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TG Therapeutics Announces Orphan Drug Designation for the Combination of TG-1101 and TGR-1202 for Treatment of Chronic Lymphocytic Leukemia

NEW YORK, Jan. 09, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation covering the combination of TG-1101 (ublituximab), the Company's novel, glycoengineered anti-CD20 monoclonal antibody, and TGR-1202 the Company's oral, next generation PI3K delta inhibitor, for the treatment of patients with chronic lymphocytic leukemia (CLL). The combination of TG-1101 and TGR-1202 is currently being evaluated in the UNITY-CLL Phase 3 Trial for patients with both frontline and previously treated CLL as well as the UNITY-DLBCL Phase 2b Trial for patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

"Receiving orphan drug designation for our proprietary combination of TG-1101 and TGR-1202 provides another layer of exclusivity protection on top of the composition of matter patents which were issued for TG-1101 and TGR-1202 last year and patents on the combination that have been filed and are pending approval," stated Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics. "Additionally, with enrollment into our UNITY-CLL Phase 3 trial currently exceeding our expectations, we expect to be able to commence a regulatory filing for the combination in 2018 and having orphan drug designation will provide certain cost saving advantages for us during the regulatory approval process."

ABOUT ORPHAN DRUG DESIGNATION

Orphan drug designation is granted by the FDA to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides certain incentives which may include tax credits towards the cost of clinical trials and prescription drug user fee waivers. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity.

ABOUT CHRONIC LYMPHOCYTIC LEUKEMIA

Chronic lymphocytic leukemia (CLL) is a type of cancer in which the bone marrow makes too many lymphocytes (a type of white blood cell). CLL usually gets worse slowly and is one of the most common types of leukemia in adults. It often occurs during or after middle age. It is estimated that there are approximately 20,000 new cases of CLL diagnosed each year in the United States.

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 anticipating benefits from Orphan Drug Designation for TG-1101 in combination with TGR-1202, 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 pre-clinical 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 pre-clinical 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 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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