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TG Therapeutics, Inc. Initiates First Combination Clinical Trial of TG-1101 and TGR-1202 in Patients With Relapsed and/or Refractory CLL and NHL

- Combination trial led by Susan O'Brien, MD and Nathan Fowler, MD from the MD Anderson Cancer Center in Houston, Texas
- Nodal responses observed at 800mg once per day; Company initiates first expansion cohort of TGR-1202 as a single agent while dose escalation continues

NEW YORK, Nov. 25, 2013 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), an innovative, clinical-stage biopharmaceutical company today announced that it has initiated a multi-center, Phase I trial to evaluate the safety and efficacy of the combination of TG-1101 (ublituximab) and TGR-1202 for patients with relapsed and/or refractory Chronic Lymphocytic Leukemia (CLL) and non-Hodgkin's Lymphoma (NHL). This will be the first clinical trial evaluating the combination of TG-1101, the Company's novel glycoengineered anti-CD20 monoclonal antibody, and TGR-1202, the Company's novel, once per day, PI3K Delta inhibitor. In this study, dosing of TGR-1202 will commence at 800mg once per day (or QD) with dose escalation proceeding in a 3+3 design.

The trial, entitled "A Multi-center Phase I/Ib Study Evaluating the Efficacy and Safety of TG-1101 (Ublituximab), a novel Glycoengineered Anti-CD20 Monoclonal Antibody, in Combination with TGR-1202, a Novel PI3k Delta Inhibitor, in Patients with B-cell Malignancies," will enroll CLL and NHL patients whose disease is relapsed from or refractory to prior therapies, including prior anti-CD20 monoclonal antibodies, PI3K Delta inhibitors, and/or BTK inhibitors. The MD Anderson Cancer Center will be the lead center for the trial. Susan O'Brien, MD, Professor in the Department of Leukemia, will be the Study Chair for the CLL patient group, and Nathan Fowler, MD, Assistant Professor and Co-Director of Clinical Research in the Department of Lymphoma, will be the Study Chair for the NHL patient group.

In addition, TG Therapeutics announced today that it has opened its first expansion cohort in its ongoing single agent Phase 1 dose escalation study of TGR-1202. The expansion cohort will enroll additional patients at the 800mg QD dose level. As a maximum tolerated dose has not been reached, dose escalation continues in this study. To date, the Company has not observed any TGR-1202 drug-related liver toxicity. At the upcoming American Society of Hematology Meeting (ASH) in December 2013, the Company intends to present detailed pharmacokinetic and safety data for all patients in the ongoing single agent study of TGR-1202 through the 1200mg QD cohort as well as efficacy data through the 800mg QD dose escalation cohort (Abstract 4373 which can be found at https://ash.confex.com/ash/2013/webprogram/Paper61825.html).

"With the confirmation of activity of TGR-1202, we are one step closer to fulfilling our vision of bringing highly active, less toxic, non-chemotherapy based combination treatment options to patients with B-cell malignancies," stated Michael S. Weiss, Executive Chairman and Interim CEO, who continued, "The commencement of this combination study today represents a major milestone for the Company and is the beginning of what we expect to be a robust combination clinical program, which will include our much anticipated combination of TG-1101 with ibrutinib. We are very excited to have MD Anderson as our lead center and to be working with Dr. O'Brien and Dr. Fowler, as co-lead investigators for this important clinical trial."

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is an innovative, clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. Currently, the company is developing two therapies targeting hematological malignancies. TG-1101 (ublituximab) 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 TGR-1202, an orally available PI3K delta inhibitor, jointly with Rhizen Pharmaceuticals S A. 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 TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release, particularly those anticipating future clinical trials and business prospects for TG-1101 and TGR-1202 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 pre-clinical and clinical trials for TG-1101 and TGR-1202; the risk that pre-clinical and early clinical results that supported our decision to move forward with TG-1101 and TGR-1202 will not be reproduced in additional patients or in future studies; the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following completion of the current phase 1 study; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior pre-clinical and clinical trials; our ability to achieve the milestones we project over the next year; our ability to manage our cash in line with our projections, 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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CONTACT: Jenna Bosco

Director- Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4484

Email: ir@tgtxinc.com



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