TG Therapeutics Announces Final Long-Term Results from the Phase 3 GENUINE Study Demonstrated that Ublituximab in Combination with Ibrutinib Improved Progression-Free Survival in Patients with High-Risk Relapsed/Refractory Chronic Lymphocytic Leukemia as Compared to Ibrutinib Monotherapy

October 24, 2019

Combination was well tolerated with no new safety signals identified with median follow-up of >4 years

GENUINE met its primary endpoint of improved overall response rate, as previously reported

TG plans to present these final data at a future medical conference and share these results with the FDA

NEW YORK, Oct. 24, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced that final long-term results from the Phase 3 GENUINE study demonstrated that ublituximab in combination with ibrutinib improved progression-free survival (PFS), as determined by Independent Review Committee (IRC). The GENUINE Phase 3 study evaluated ublituximab, the Company's novel, glycoengineered anti-CD20 monoclonal antibody, in combination with ibrutinib, compared to ibrutinib monotherapy in patients with relapsed/refractory high-risk chronic lymphocytic leukemia (CLL). As previously reported, the GENUINE study met its primary endpoint of improved IRC-assessed overall response rate (ORR), as well as increased centrally-assessed rate of minimal residual disease (MRD). The combination of ublituximab and ibrutinib was well tolerated with no new safety signals identified at a median follow-up of >4 years.

The Company plans to present these final data at a future medical conference, as well as share the results with the U.S. Food and Drug Administration (FDA).

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are pleased with the final results from the Phase 3 GENUINE trial with median follow-up of over 4 years. The improvement in PFS observed in these high-risk CLL patients is extremely encouraging, and we look forward to presenting the full data at a future medical conference."

ABOUT THE PHASE 3 GENUINE STUDY

The Phase 3 GENUINE study is a randomized, open label, multicenter clinical trial to evaluate the safety and efficacy of ublituximab in combination with ibrutinib compared to ibrutinib monotherapy in adult patients with high-risk chronic lymphocytic leukemia (CLL) who received at least one prior therapy for their disease. In this study, high-risk was defined as having any one or more of the following: 17p deletion, 11q deletion or p53 mutation.

The study was conducted at 160 clinical trial sites in the US and Israel and randomized 126 patients. Patients received ibrutinib orally at 420 mg once daily in both arms and in the treatment arm those patients also received intravenous infusions of ublituximab at 900 mg dosed on days 1, 8 and 15 of cycle 1 and day 1 of cycles 2-6. Patients in the treatment arm who had not progressed received quarterly infusions of ubltuximab maintenance at 900 mg.

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, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801, into Phase 1 development. 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 preclinical and clinical trials; the risk that the combination of ublituximab and ibrutinib studied in the GENUINE Phase 3 trial, will not prove to be a safe and efficacious combination; the risk the company does not share the final GENUINE data with the FDA; the risk that the final GENUINE results will not be accepted for presentation at a major medical meeting or publication; the risk that the final GENUINE data will not be useful for any FDA regulatory purpose. 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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