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TG Therapeutics, Inc. Announces Investigator Initiated Trial at the University of Nebraska Medical Center to Study TGR-1202 in Combination with Ibrutinib in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma

Phase 2 trial of TGR-1202 plus ibrutinib designed to target B-cell receptor (BCR) pathway at multiple points in DLBCL patients relapsed from or ineligible for stem cell transplant

NEW YORK, Jan. 04, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced the opening of an investigator initiated Phase 2 study at the University of Nebraska Medical Center (UNMC) to evaluate the safety and efficacy of TGR-1202, the Company's oral PI3K delta inhibitor in combination with ibrutinib, in patients with relapsed or refractory Diffuse Large B-cell Lymphoma (DLBCL). TG Therapeutics and Janssen Pharmaceuticals will each provide drug and equally share study-related costs.

The rationale for combining these two agents is based on the prior clinical activity and tolerable safety profile observed with TGR-1202 both alone and in combination with ibrutinib in previous studies, as well as preclinical work conducted as part of a research collaboration with Dr. Michael Green and the University of Nebraska Medical Center's Lymphoma Precision Medicine Laboratory in Omaha, NE. The combination of TGR-1202 and ibrutinib has been studied previously in patients with Chronic Lymphocytic Leukemia (CLL) and non-Hodgkin's lymphoma, both with and without the addition of the anti-CD20 monoclonal antibody TG-1101 (ublituximab). Data on the combination of TGR-1202 plus ibrutinib were presented most recently at the 2016 American Society of Hematology (ASH) meeting, with data demonstrating an acceptable safety profile at full doses of both ibrutinib and TGR-1202.

The Phase 2 study will evaluate the safety and efficacy of the combination of TGR-1202 and ibrutinib, as well as explore correlative analyses related to the combination.

"We are excited to launch this study led by Drs. Matthew Lunning and Michael Green. Dr. Lunning has extensive experience treating lymphoma patients with TGR-1202 as a doublet in combination with TG-1101 and also as a triple therapy with ibrutinib. While the triple combination appears safe, well tolerated and active, looking at the effects of the all oral doublet combination will expand our understanding of the effects of these agents together and the contribution of TG-1101 in a triple combination," stated Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer.

"Success with small molecule inhibitors that abrogate the abnormal signaling through the BCR pathway observed in B-cell malignancies has brought upon an exciting paradigm shift in the management of B-cell NHL. However, DLBCL patients who relapse from transplant or are refractory to front-line or subsequent therapies continue to have a poor prognosis and new novel combinations are desperately needed. At present, targeted agents against the BCR pathway have been primarily explored as single agents or in combination with a CD20 monoclonal antibody. Based on the existing clinical data in other lymphomas and the exciting preclinical data completed here by my colleague Dr. Green at UNMC, we are excited to launch this novel chemo-free all oral combination trial of TGR-1202 and ibrutinib which may be an attractive combination for this difficult to treat patient population," stated Dr. Matthew Lunning of the Fred & Pamela Buffett Cancer Center, which is the National Cancer Institute-designated cancer center located on the campus of UNMC and its clinical partner, Nebraska Medicine, in Omaha, NE.

This study is currently open to enrollment. 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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