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TG Therapeutics, Inc. Announces the Launch of the Phase 1/2 Study of TGR-1202 and Carfilzomib in Patients with Relapsed or Refractory Lymphoma

Phase 1/2 Study to be conducted at Columbia University Medical Center

First trial to combine these two treatments to explore the synergistic effects seen on c-Myc inhibition in extensive preclinical testing

NEW YORK, Oct. 20, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced the launch of a Phase 1/2 study to evaluate the safety and efficacy of TGR-1202, the Company's oral PI3K delta inhibitor in combination with carfilzomib, the FDA-approved proteasome inhibitor, in patients with relapsed or refractory lymphoma.

The rationale for combining these two agents is based on extensive preclinical work conducted as part of a research collaboration supported by TG Therapeutics at the Center for Lymphoid Malignancies, Columbia University Medical Center. Portions of this work were presented in an oral presentation at the American Society of Hematology Meeting in December 2015, by Dr. Changchun Deng of the Center for Lymphoid Malignancies. The presentation contained data demonstrating that the combination of TGR-1202 and carfilzomib was uniquely synergistic as compared to any other combination of a PI3K-delta inhibitor and proteasome inhibitor, including the combination of idelalisib and carfilzomib and idelalisib and bortezomib. Of particular interest, the combination of TGR-1202 and carfilzomib was found to potently inhibit cap dependent translation of c-Myc in all cell lines tested, including diffuse large B-Cell lymphoma (DLBCL), mantle cell lymphoma (MCL), multiple myeloma, T-cell lymphoma, and chronic lymphocytic leukemia (CLL) cells. A more in depth presentation of the preclinical work has been submitted to a leading medical journal and is awaiting publication.

In the Phase 1 portion, the study will evaluate the safety, tolerability, and appropriate dose of carfilzomib when combined with 800mg of TGR-1202. Once a recommended Phase 2 dose is identified, the Phase 2 portion will further evaluate the safety and effectiveness of the combination at the chosen dose. TG Therapeutics will supply the TGR-1202 and assume up to 50% for the cost for the trial.

"We are very excited about the launch of this combination study, building on the extensive preclinical work completed by Dr. Deng, Dr. Owen A. O'Connor and the team from Columbia Presbyterian Medical Center, allowing us to move the science from bench to bedside and into patients in need of combination therapies. TGR-1202 continues to exhibit best-in-class safety and efficacy results and has demonstrated itself as a uniquely combinable PI3k-delta inhibitor. Our hope is that combination therapies with TGR-1202 could significantly improve the outcomes for patients with lymphoma," stated Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer."

"C-myc continues to be one of the most challenging tumor mutations to target. C-myc tumors include some of the most difficult to treat, including double hit lymphoma and triple negative breast cancer, which are generally resistant to currently available therapies leading to very poor outcomes for patients. The work we completed at Columbia appears to identify a novel mechanism for targeting c-myc by combining these two agents and we are eager to see if the work in the lab translates into helping these patients. We look forward to working with TGR-1202 and carfilzomib in this important clinical research project," stated Dr. Owen O'Connor, Director Lymphoid Malignancies at Columbia Presbyterian Medical Center.

This study is currently open to enrollment at the Center for Lymphoid Malignancies, Columbia Presbyterian Medical Center, New York, NY. More information on this clinical study can be found at www.clinicaltrials.gov.

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. 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. 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, with TG-1101 recently entering clinical development for autoimmune disorders. The Company also has preclinical programs to develop IRAK4 inhibitors, BET

inhibitors, and anti-PD-L1 and anti-GITR antibodies. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release, particularly those with respect to future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies 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 for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies; the risk that early preclinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies will not be reproduced in additional patients or in future studies; the risk that trends observed which underlie certain assumptions of future performance of TGR-1202 will not continue, the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase 1 study; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303, will not prove to be a safe and efficacious backbone for triple and quad combination therapies; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior preclinical and clinical trials; the risk that trials will take longer to enroll than expected; 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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