# TG Therapeutics Announces Phase I Study of Novel BTK inhibitor, TG-1701, in Patients with Relapsed or Refractory B-cell Malignancies is Open for Enrollment

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**First dose cohort fully enrolled**

**First patient enrolled with relapsed/refractory Mantle Cell Lymphoma achieved Partial Response (PR) to lowest dose being tested**

NEW YORK, Nov. 13, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced the first Company sponsored Phase I study of its novel, orally available and covalently-bound Bruton Tyrosine Kinase (BTK) inhibitor, TG-1701, is open for enrollment for patients with relapsed or refractory B-cell malignancies. The first cohort evaluating TG-1701 at a dose of 100 mg once-daily has been fully enrolled, and the first patient enrolled, a patient with relapsed/refractory Mantle Cell Lymphoma (MCL), achieved a partial response (PR) at the first efficacy assessment. The remaining two patients are too early to evaluate.

This Phase I open label trial is designed to assess the safety, pharmacokinetics, pharmacodynamics and efficacy of TG-1701 in patients with non-Hodgkin's Lymphoma ( NHL) and Chronic Lymphocytic Leukemia (CLL). The trial is first evaluating TG-1701 as a single agent, with subsequent cohorts designed to evaluate the triple combination of TG-1701 with ublituximab, the Company's novel glycoengineered anti-CD20 monoclonal antibody and umbralisib, the Company's novel PI3K delta inhibitor, the combination referred to as "U2". The primary objective of the study is to determine the Maximum Tolerated Dose (MTD) of TG-1701, with secondary objectives including evaluation of efficacy. The study is being led by Constantine Tam, M.D., Director of Hematology, St. Vincent's Hospital and Consultant Hematologist, Peter MacCallum Cancer Center, in Australia.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased to announce the commencement of our first TG sponsored trial of TG-1701, our proprietary BTK inhibitor which was licensed from Jiangsu Hengrui earlier this year. The pre-clinical data presented at the European Hematology Association (EHA) annual congress this past summer on TG-1701 showed a highly selective kinase profile giving us confidence in its clinical potential." Mr. Weiss continued, "We are excited to see the study is off to a strong start with the first cohort rapidly enrolled and the first patient achieving a PR at our lowest evaluated dose. Seeing early activity should accelerate our ability to identify a dose appropriate for use in combination with U2 and for expansion cohorts. We look forward to seeing more data from TG-1701 in 2019 and starting combination therapy with U2."

**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 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 umbralisib is not a differentiated PI3K delta inhibitor; the risk that the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2, and being studied in the UNITY clinical trials and other studies, will not prove to be safe and efficacious for any indication or will not prove to be a safe and efficacious backbone for future triple or quad therapies; the risk that we will not study the triple combination of ublituximab, umbralisib and TG-1701 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.

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