November 22, 2016

TG Therapeutics Announces Positive DSMB Recommendation for Continuation of the UNITY-CLL Phase 3 Trial

No safety concerns identified; UNITY-CLL Phase 3 trial to continue as planned

NEW YORK, Nov. 22, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced that the independent Data Safety Monitoring Board (DSMB) providing oversight for the UNITY-CLL Phase 3 trial reviewed the cumulative safety data from the ongoing clinical study and informed the Company that it has identified no safety concerns, and recommended the continuation of the study with no modifications. Per the protocol's pre-specified DSMB charter, the DSMB is scheduled to meet approximately every 6-9 months to review cumulative safety data. "We are encouraged by the positive outcome of the first DSMB safety review, especially since over two-thirds of the patients currently enrolled in the study are treatment naive CLL patients. Many may recall, as reported by Dr. Jennifer Brown at last year's ASH meeting, and published earlier this year in *Blood*, that idelalisib in treatment naive CLL patients was observed to cause rapid (most within $\leq$ 5 weeks) and profound (Grade 3/4) liver toxicity in approximately 50% of the patients treated. Given those findings, we are pleased to report that the DSMB did not find any safety concerns and recommended the study continue without modification," stated Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer. Mr. Weiss continued, "We are also excited to report that the UNITY-CLL study continues to enroll well and we are still targeting completion of enrollment in the first half of 2018."

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 UNITY-CLL study and the future safety profile of TGR-1202 based on the DSMB findings, 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 findings of the DSMB reported today will not be maintained at future DSMB reviews of the safety data and the UNITY-CLL will be required to be modified or terminated early; 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.

TGTX - G

CONTACT:

Jenna Bosco

Vice President, Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4351

Email: ir@tgtxinc.com

Primary Logo

Source: TG Therapeutics, Inc.