TG Therapeutics, Inc. Announces Oral Presentation of Umbralisib plus Ruxolitinib in Patients with Myelofibrosis at the 23rd Congress of the European Hematology Association

June 15, 2018

Data demonstrates that the addition of umbralisib to ruxolitinib can induce responses in patients with sub-optimal response to ruxolitinib single agent

NEW YORK, June 15, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced updated clinical data from its ongoing Phase I study evaluating umbralisib (TGR-1202), the Company's PI3K delta inhibitor in combination with ruxolitinib, the JAK 1/2 inhibitor, in ruxolitinib experienced patients with myelofibrosis (MF). Data from this trial are being presented this morning during the 23rdCongress of the European Hematology Association (EHA).

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "The data presented in patients with myelofibrosis represents yet another unique opportunity for umbralisib, in this case providing a treatment option to patients who are not achieving an optimal response to ruxolitinib monotherapy. This type of study highlights the unique breadth of activity of PI3K delta inhibition across hematological malignancies and underscores the importance of umbralisib's safety profile, that permits a wide range of combinations." Mr. Weiss continued, "We look forward to evaluating this combination further, potentially in a randomized pivotal setting."

Highlights from this morning's presentation include the following:

Oral Presentation: Resurrecting response to ruxolitinib: a phase I study testing the combination of ruxolitinib and the PI3Kdelta inhibitor umbralisib in ruxolitinib-experienced myelofibrosis (Abstract Number S133)

This oral presentation includes data from patients with myelofibrosis treated with the combination of ruxolitinib, the JAK1/2 inhibitor and umbralisib (TGR-1202). Importantly, per protocol, all enrolled patients were on a stable dose of ruxolitinib monotherapy and had achieved their best response to ruxolitinib prior to enrolling to receive umbralisib. Presentation highlights included:

- The combination of umbralisib + ruxolitinib was well-tolerated with limited Grade 3/4 adverse events;
  - Dose-limiting toxicities of asymptomatic amylase/lipase elevations were observed of unclear clinical consequence;
  - Only one event of colitis (in a patient with underlying GI disorder at study entry) and no pneumonitis was observed.
- Increases in hemoglobin, improvements in spleen size, and reduction in symptoms meeting IWG-MRT criteria for clinical improvement were seen in 13 (57%) ruxolitinib-experienced myelofibrosis patients;
- Importantly, 2 patients (9%) achieved a durable complete remission after progressing on ruxolitinib;
- The addition of umbralisib to ruxolitinib demonstrates the ability to augment or resurrect a response in myelofibrosis patients who had suboptimal or lost response to ruxolitinib alone.

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 we will not evaluate the combination of ruxolitinib and umbralisib in myelofibrosis or any other indication; 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.