TG Therapeutics, Inc. Presents Phase 2 Data Evaluating Umbralisib in CLL Patients Intolerant to Prior BTK or PI3K Delta Inhibitor Therapy at the 23rd Congress of the European Hematology Association (EHA)

June 18, 2018

NEW YORK, June 18, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced an oral presentation of clinical data from its ongoing Phase 2 study evaluating umbralisib (TGR-1202), the Company's PI3K delta inhibitor, in patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) who are intolerant to prior BTK or PI3K delta inhibitor therapy. Data from this trial were presented over the weekend during an oral session at the 23rdCongress of the European Hematology Association (EHA).

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are pleased to present data evaluating umbralisib in patients intolerant to currently approved BTK or PI3K therapies during the EHA annual congress. While there have been great advancements in recent years in the treatment of CLL, this study confirms that there are many patients still in need of an alternative treatment option and that umbralisib can be used safely and effectively in those patients who were not able to tolerate a prior BTK or PI3K therapy. The rate of patients withdrawing from kinase treatment for CLL in real world settings has been estimated to reach upwards of 40%, representing a significant unmet medical need." Mr. Weiss continued, "We are extremely pleased with the data presented at ASCO and EHA this month and we look forward to presenting the topline response rate data from the UNITY- CLL Phase 3 trial by the end of summer 2018."

Highlights from the oral presentation include the following:

Oral Presentation: A Phase 2 Study to Assess the Safety and Efficacy of Umbralisib (TGR-1202) In Patients with Chronic Lymphocytic Leukemia (CLL) Who Are Intolerant to Prior BTK or PI3K-delta Inhibitor Therapy (Abstract Number S808)

This presentation includes data from patients with CLL who are intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent umbralisib (TGR-1202). To be eligible for the study patients had to have received prior treatment with a BTK inhibitor (ibrutinib, acalabrutinib) or a PI3K delta inhibitor (idelalisib, duvelisib) and discontinued therapy due to intolerance within 12 months of starting treatment on this study. Forty-seven patients were evaluable for safety of which 46 were evaluable for Progression Free Survival (PFS), (1 patient had a confirmed Richter's Transformation (RT) at enrollment which did not meet eligibility criteria).

Highlights from this presentation include:

- Umbralisib demonstrated a favorable safety profile in patients intolerant to prior BTK or PI3K therapy
- Only 13% discontinued due to an adverse event, of which only one patient discontinued due to a recurrent adverse event (AE) also experienced with prior kinase inhibitor therapy
- Median progression free survival (PFS) and overall survival has not been reached with a median follow-up of 9.5 months
- In this relapsed/refractory CLL population, of which 77% required treatment within 6 months of prior KI discontinuation, 64% had a high-risk molecular / genetic marker and 6% had an ibrutinib resistance mutation, significant clinical activity has been observed

PRESENTATION DETAILS

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

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 orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. 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 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 or in the abstracts mentioned 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. Among the 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 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 or in the final presentations; the risk that the differentiated tolerability profile for umbralisib observed will not be reproduced in full presentations or later larger studies; the risk that the final data from either GENUINE or UNITY-CLL will not support a regulatory filing or approval or that the company will choose not to file a BLA/NDA or seek accelerated approval based on those studies; the risk that the topline overall response rate data from the UNITY-CLL trial is not be statistically significant 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.

CONTACT:

Jenna Bosco
SVP, Corporate Communications
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

Primary Logo

Source: TG Therapeutics, Inc.