TG Therapeutics Announces Publication of Phase 2 Data Evaluating Umbralisib in Patients with Chronic Lymphocytic Leukemia Who Are Intolerant to Prior BTK or PI3K Inhibitor Therapy in Blood

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NEW YORK, Dec. 02, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced the publication of data from a Phase 2 study evaluating umbralisib, the Company's investigational once daily, oral, dual inhibitor of PI3K-delta and CK1-epsilon, in patients with chronic lymphocytic leukemia (CLL) who are intolerant to prior BTK or PI3K-delta inhibitor therapy, in *Blood*, the Journal of the American Society of Hematology.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely encouraged by the data published today demonstrating that umbralisib monotherapy induced durable responses and enhanced progression-free survival in patients who were unable to tolerate their prior BTKi or PI3K delta therapy. Despite many advances in the treatment of CLL in recent years, early termination of kinase inhibitors due to tolerability is an emerging issue leaving too many CLL patients without adequate therapy." Mr. Weiss continued, "With our rolling BLA submission recently initiated for ublituximab in combination with umbralisib for patients with CLL, and our ongoing clinical studies evaluating triplet regimens in this disease, we remain committed to addressing unmet needs in CLL."

The manuscript includes data from 51 chronic lymphocytic leukemia (CLL) patients who were previously treated with and became intolerant to prior BTK or PI3K inhibitor therapy (44 BTK intolerant and 7 PI3K intolerant patients). Patients were treated with 800 mg of umbralisib once daily. The primary endpoint was progression-free survival (PFS). Safety data was available from all patients enrolled (n=51). Key highlights from this manuscript include:

- The most common (≥5%) grade ≥3 AEs were neutropenia (18%), leukocytosis (14%), thrombocytopenia (12%), pneumonia (12%), and diarrhea (8%).
- Six patients (12%) discontinued umbralisib due to an AE. Eight patients (16%) had dose reductions and were successfully re-challenged allowing them to continue on umbralisib.
- Median progression free survival (PFS) was 23.5 months (95% CI 13.1-not estimable).
- As of the data cut off, 58% of patients had been on umbralisib for a longer duration than their prior kinase inhibitor.

These data are described further in the manuscript entitled, "Phase 2 Study of the Safety and Efficacy of Umbralisib in Patients with CLL Who Are Intolerant to BTK or PI3Kδ Inhibitor Therapy," which was published online in the First Edition section of *Blood,* the Journal of the American Society of Hematology. The online version of the article can be accessed at www.bloodjournal.org.

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 in late-stage clinical development with two investigational compounds, ublituximab and umbralisib, the combination of which is referred to as "U2", targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. Umbralisib (TGR-1202) is an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon. Umbralisib is currently under review by the U.S. Food and Drug Administration (FDA) for accelerated approval as a treatment for patients with previously treated marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen or follicular lymphoma (FL) who have received at least two prior systemic therapies. The Company also has a fully enrolled Phase 3 clinical trial evaluating U2 in patients with treatment naïve and relapsed/refractory chronic lymphocytic leukemia (CLL), and two fully enrolled identical Phase 3 trials evaluating ublituximab monotherapy in patients with relapsing forms of multiple sclerosis (RMS). Additionally, the Company has recently brought into Phase 1 clinical development its anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), its 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 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 preclinical and clinical trial results, that may have supported the acceptance of our data for publication or influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies or in future data presentations; and the risk that as patients continue to be treated with umbralisib for longer durations in clinical studies and more patients are enrolled in clinical studies evaluating umbralisib, additional safety data, when available, will not be acceptable or consistent with results of previously reported studies; the risk that we will not complete the BLA submission of ublituximab in combination with umbralisib in patients with CLL in the timeline we project and that, if completed, FDA will not accept the BLA submission; the risk that we will not obtain regulatory approval of any of our product candidates, including ublituximab and umbralisib, and that, if approved, our product candidates will not be commercially successful. 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.

CONTACT:
Jenna Bosco
Senior Vice President,
Corporate Communications
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

Source: TG Therapeutics, Inc.