TG Therapeutics Announces Final Results of the GENUINE Phase 3 Study Evaluating Ublituximab plus Ibrutinib in Previously Treated High-Risk Chronic Lymphocytic Leukemia at the 56th American Society of Clinical Oncology Annual Meeting

May 29, 2020

The addition of ublituximab to ibrutinib significantly improved PFS, ORR, CR rate, and increased rates of uMRD compared with ibrutinib monotherapy

NEW YORK, May 29, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced the final results from the GENUINE Phase 3 study evaluating the combination of ublituximab, the Company's novel glycoengineered anti-CD20 monoclonal antibody, plus ibrutinib compared to ibrutinib alone in patients with previously treated high-risk chronic lymphocytic leukemia (CLL) at the 56th American Society of Clinical Oncology (ASCO) annual meeting.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased with the final results of the GENUINE Phase 3 trial presented today. Not only is this the first randomized trial to show a PFS benefit with the addition of an anti-CD20 antibody to ibrutinib, compared to ibrutinib monotherapy, it was also highly encouraging to see the combination significantly improved overall response rate, complete response rate, and importantly increased the rates of undetectable minimal residual disease." Mr. Weiss continued, "We believe these data support the potential of combination therapies to improve outcomes for patients with high risk CLL, especially those with 17p deletion/TP53 mutation, who continue to progress more rapidly than those without high risk cytogenetics."

Details of the data presentation are included below.

Presentation Title: Effect of Adding Ublituximab to Ibrutinib on PFS, ORR, and MRD Negativity in Previously Treated High-Risk Chronic Lymphocytic Leukemia: Final Results of the GENUINE Phase III Study

The GENUINE trial is an open-label, multicenter, randomized, Phase III study in relapsed or refractory high-risk CLL (del17p, del11q, or *TP53*mutation). This presentation includes data from 117 patients treated with either ublituximab plus ibrutinib (n=59) or ibrutinib alone (n=58). As of the cut-off date of September 1, 2019, patients had a median follow-up time of 41.9 months. The primary endpoint for this trial was overall response rate (ORR) as determined by an independent review committee (IRC). The secondary endpoints included progression free survival (PFS) and complete response (CR) rate as determined by an IRC, and undetectable minimal residual disease (uMRD) assessed by central lab.

Efficacy and safety highlights include:

- The addition of ublituximab to ibrutinib compared to ibrutinib monotherapy significantly improved ORR (93% compared to 78%; p=0.019), complete response/complete response with incomplete blood count recovery (CR/CRi) rate (20% vs. 5%; p=0.024), and increased rates of uMRD (46% vs. 7%; p<0.001) in patients with relapsed/refractory CLL with high-risk cytogenetics
- At a median follow-up of 41.9 months, median PFS was not reached in the ublituximab plus ibrutinib arm and was 35.9 months in the ibrutinib monotherapy arm (hazard ratio 0.46), with del17p/TP53mut patients seeing the greatest difference in PFS
- The addition of ublituximab to ibrutinib did not significantly alter the known safety profile of ibrutinib however the combination resulted in slightly higher rates of neutropenia (36% compared to 21%) and atrial fibrillation (14% compared to 7%)

The data presented is available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

ABOUT THE GENUINE PHASE 3 STUDY
The GENUINE Phase 3 study is a randomized, open label, multicenter clinical trial to evaluate the safety and efficacy of ublituximab plus ibrutinib compared to ibrutinib alone in adult patients with high-risk chronic lymphocytic leukemia (CLL) who received at least one prior therapy for their disease.

Patients received ibrutinib orally at 420 mg once daily in both arms and in the combination 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 combination arm who had not progressed received quarterly infusions of ublituximab 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 multiple 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 dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. 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 into Phase 1 clinical development its anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801. TG Therapeutics is headquartered in New York City.

Cautionary Statement
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. For these statements, which are subject to a number of risks and uncertainties, 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 our ongoing and planned clinical trials; the risk that early clinical trial results (both safety and efficacy), that may have supported the acceptance of our data for presentation or influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; the risk that the GENUINE study will not be utilized for any regulatory submission, or support any regulatory approvals for ublituximab; 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.

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