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TG Therapeutics Announces Orphan Drug Designation for TG-1101 for the Treatment of Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorder

NEW YORK, Aug. 26, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for TG-1101 (ublituximab) the Company's novel, glycoengineered anti-CD20 monoclonal antibody, for the treatment of patients with neuromyelitis optica (NMO) and neuromyelitis optica spectrum disorder (NMOSD). There are currently no FDA approved treatments for NMO or NMOSD.

"We are pleased to announce our first orphan drug designation for TG-1101 in a non-oncology indication, providing additional proprietary protection for TG-1101, which has a composition of matter patent in the U.S. through mid-2029, exclusive of patent term extensions. As demonstrated with the announcement earlier this week of the orphan drug designation for TGR-1202 in the treatment of CLL, we are committed to building strong proprietary protection around our key compounds, which includes a multi-level patent strategy and orphan drug designations where appropriate," stated Michael S. Weiss, Executive Chairman and Interim CEO of TG Therapeutics. "NMO is closely related to Multiple Sclerosis, an area of significant interest to us. We look forward to presenting early data from our current Phase 1b study of TG-1101 in NMO at the ECTRIMS (European Committee for the Treatment and Research in Multiple Sclerosis) conference this September, which we believe will provide an early peek into the effects of TG-1101 in patients with autoimmune diseases."

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

Neuromyelitis optica (NMO) and NMO Spectrum Disorder (NMOSD), also known as Devic's disease, is an immune-mediated severe chronic inflammatory disorder with involvement of different regions of the central nervous system (CNS) that primarily affects the optic nerve and the spinal cord. The damage to the optic nerves produces swelling and inflammation that cause pain and loss of vision, while damage to the spinal cord causes weakness or paralysis in the legs or arms, loss of sensation, and problems with bladder and bowel function. NMO is a relapsing-remitting form of autoimmune disease, similar to MS. During a relapse, new damage to the optic nerves and/or spinal cord can lead to accumulating disability. However, unlike MS, progressive phase of this disease is very rare. Therefore, preventing attacks is critical to a good long-term outcome. There is currently no cure or approved medicine for NMO, which affects about five in 100,000 people.

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 pre-clinical 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, 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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