



May 14, 2012

TG Therapeutics, Inc. Announces Investigational New Drug (IND) for TGTx-1101, Receives Clearance by the FDA to Commence Clinical Trials in the U.S.

NEW YORK, May 14, 2012 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (the "Company") - announced today that the U.S. Food and Drug Administration ("FDA") has cleared its Investigational New Drug Application ("IND") for TGTx-1101, also known as ublituximab, a novel third generation chimeric monoclonal antibody targeting a unique epitope on the CD20 antigen found on B lymphocytes. The Company is now permitted to commence its Phase 1/2 clinical trial in patients with B-cell Lymphomas, which it plans to do this summer.

The protocol submitted with the IND is entitled "An Open Label Phase I/II Study of the Efficacy and Safety of Ublituximab in Patients with B-cell Non-Hodgkin Lymphoma who have Relapsed or are Refractory After CD20 Directed Antibody Therapy." The study will enroll up to 36 patients in the Phase 1 dose escalation component. Once the optimal dose is determined, up to 77 patients will be enrolled and stratified by subtype of B-cell Lymphoma, including Follicular Lymphoma, Diffuse Large B-Cell Lymphoma and other NHL subtypes for the Phase II component. All enrolled patients will be relapsed or refractory to Rituxan® or a Rituxan® containing regimen, and in many cases multiple other therapies. Owen A O'Connor, MD, PhD, Professor of Medicine and Director, The Center for Lymphoid Malignancies, New York Presbyterian Hospital – Columbia University Medical Center, will lead the Phase 1/2 study.

"Having only executed the license in late January, we were delighted by the speed at which we were able to file and receive clearance of our first IND," stated Michael S. Weiss, Executive Chairman and Interim CEO, who continued, "We are excited to be able to test ublituximab in B-cell Lymphomas following the high rate of response seen in our original study in relapsed and refractory Chronic Lymphocytic Leukemia."

ABOUT UBLITUXIMAB

Ublituximab is a novel, third generation chimeric monoclonal antibody targeting a unique epitope on the CD20 antigen found on B lymphocytes. Ublituximab has been bioengineered for enhanced biological activity with an increased ability to trigger an immune response, delivering superior ADCC effects to aid in B-cell depletion. Ublituximab has displayed high single agent activity in a Phase 1/2 clinical trial in patients with relapsed Chronic Lymphocytic Leukemia, and is being developed by TG Therapeutics in multiple oncology and autoimmune indications.

Ublituximab has been granted orphan status in Europe and in the USA for B-cell Chronic Lymphocytic Leukemia.

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is an innovative, clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. Currently we are developing ublituximab (TGTx-1101), a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes.

The TG Therapeutics logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=11857>

Cautionary Statement

Some of the statements included in this press release, particularly those anticipating future clinical trials and business prospects for ublituximab 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 ublituximab; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data analyses from prior pre-clinical and clinical trials; 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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