



September 15, 2014

TG Therapeutics Announces Special Protocol Assessment (SPA) Agreement With the FDA for Its First Phase 3 Clinical Trial of TG-1101 (ublrituximab) in Combination With Imbruvica(R) (ibrutinib) for Patients With Previously Treated Chronic Lymphocytic Leukemia

Overall Response Rate (ORR) to be the Primary Endpoint to Support Accelerated Approval with Progression-Free Survival (PFS) to Support Full Approval

Safety and Efficacy Data from Over 30 CLL Patients from the On-going Phase 2 Trial of the Combination of TG-1101 plus ibrutinib Anticipated to be Presented at ASH 2014

NEW YORK, Sept. 15, 2014 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX) announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for TG-1101 (ublrituximab), its glycoengineered anti-CD20 monoclonal antibody, in combination with Imbruvica® (ibrutinib) for the treatment of Chronic Lymphocytic Leukemia (CLL) in patients with high risk cytogenetics. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that would support the regulatory submission for drug approval.

Full details of the Phase 3 clinical trial will be released at the launch of the study, which is expected to occur before the end of the year. In this randomized controlled trial, patients will receive either TG-1101 plus ibrutinib or ibrutinib alone. The trial will enroll approximately 330 patients, with approximately the first two-thirds of the patients included in the ORR assessment. As per the SPA, the Company plans to use the ORR data from the trial as the basis for submission of a Biologics License Application (BLA) for accelerated approval for TG-1101. All patients will then be followed for PFS assessment, which is designed to support full approval.

Additionally, the Company reported that enrollment into the CLL cohort of its ongoing combination Phase 2 study of TG-1101 plus ibrutinib is now closed. The Company expects it will have over 30 CLL patients evaluable for safety and efficacy available for presentation at the Annual Meeting of the American Society of Hematology (ASH) this December.

Dr. Jeff Sharman, Medical Director of Hematology Research for the US Oncology Network, and currently the lead investigator on the Company's Phase 2 combination trial of TG-1101 plus ibrutinib, will be the Study Chair for this Phase 3 trial. Dr. Sharman commented, "We have been very pleased with the safety and activity profile of the combination seen thus far in our Phase 1/2 trial, and are excited to lead this important clinical trial. Combining a glycoengineered anti-CD20 monoclonal antibody with ibrutinib has the potential to materially increase the number of patients benefitting from treatment with ibrutinib therapy. The Phase 2 trial has enrolled very quickly throughout our clinical research network with patients, physicians, and nurses recognizing the benefits of this study."

Michael S. Weiss, Executive Chairman and Interim Chief Executive Officer of TG Therapeutics, stated, "The TG-1101 SPA agreement is a major milestone for us as it represents the first clearly defined development and regulatory pathway for the approval of TG-1101 for the treatment of CLL. As we've mentioned previously, reaching agreement with the FDA on this combination trial with ORR as a primary endpoint for accelerated approval was our number one priority. We are thrilled to get this first SPA in place earlier than anticipated, which puts us in an excellent position to build out the remainder of our registration program for both TG-1101 and TGR-1202. We would like to thank the FDA for its invaluable guidance throughout this process. The speed at which the FDA reviewed the submission demonstrates a real commitment to drive novel medicines to the patients who need them as rapidly as possible." Mr. Weiss continued, "We look forward to launching this trial by year end and are excited to continue to work with Dr. Sharman, the entire US Oncology team, and all investigators, who have been instrumental in our development of this important combination."

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is an innovative, clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for cancer and autoimmune diseases. Currently, the company is developing two therapies targeting hematological malignancies. TG-1101 (ublrituximab) 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. The Company also has a pre-clinical

program to develop IRAK4 inhibitors. TG Therapeutics is headquartered in New York City.

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application.

Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessment, please visit: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf>.

Cautionary Statement

Some of the statements included in this press release, particularly those anticipating future clinical trials, the timing of commencing, completing or reporting such trials and the business prospects for TG-1101 and TGR-1202, 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 and TGR-1202; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101 and TGR-1202 will not be reproduced in additional patients or in future studies; 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 our ongoing or contemplated drug combinations may not prove tolerable or efficacious; 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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Source: TG Therapeutics, Inc.

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