

TG Therapeutics, Inc. Announces Follow-Up Data from the Triple Combination of Ublituximab, Umbralisib, and Bendamustine in Patients with DLBCL and FL at 60th American Society of Hematology Annual Meeting and Exposition

December 4, 2018

NEW YORK, Dec. 04, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated clinical data from its Phase I/lb trial of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with umbralisib (TGR-1202), the Company's oral, next generation PI3K delta inhibitor, and bendamustine, in patients with Diffuse Large B-cell Lymphoma (DLBCL) and Follicular Lymphoma (FL). Data from this trial was presented yesterday evening during a poster session at the 60thAmerican Society of Hematology (ASH) Annual Meeting and Exposition.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "The data presented yesterday further supports our belief that our proprietary U2 combination is an ideal backbone regimen on which to build novel multi-drug combinations. The triple therapy of U2 plus bendamustine is highly active and well tolerated in advanced patients, resulting in durable responses with some patients on study 36+ months." Mr. Weiss continued, "We are looking forward to an exciting 2019, with pivotal data expected from the ongoing UNITY-NHL registration directed program in the first half of the year."

Below summarizes the data from the poster presentation.

Combination of Umbralisib, Ublituximab, and Bendamustine is Safe and Highly Active in Patients with Advanced DLBCL and Follicular Lymphoma (Abstract 4197)

This poster presentation includes data from patients with relapsed or refractory DLBCL or FL treated with the triple combination of umbralisib, ublituximab and bendamustine. Thirty-nine patients were evaluable for safety of which 38 were evaluable for efficacy (one patient discontinued due to a treatment-related adverse event (AE), neutropenia, prior to first efficacy assessment). Twenty-two patients (56%) were refractory to prior treatment. Overall, the triple combination was well tolerated and highly active in patients with advanced indolent and aggressive NHL, including those not eligible for HD/SCT or CD19 CART therapy.

Efficacy highlights from this poster include:

- 85% (11 of 13) ORR, including a 54% CR rate, observed in patients with relapsed or refractory FL
- 48% (12 of 25) ORR, including a 36% CR rate, observed in patients with relapsed or refractory DLBCL

PRESENTATION DETAILS:

The above referenced presentation is 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, TG-1501, as well as its covalently-bound Bruton Tyrosine Kinase (BTK) inhibitor, TG-1701, 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 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. 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 the highlighted early clinical trial results, including the safety and efficacy results seen with the combination of ublituximab (TG-1101), umbralisib (TGR-1202) plus bendamustine 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 combination of ublituximab and umbralisib, referred to as U2 and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations; the risk that data from the UNITY-NHL trial will not be delivered on time or as planned. 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: <u>ir@tgtxinc.com</u>



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