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TG Therapeutics Announces Novel "Chemo-free" Triple Therapy Combination Clinical Study for Patients With Chronic Lymphocytic Leukemia and Other B-cell Malignancies

Represents the First Time Patients Will be Treated With the Combination of a Glycoengineered Anti-CD20 Monoclonal Antibody (TG-1101) With a PI3k Delta Inhibitor (TGR-1202) and a BTK-inhibitor (ibrutinib)

NEW YORK, Aug. 15, 2014 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), today announced the commencement of a novel triple therapy clinical study that combines the Company's two experimental drugs, TG-1101, a glycoengineered anti-CD20 monoclonal antibody, and TGR-1202, a PI3K delta inhibitor, with the marketed BTK-inhibitor, ibrutinib (Imbruvica®). This is the first time that a BTK-inhibitor and a PI3k delta inhibitor have been used in combination with each other in patients. The trial is being led by Drs. Susan O'Brien and Nathan Fowler at MD Anderson, and Drs. Julie Vose and Matt Lunning of University of Nebraska, and will be run as a component of the previously announced and on-going Phase 1 study of the combination of TG-1101 and TGR-1202. The study will utilize fixed doses of TG-1101 and ibrutinib and will provide for dose escalation of TGR-1202.

As previously announced, preliminary data from this combination study of TG-1101 plus TGR-1202 was presented at the 2014 Pan Pacific Lymphoma Conference, where the combination appeared well-tolerated at the doses tested to date. Preliminary signs of efficacy in high-risk CLL patients were very encouraging with 4 of 5 patients from the CLL cohort achieving a partial response (> 50% decrease in disease) at first assessment and the fifth patient achieving stable disease with a nodal reduction of nearly 45% awaiting a second efficacy assessment.

Additionally, at the European Hematology Association meeting in June, the Company announced preliminary data from an ongoing study utilizing the combination of TG-1101 plus ibrutinib. The combination appeared to be well-tolerated with minimal grade 3/4 events observed, and significant efficacy demonstrated with 10 of 10 patients achieving a complete or partial response (as updated on the Company's recent quarterly conference call).

Given the favorable safety profile and significant activity of these two doublet combinations, it was hypothesized that the triple therapy may be safe and well-tolerated, and offer even greater activity over either doublet regimen.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO, stated, "Our mission has been and continues to be to develop novel combination therapies for the treatment of B-cell malignancies that can provide better patient outcomes without the use of harsh chemotherapies. We believe that to achieve this goal, combinations of multiple targeted agents will be required, and we plan to continue to be the leader in exploring novel combinations exploiting a variety of mechanisms. The start of today's triple therapy study marks the beginning of the next level of exploration and our commitment to patients living with this disease as well as demonstrates the speed at which we can move forward novel combinations. We are fortunate that our vision is shared by some of the leading investigators in the field of hematologic malignancies, and we thank the Study Chairs, Dr. O'Brien and Dr. Fowler, as well as all the investigators involved in this exciting combination trial for their continued support and enthusiasm to innovate and drive the field forward to next level."

Dr. Susan O'Brien, Professor in the Department of Leukemia at MD Anderson Cancer Center and Study Chair for the CLL patient group stated, "We are excited to be able to move quickly and test this triple combination of chemo-free targeted agents, and feel TGR-1202, with its safety profile demonstrated to date, is uniquely suited to combination with ibrutinib. Chemotherapy combinations have long been the standard of care for patients with CLL, and with the development of these novel, targeted agents, we hope to induce greater responses and longer durations of remission without compromising safety."

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 therapies targeting hematological malignancies. TG-1101 (ublituximab) 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.

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, the business prospects for TG-1101 and TGR-1202, the potential benefits of combining TG-1101 and TGR-1202 and the potential benefits that might be achieved with the micronized formulation and fed-state dosing 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 enhanced absorption seen in the healthy human volunteer bioequivalence studies will not be seen in whole or in part when the modified formulation and fed-state dosing are studied in patients with B-cell malignancies; the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current phase 1 study; 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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