October 5, 2017

TG Therapeutics, Inc. Announces Advancement of its Anti-PD-L1 Monoclonal Antibody into Clinical Development

NEW YORK, Oct. 05, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDQ:TGTX), today announced that the first patient has been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of its proprietary fully-human anti-PD-L1 monoclonal antibody. This first-in-human, Phase I, open-label, multicenter study is evaluating the safety and tolerability of ascending doses of our anti-PD-L1 monoclonal antibody in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Secondary endpoints for this study include the evaluation or characterization of the pharmacokinetics, immunogenicity and preliminary efficacy. This study will initially enroll patients in sites across Australia and New Zealand.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are excited to bring our first immuno-oncology asset into clinical development. This first-in-human study is being conducted in solid tumors to expedite enrollment and enrich for patients most likely to respond to anti-PD-L1 therapy. Once a recommended Phase 2 dose is identified, we plan to commence a study in B-cell malignancies both as a single agent and in combination with our other pipeline products. We have already piloted the concept by combining our proprietary 'U2' (TG-1101 + TGR-1202) regimen with the PD-1 inhibitor, pembrolizumab, and believe that experience will speed the development of our proprietary triplet." Mr. Weiss continued, "As always, our vision is to develop best-in-class combination therapies and we believe adding PD-1/PD-L1 therapy to targeted therapy represents the next generation of treatment options for patients with B-cell malignancies. Advancing our proprietary anti-PD-L1 into the clinic is an important first step in reaching this goal."

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 (umbralisib), 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, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for autoimmune disorders. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody 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, particularly those anticipating future clinical trials, timing of clinical trials for anti-PD-L1 antibodies and business prospects and potential uses for anti-PD-L1 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 demonstrate that our anti-PD-L1 antibody is safe in humans or that we can identify a dose that is both safe for humans and has anti-cancer activity to support future development, our ability to successfully and cost-effectively complete additional pre-clinical and clinical trials for our anti-PD-L1 antibody; the risk that any potential benefit that may be seen in Phase 1 in therapy-naïve patients with selected recurrent or metastatic cancers will not be indicative of potential efficacy in patients with B-cell malignancies; the risk that even if a safe and an effective dose can be identified for our anti-PD-L1 antibody as a single agent, that we still may not be able to safely combine our anti-PD-L1 antibody with our other product candidates, for example TG-1101 and TGR-1202 (collectively, the U2 regimen) blocking our ability to create a proprietary triple therapy; the risk that even if our anti-PD-L1 antibody can be combined safely with our other product candidates, that the triple combination will not prove to be more efficacious than our current doublet U2 therapy or any doublet therapy we develop in the future; 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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