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TG Therapeutics, Inc. Launches Combination Clinical Trial of TG-1101 and Ibrutinib in Patients With Select B-Cell Malignancies

Combination Trial Led by Jeff Sharman, MD, Medical Director Hematology Research, US Oncology and Owen A. O'Connor, MD, PhD, Director of the Center for Lymphoid Malignancies, Columbia University Medical Center in New York, NY

NEW YORK, Dec. 6, 2013 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), an innovative, clinical-stage biopharmaceutical company today announced that it has initiated a multi-center Phase 2 clinical trial to evaluate the safety and efficacy of the combination of TG-1101 (ublituximab) and ibrutinib (IMBRUVICA®) for patients with Chronic Lymphocytic Leukemia (CLL) and Mantle Cell Lymphoma (MCL). This will be the first clinical trial evaluating the combination of TG-1101, the Company's novel glycoengineered anti-CD20 monoclonal antibody, and ibrutinib, the oral Bruton Tyrosine Kinase (BTK) inhibitor which was recently granted approval by the U.S. Food and Drug Administration (FDA).

The trial, entitled "A Multi-center Phase 2 Study with Safety Run-in Evaluating the Efficacy and Safety of Ublituximab in Combination with Ibrutinib in Patients with Select B-Cell Malignancies," will enroll patients with CLL and MCL who are eligible to receive ibrutinib. TG Therapeutics has partnered with the US Oncology Network, Columbia University and other select centers throughout the United States on the study. Jeff Sharman, MD, Medical Director for Hematology Research, US Oncology Network, will be the Study Chair for the CLL patient group, while Owen A. O'Connor, MD, PhD, Professor and Director of the Center for Lymphoid Malignancies, Columbia University Medical Center will be the Study Chair for the MCL patient group.

"I am impressed with the speed at which our team was able to launch this important combination study, with ibrutinib being approved just over three weeks ago," stated Michael S. Weiss, Executive Chairman and Interim CEO, who continued, "the launch of this combination study today represents another significant milestone for the Company following our recent announcement of our combination trial of TG-1101 with TGR-1202, our novel PI3K-delta inhibitor. We believe the addition of TG-1101 to ibrutinib will significantly enhance the efficacy demonstrated with ibrutinib alone in patients with CLL and MCL. We are excited to partner with the US Oncology Network, along with Dr. Sharman and Dr. O'Connor as co-lead investigators for this important clinical trial."

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, jointly with Rhizen Pharmaceuticals S A. 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.

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 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 TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following 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; 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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