January 24, 2017

TG Therapeutics Announces Orphan Drug Designation for the Combination of TG-1101 and TGR-1202 for the Treatment of Diffuse Large B-cell Lymphoma

NEW YORK, Jan. 24, 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 diffuse large B-cell lymphoma (DLBCL).

The combination of TG-1101 and TGR-1202 is currently being evaluated in the UNITY-DLBCL Phase 2b Trial for patients with relapsed or refractory DLBCL as well as the UNITY-CLL Phase 3 Trial for patients with both frontline and previously treated chronic lymphocytic leukemia (CLL).

"We are pleased to receive orphan drug designation for our proprietary combination of TG-1101 and TGR-1202 in diffuse large B-cell lymphoma. This status complements our already strong proprietary protection portfolio which includes composition of matter patents issued for both TG-1101 and TGR-1202, as well as orphan drug designation already granted for the combination in CLL," stated Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics. Mr. Weiss continued, "DLBCL is an area of significant unmet medical need and we are highly encouraged by the early clinical data we have seen in DLBCL patients treated with 1101 plus 1202 and look forward to evaluating this further in our ongoing Phase 2b registration directed trial."

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 DIFFUSE LARGE B-CELL LYMPHOMA

According to the American Cancer Society, diffuse large B-cell lymphoma (DLBCL) is an aggressive (fast growing) type of non-Hodgkin lymphoma (NHL), a cancer that starts in cells called lymphocytes, which are part of the body's immune system. Diffuse large B-cell lymphoma is the most common type of NHL in the United States, accounting for about 30% of newly diagnosed cases of NHL. DLBCL occurs in both men and women and can affect any age group, although its prevalence increases with age, with the average age of diagnosis being in the mid-60s.

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.

TGTX - G

CONTACT:

Jenna Bosco

Vice President, Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4351

Email: ir@tgtxinc.com

Primary Logo

Source: TG Therapeutics, Inc.