May 3, 2016

TG Therapeutics, Inc. Launches First Clinical Trial in Multiple Sclerosis (MS) for TG-1101 (Ublituximab)

Phase 2 study commenced to determine optimal dosing regimen in Relapsing MS patients

MS Program for TG-1101 targeted to enter Phase 3 in 2017

NEW YORK, May 03, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced the opening of its Phase 2 clinical study of TG-1101 (ublituximab), the Company's glycoengineered anti-CD20 monoclonal antibody, in patients with relapsing remitting multiple sclerosis (RRMS), a chronic demyelinating disease of the central nervous system (CNS). This is the first company sponsored clinical trial evaluating the safety, tolerability, and efficacy of TG-1101 in autoimmune diseases. The Company is also supporting an investigator-sponsored study at John's Hopkins University Medical Center that is currently enrolling patients with Neuromyelitis Optica (NMO), a related demyelinating disease similar to MS but of the optic nerve and spinal cord.

The study, entitled "A Placebo-Controlled Multi-Center Phase 2 Dose Finding Study of Ublituximab, a Third-Generation Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis," is being led by Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX. The primary objective of the study is to determine the optimal dosing regimen for TG-1101 with a focus on accelerating infusion times. In addition to monitoring for safety and tolerability at each dosing cohort, B-cell depletion and established MS efficacy endpoints will also be evaluated.

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer commented on the news, "We are excited to launch our first study in the treatment of patients with relapsing forms of MS, an area of significant unmet medical need. B-cell depletion therapy has recently proven to be highly effective in the treatment of both relapsing and progressive forms of MS. TG-1101 is a potent b-cell depleting agent; in our oncology studies TG-1101 has demonstrated an ability to cause rapid and profound B-cell depletion with a favorable safety profile. Additionally, early B-cell depletion data from our NMO study appears to confirm TG-1101's potent B-cell depleting effects." Mr. Weiss continued, "This Phase 2 trial has been uniquely designed to evaluate rapid administration schedules for TG-1101, potentially allowing us to offer a very attractive and convenient treatment option for patients. We look forward to collaborating with Dr. Fox and the other investigators in this important study and launching a Phase 3 trial for TG-1101 in MS next year."

Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX and Study Chair of the Phase 2 study added, "We look forward to collaborating with TG Therapeutics on this first clinical trial of TG-1101 in patients with relapsing forms of MS. An increasing amount of data strongly suggests a critical role for B-cells in the pathophysiology of MS. B-cell depletion therapy through the use of an anti-CD20 monoclonal antibody has the potential to offer a highly effective treatment option that has an acceptable safety and tolerability profile."

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 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 for various hematologic malignancies. 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 now entering clinical development for autoimmune disorders. 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, especially those for MS and other autoimmune diseases, 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 TG-1101 will not prove to be safe or efficacious in autoimmune diseases or that we will be unable to start or complete trials in MS and/or other autoimmune diseases on time or at all; 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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