TG Therapeutics Announces Positive Data Safety Monitoring Board Reviews of UNITY-CLL and UNITY-NHL Clinical Trials

March 8, 2019

UNITY-CLL DSMB conducted a pre-planned futility analysis of progression-free survival, and determined that the study was not futile and should continue as planned

No safety concerns identified by the independent DSMBs and both the UNITY-CLL and UNITY-NHL trials continue without modification

NEW YORK, March 08, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company dedicated to developing medicines for patients with B-cell mediated cancers and autoimmune diseases, today announced the successful outcome of meetings held by the independent Data Safety Monitoring Boards (DSMBs) for both the UNITY-CLL trial and for the UNITY-NHL trial.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are highly encouraged that based on the progression-free survival data accumulated to date, the UNITY-CLL DSMB determined that the study was not futile and supported continuation of the trial as planned. We are also extremely pleased that the DSMBs, which collectively evaluated safety data from over 750 patients treated with umbralisib, did not raise any safety concerns and recommended that both the UNITY-CLL and the UNITY-NHL trials continue unmodified." Mr. Weiss continued, “We look forward to presenting interim safety and efficacy data from the MZL cohort of the UNITY- NHL trial in an oral presentation next month at the AACR conference.”

The UNITY-CLL Trial DSMB

The UNITY-CLL DSMB met to conduct a pre-planned futility analysis of progression-free survival (PFS). The DSMB determined that the trial was not futile and recommended the UNITY-CLL trial continue as planned. The term 'futility' is used to refer to the inability of a clinical trial to achieve its primary objective. Thus, futility analyses are used to stop a clinical trial when the interim results suggest that it is unlikely to achieve statistical significance. The pre-specified futility analysis of the UNITY-CLL trial did not allow for early stopping due to positive efficacy but only for lack of efficacy.

The UNITY-CLL DSMB also reviewed safety information from all 600+ chronic lymphocytic leukemia (CLL) patients on trial, including over 300 treatment naïve and previously treated patients on umbralisib alone or in combination with ublituximab. Based on its review, no safety concerns were identified and the DSMB recommended the UNITY-CLL trial continue without modification.

The UNITY-NHL Trial DSMB

Separately, the UNITY-NHL DSMB met to review safety data on over 470 patients with non-Hodgkin’s lymphoma (NHL) across all cohorts of the trial, including all patients enrolled in the marginal zone lymphoma (MZL) cohort. Based on its review, no safety concerns were identified, and the DSMB recommended the UNITY-NHL trial continue without modification.

ABOUT THE UNITY-CLL PHASE 3 TRIAL

UNITY-CLL is a global Phase 3 randomized, controlled clinical trial comparing the combination of ublituximab plus umbralisib (referred to as “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 plus umbralisib compared to each agent in the single arm cohorts, which allowed for the termination of the single agent arms in May 2017. Accordingly, the UNITY-CLL 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 trial completed in October of 2017. This trial enrolled approximately 60% treatment naïve CLL patients and 40% relapsed refractory CLL patients. The primary objective for this study is to demonstrate superiority in Progression Free Survival (PFS) for the U2 combination over the control arm to support a marketing authorization application for full approval of the U2 combination in CLL. The UNITY-CLL Phase 3 trial is being conducted under Special Protocol Assessment (SPA) with the Food and Drug Administration (FDA).

ABOUT THE UNITY-NHL PHASE 2B TRIAL

The UNITY-NHL study is a global multi-cohort Phase 2b trial designed to evaluate the efficacy and safety of umbralisib monotherapy and in combination with ublituximab in previously treated subjects with non-Hodgkin’s lymphoma (NHL). The trial is currently evaluating cohorts of patients with marginal zone lymphoma (MZL), follicular lymphoma (FL)/ small lymphocytic lymphoma (SLL), diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma (MCL).

Marginal Zone Lymphoma (MZL) Cohort

The MZL cohort of the UNITY-NHL study is currently evaluating the safety and efficacy of single agent umbralisib in patients with MZL who have received at least one prior anti-CD20 regimen. The primary endpoint is overall response rate (ORR) as determined by Independent Review Committee (IRC) assessment. The primary analysis of ORR will be conducted once all treated patients have had at least 9 cycles (cycle = 28 days) of follow-up. Secondary endpoints include safety, duration of response, and progression-free survival (PFS).

The MZL cohort completed enrollment in August 2018 with a total of 69 patients enrolled and receiving at least one dose of umbralisib. The positive ORR outcome announced in February 2019 was based on all 69 enrolled and treated patients, however all patients had not yet been followed for a

minimum of 9 cycles as required for the primary analysis of ORR. The study is ongoing and patients with benefit on therapy (stable disease or in response) remain on study.

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 oral, once-daily inhibitor of PI3K-delta. Umbralisib uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K-delta inhibitors. 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, TG-1501, as well as its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, 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 or UNITY-NHL trials or deliver data on schedule as planned; the risk that while the DSMBs did not identify any safety issues to the Company, no assurance can be given that safety issues don't exist today, or will not arise in the future, that could result in a modification or termination either or both trials; the risk that while the DSMB found that the UNITY-CLL trial was not futile as of the date of the meeting, no assurance can be given that it will not be deemed futile as a result of a future pre-planned futility analysis or despite passing all pre-planned futility analyses that the trial will ultimately be successful; the risk that the differentiated tolerability profile for umbralisib previously observed thus far in clinical trials will not be reproduced in the UNITY-NHL study, the UNITY-CLL study or any other on-going studies; the risk that the combination of ublituximab and umbralisib referred to as "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 safety issues or trends will be observed in the UNITY-CLL or UNITY-NHL studies or any other on-going studies that prevent approval of either ublituximab and/or umbralisib; the risk that the UNITY-CLL or UNITY-NHL trials, 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 UNITY-CLL will not demonstrate a PFS advantage and therefore will not meet its primary endpoint; the risk that the predetermined number of events required to unblind the UNITY-CLL study and analyze the PFS data may not come in the timeframe we expect or at all; 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. 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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