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TG Therapeutics, Inc. Launches Phase 1/2 "Triple-Therapy" Study With TGR-1202 + TG-1101 + the PD-1 Checkpoint Inhibitor Pembrolizumab in Patients With Advanced Chronic Lymphocytic Leukemia (CLL) at the University of Pennsylvania's Abramson Cancer Center

NEW YORK, Sept. 9, 2015 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced the initiation of a Phase 1/2 clinical study that will investigate the use of TGR-1202, the Company's oral PI3K delta inhibitor and TG-1101 (ublituximab), the Company's glycoengineered anti-CD20 monoclonal antibody in combination with pembrolizumab the anti-PD-1 immune checkpoint inhibitor, in patients with relapsed or refractory CLL. This will be the first clinical trial evaluating the safety, tolerability and effectiveness of the triple combination of a PI3K delta inhibitor with an anti-CD20 mAb and an anti-PD-1 checkpoint inhibitor.

"We are very excited about the launch of this combination study and its potential in treating patients with CLL. To date, engaging T-cells to fight CLL has been promising but has yet to produce the dramatic effects seen in other settings. We believe our proprietary TG-1101 plus TGR-1202 regimen in combination with T-cell enhancing therapies, like anti-PD-1, could significantly improve the outcomes for patients with CLL," stated Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer. Mr. Weiss continued, "Additionally, with our own anti-PD-L1 antibody expected to enter clinical trials next year, this trial will give us a nice head start in designing our proprietary combination clinical program."

Dr. Anthony Mato, an assistant professor in the Perelman School of Medicine at the University of Pennsylvania, Director of the Center for CLL at Penn's Abramson Cancer Center and Study Chair of the Phase 1/2 study added, "We look forward to collaborating with TG Therapeutics on this novel combination clinical trial. Our center has been intimately involved with T-cell therapies for hematologic diseases and we are firm believers in the promise they hold broadly for cancer patients. The combination of TG-1101 and TGR-1202 has demonstrated unique tolerability and activity which we believe represents a strong backbone on which to add additional novel therapies. We believe the novel approach utilized in this study, where we will induce a response with TG-1101 and TGR-1202, followed by consolidation with anti-PD-1 therapy, could maximize the potential benefit of T-cell therapy in CLL. We are thrilled to have moved this study from concept to first patient enrolled in just a few months, and look forward to offering patients with advanced CLL new options with this novel triple combination."

The Phase 1 part of the study will evaluate the safety, tolerability, and appropriate dose of pembrolizumab when combined with TGR-1202 and TG-1101 in patients with advanced CLL. The Phase 2 part of the study will further evaluate the safety and effectiveness of the triple combination at the recommended Phase 2 dose.

This study is currently open to enrollment at the Abramson Cancer Center of the University of Pennsylvania in Philadelphia, PA. 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. 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. The Company also has pre-clinical programs to develop IRAK4 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 anticipating future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 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 pre-clinical and clinical trials for TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 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 the results seen from the triple combination of TGR-1202, TG-1101 and pembrolizumab will not be sufficiently promising to warrant additional clinical testing with anti-PD-L1/anti-PD-1 anitbodies; 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 data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior pre-clinical 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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