



September 5, 2012

## **TG Therapeutics, Inc. Initiates a Phase I/II Clinical Trial of Its Novel Third-Generation Anti-CD20 Monoclonal Antibody, Ublituximab, in Patients With Relapsed or Refractory B-cell Non-Hodgkin's Lymphoma**

*Multi-Center Phase I/II Trial Led by Dr. Owen O'Connor, MD, PhD, Director, Center for Lymphoid Malignancies, New York Presbyterian Columbia Medical Center*

*TG Therapeutics to Host a Conference Call on Thursday, September 6, 2012 at 8:30am EDT to Provide an Update on the Company's Business and Clinical Developments*

NEW YORK, Sept. 5, 2012 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (TGTX) today announced that it has initiated a Phase I/II trial to evaluate the safety, tolerability and efficacy of ublituximab, the company's novel third-generation anti-CD20 monoclonal antibody, for patients with relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL) who were previously treated with rituximab (Rituxan®). This is the company's first clinical trial conducted in North America and the first trial of ublituximab in patients with NHL. Previously, at the 53<sup>rd</sup> Annual American Society of Hematology meeting in December 2011, Phase I data from a trial conducted in France of ublituximab administered as a single agent to patients with relapsed and refractory Chronic Lymphocytic Leukemia (CLL) reported an objective response rate of 45%.

The trial, entitled "An Open Label Phase I/II Trial 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," will enroll up to 36 patients in the Phase I dose escalation component. Once the optimal dose is determined, up to 77 patients total will be enrolled for the Phase II component and stratified by subtype of B-cell Lymphoma, including Follicular Lymphoma, Diffuse Large B-cell Lymphoma, Marginal Zone Lymphoma and other NHL subtypes. All enrolled patients will be relapsed or refractory to Rituxan® or a Rituxan® containing regimen, and in most cases multiple other lines of therapy.

"Ublituximab has demonstrated profound and sustained B-cell depletion in multiple pre-clinical NHL models, as well as impressive single agent activity in patients with relapsed/refractory CLL, and could now represent an important therapy for patients relapsed from or refractory to prior rituximab. We are excited to evaluate the role of ublituximab in this NHL patient population which is in great need of more effective therapies," stated Dr. Owen O'Connor, Professor of Medicine and Director, Center for Lymphoid Malignancies at New York Presbyterian Columbia Medical Center, and principle investigator of the trial.

"We are excited to begin working with Dr. O'Connor and the other high-quality centers involved in our first North American trial," stated Michael S. Weiss, Executive Chairman and Interim CEO, who continued, "We believe ublituximab, through its recognition of a novel epitope on CD20 and ability to induce considerably greater ADCC than rituximab, has the potential to represent a new treatment paradigm, extending and enhancing anti-CD20 therapy for patients with B-cell malignancies."

TGTX will host a conference call Thursday, September 6, 2012, at 8:30am EDT to provide an update on the Company's recent developments and upcoming events. In order to participate in the conference call, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), conference title: TG Therapeutics. The audio recording of the conference call will be available for replay at <http://www.tgtherapeutics.com>, for a period of 30 days after the call.

### **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 I/II 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, the company is developing two advanced therapies targeting hematological malignancies. TGTX-1101 (ublituximab) is a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes, currently in clinical development for patients with relapsed and refractory non-Hodgkin's lymphoma. TG Therapeutics is also developing TGR-1202, a highly specific, 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. TG Therapeutics is headquartered in New York City.

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](http://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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