients with both treatment naïve and relapsed or refractory Chronic Lymphocytic Leukemia (CLL). The trial randomized patients into four treatment arms: ublituximab single agent, umbralisib single agent, ublituximab plus umbralisib and an active control arm of obinutuzumab plus chlorambucil. A pre-specified analysis was conducted to assess the contribution of ublituximab and umbralisib in the combination regimen of ublituximab plus umbralisib and allowed for the termination of the single agent arms. Accordingly, the UNITY-CLL Phase 3 trial continued enrollment in a 1:1 ratio into the two combination arms: the investigational arm of U2 and the control arm of obinutuzumab plus chlorambucil. Full enrollment into the UNITY-CLL Phase 3 trial completed in October of 2017. This trial enrolled approximately 60% treatment naïve CLL patients and 40% relapsed refractory CLL patients. The primary endpoint for this study is to demonstrate superiority in Progression Free Survival (PFS) for the U2 combination over the control arm to support the submission for full approval of the U2 combination in CLL. The UNITY-CLL Phase 3 trial is being conducted under Special Protocol Assessment (SPA) agreement with the Food and Drug Administration (FDA).

**CONFERENCE CALL INFORMATION**

The Company will host a conference call today, Tuesday, September 25, 2018 at 8:30 am ET to discuss the UNITY-CLL Phase 3 Trial. In order to participate in the conference call, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), Conference Title: TG Therapeutics Update Call.

A live webcast of this presentation will be available on the Events page, located within the Investors & Media section, of the Company's website at www.tgtherapeutics.com. An audio recording of the conference call will also be available for replay at www.tgtherapeutics.com, for a period of 30 days after the call.

**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. Ublituximab (TG-1101) 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 umbralisib (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 ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab 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 complete the UNITY-CLL trial or deliver data on schedule as planned; the risk that the combination of ublituximab and umbralisib referred to as “U2” or previously as “TG-1303” 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 the UNITY-CLL ORR results are not positive; the risk that UNITY-CLL will not demonstrate a PFS advantage and therefore will not meet its primary endpoint; 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 ublituximab and/or umbralisib; 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 submission or approval; the risk that a filing based on GENUINE, UNITY-CLL, UNITY-NHL, ULTIMATE clinical trials or any other registration-directed trials cannot be made on schedule as targeted or at all; the risk that we are unable to manage cash in line with our expectations and meet our development milestones and/or continue our operations without raising capital; the risk that we are unable to raise capital on acceptable terms;  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. 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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