TG Therapeutics Announces Fast Track Designation Granted by the FDA to Ublituximab in Combination with Umbralisib for the Treatment of Adult Patients with Chronic Lymphocytic Leukemia

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NEW YORK, Oct. 21, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to the combination of ublituximab, the Company's investigational glycoengineered anti-CD20 monoclonal antibody, and umbralisib, the Company's investigational once-daily, oral, dual inhibitor of PI3K-delta and CK1-epsilon, for the treatment of adult patients with chronic lymphocytic leukemia (CLL).

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are extremely pleased to have received Fast Track designation for the ublituximab plus umbralisib regimen, or the U2 combination, to treat adult patients with CLL. The application for Fast Track was based on data from the UNITY-CLL Phase 3 study that we announced earlier this year had met its primary endpoint of progression free survival. This designation holds several important advantages to potentially expedite the development and regulatory review of U2 and underscores the significant unmet medical need that still exists for patients with CLL." Mr. Weiss continued, "We look forward to presenting data from the UNITY-CLL Phase 3 trial later this year, which we plan to use as the basis of a U2 regulatory submission for CLL."

ABOUT FAST TRACK
Fast Track is a program designed to expedite the development and review of drugs that treat serious conditions and that demonstrate the potential to address an unmet medical need. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy that may be potentially better than available therapy.

A drug that receives *Fast Track* designation is eligible for more frequent interactions with the FDA, priority review if relevant criteria are met, and rolling submission of the Biologic License Application or New Drug Application.

ABOUT UNITY-CLL PHASE 3 TRIAL
UNITY-CLL is a global Phase 3 randomized controlled clinical trial comparing the combination of ublituximab plus umbralisib, or 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 prespecified analysis was conducted to assess the contribution of ublituximab and umbralisib in the U2 combination arm and allowed for the termination of the single agent arms. Accordingly, the UNITY-CLL Phase 3 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 Phase 3 trial completed in October of 2017 with approximately 420 subjects enrolled to the two combinations arms. This trial enrolled approximately 60% treatment-naïve CLL patients and 40% relapsed or refractory CLL patients. The primary endpoint for this study was superior Progression Free Survival (PFS) for the U2 combination compared to the control arm to support the submission for full approval of the U2 combination in CLL. Positive topline results from this trial were announced in May 2020. The UNITY-CLL Phase 3 trial is being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

ABOUT CHRONIC LYMPHOCYTIC LEUKEMIA
Chronic lymphocytic leukemia (CLL) is the most common type of adult leukemia, and in 2020 it is estimated there will be more than 20,000 new cases of CLL diagnosed in the United States[1]. Although signs of CLL may disappear for a period of time after initial treatment, the disease is considered incurable and many people will require additional treatment due to the return of malignant cells.

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 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.

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[1] Cancer Stat Facts: Leukemia – Chronic Lymphocytic Leukemia
https://seer.cancer.gov/statfacts/html/clyl.html

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 include the following: the risk that we are not able to successfully deliver the complete data set from the UNITY-CLL trial on schedule as planned; the risk that safety issues or trends will be observed in the UNITY-CLL study when the full safety dataset is available or in any other on-going studies that prevent approval of either ublituximab and/or umbralisib; the risk that the safety and efficacy profile observed in the UNITY-CLL study is not supportive of a differentiated profile; the risk that the UNITY-CLL trial, 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; and the risk that we are not able to achieve the milestones we project, including the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones. 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.