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TG Therapeutics, Inc. Initiates a Phase I/II Clinical Trial of Its Novel Third-Generation Anti-CD20 Monoclonal Antibody, TG-1101 (Ublituximab), in Combination With Lenalidomide (Revlimid(R)) in Patients With B-Cell Lymphoid Malignancies

Second North American Study of TG-1101 Now Open for Patient Enrollment

NEW YORK, Dec. 7, 2012 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (OTCBB:TGTX) today announced that it has initiated a Phase I/II trial to evaluate the safety, tolerability and efficacy of TG-1101, the company's novel third-generation anti-CD20 monoclonal antibody, in combination with lenalidomide (Revlimid®) for patients with relapsed or refractory B-cell lymphoid malignancies who were previously treated with anti-CD20 antibody therapy. This multicenter trial will be led by Dr. Marshall Schreeder of the Clearview Cancer Institute in Huntsville, AL. This marks the company's second clinical trial of TG-1101 in North America, following the initiation of the Company's on-going Phase I/II trial with single agent TG-1101 in patients with Non-Hodgkin's Lymphoma (NHL), which opened for enrollment in September of this year. These studies build upon the Company's first in man clinical trial reported last year at ASH in which TG-1101 was studied in patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL). In that study, which was presented at the 53rd Annual American Society of Hematology meeting in December 2011, TG-1101 demonstrated a 45% ORR.

This trial, entitled "TG-1101-102: A Phase I/II Study of Ublituximab in Combination with Lenalidomide (Revlimid®) in Patients with B-Cell Lymphoid Malignancies who have Relapsed or are Refractory After CD20 Directed Antibody Therapy," will enroll up to 30 patients in the Phase I dose escalation component. Once the optimal dose is determined, the Phase II component will enroll up to an additional 30 patients, stratified by B-cell malignancy subtype, including CLL and various NHL subtypes. All enrolled patients will be relapsed or refractory to a prior anti-CD20 antibody containing regimen (Rituxan® and/or Arzerra®), and in most cases multiple other lines of therapy.

"We are very excited to announce the launch of our second clinical trial this year for TG-1101, now in combination with lenalidomide, targeting patients with advanced B-cell lymphoid malignancies, including CLL," stated Michael S. Weiss, Executive Chairman and Interim CEO, who continued, "Lymphoma experts widely believe the combination of anti-CD20 therapy with lenalidomide has the potential to dramatically alter the treatment paradigm for patients with B-cell malignancies. With a demonstrated ability to induce significantly greater ADCC activity over rituximab, TG-1101 is uniquely positioned to take advantage of the NK-cell activating properties exhibited by lenalidomide; providing a strong biological rationale for clinically meaningful synergy in the combination of these two agents."

ABOUT TG-1101 (UBLITUXIMAB)

TG-1101 is a novel, third generation chimeric monoclonal antibody targeting a unique epitope on the CD20 antigen found on B-lymphocytes. TG-1101 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. TG-1101 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. TG-1101 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 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. TG Therapeutics is headquartered in New York City. For more information, visit the TG Therapeutics website at www.tgtherapeutics.com.

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 TG-1101 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; 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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