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TG Therapeutics, Inc. Opens Expansion Cohorts in Its Phase I/II Trial of TG-1101 (Ublituximab) in Patients With Rituximab Relapsed or Refractory B-cell Non-Hodgkin's Lymphoma

Cohort Expansion Now Open for Enrollment Following Early Signs of Clinical Activity

NEW YORK, Feb. 11, 2013 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (TGTX) today announced that it has amended its Phase I/II study of single agent ublituximab to initiate its first expansion cohort following early signs of clinical activity. The protocol has been expanded to enroll up to 25 additional patients at the 900 mg dose level in the Phase I/II trial evaluating the safety, tolerability and efficacy of ublituximab, the Company's novel third-generation anti-CD20 monoclonal antibody, for patients with rituximab (Rituxan®) relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL). Dose escalation will continue as planned to the 1200 mg dose cohort. Following successful completion of the dose escalation component of the study, an additional expansion cohort may be added at the highest dose of 1200 mg.

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," (NCT01647971) has completed enrollment in 3 cohorts (450, 600 and 900mg) in the Phase I dose escalation component. All patients continue to be stratified by subtype of B-cell Lymphoma and all enrolled patients will be relapsed or refractory to Rituxan® or a Rituxan® containing regimen, and in most cases multiple other lines of therapy.

In addition to the cohort expansion, the study was amended to now allow enrollment of patients with Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL) as well as Primary Central Nervous System Lymphoma (PCNSL). Phase I data from a trial conducted in France with ublituximab administered as a single agent at a dose of 450 mg to relapsed and refractory CLL patients reported an objective response rate of 45%, with a manageable safety profile.

Dr. Owen O'Connor, Professor of Medicine and Director, Center for Lymphoid Malignancies at New York Presbyterian Columbia Medical Center, and the principal investigator of the trial stated "Ublituximab has been well-tolerated at all dose levels tested with no dose limiting toxicities seen to date. Coupled with the clinical activity seen in both rituximab relapsed and refractory patients across the dose levels tested thus far, we made the determination to expand the 900mg dose while we continue dose escalating. We look forward to expanding the study to better evaluate the safety and efficacy profile of ublituximab in multiple sub-types of B-cell malignancies."

"We are very excited about the early results from this first U.S.-based study of ublituximab in NHL. The early activity seen thus far, along with the activity seen in our Phase 1 study in patients with CLL, gives us a high degree of confidence that ublituximab is an active anti-CD20 monoclonal antibody for the treatment of B-cell malignancies," stated Michael S. Weiss, Executive Chairman and Interim CEO.

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 for patients with various hematologic malignancies. 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. TG-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. 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. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies. 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 TG-1101 and TGR-1202 and 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 clinical results that supported our decision to move forward into expansion cohorts will not be reproduced once additional patients are treated with TG-1101; 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; 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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