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TG Therapeutics Announces Collaboration for a Clinical Trial of TGR-1202 in Combination With Ibrutinib (Imbruvica(R)) for Patients With Select B-Cell Malignancies

NEW YORK, Dec. 1, 2014 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX) announced today the initiation of a multi-center, Phase I trial to evaluate the safety and efficacy of the combination of TGR-1202 and ibrutinib for patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL). This is the first clinical trial evaluating the "all oral" combination of TGR-1202, the company's novel, once per day, PI3K Delta inhibitor with ibrutinib, the oral Bruton's tyrosine kinase (BTK) inhibitor approved by the U.S. Food and Drug Administration (FDA). The study is being run in collaboration with the Blood Cancer Research Partnership and Dana-Farber Cancer Institute (DFCI), Boston, MA.

The trial, entitled "A Multi-center Phase I/Ib Study Evaluating the Efficacy and Safety of the Novel PI3k Delta Inhibitor TGR-1202 in Combination with Ibrutinib in Patients with Select B-Cell Malignancies" is enrolling patients with CLL and MCL whose disease is relapsed from or refractory to prior therapy, including prior PI3K Delta inhibitors, and/or BTK inhibitors. DFCI is the lead center for the trial, with Matthew S. Davids, MD, MMSc as the Study Chair.

The trial is being supported in part by the Blood Cancer Research Partnership (BCRP), a network of sites for clinical trial testing of innovative blood cancer therapies, established by The Leukemia & Lymphoma Society (LLS) and DFCI. More information on the Blood Cancer Research Partnership can be found at http://www.dana-farber.org/Research/Departments-and-Centers/Blood-Cancer-Research-Partnership.aspx.

Michael S. Weiss, Executive Chairman and Interim Chief Executive Officer of TG Therapeutics, stated, "TGR-1202 has continued to demonstrate a unique safety profile, particularly as it relates to liver toxicity, as compared to other PI3K delta inhibitors that we believe makes it well suited for combination therapy. We are excited to launch the first, novel "all oral" and once-daily combination of our PI3K delta inhibitor, TGR-1202, with ibrutinib. We greatly appreciate the support and interest from the BCRP, the LLS as well as the team from Dana-Farber, and look forward to a strong collaboration."

Dr. Matthew Davids added "In the past year, we have witnessed the approval of targeted oral agents such as ibrutinib that are well-tolerated and highly efficacious in CLL and other B cell malignancies. This therapeutic revolution has only just begun, and the critical next step will be to evaluate rational combinations of new oral agents to determine the safety and efficacy of combination therapy. We are excited by the opportunity to evaluate the combination of one of the most promising novel agents in development, TGR-1202, with ibrutinib in CLL and MCL."

Additional details of the Phase I trial are available on www.clinicaltrials.gov, Identifier: NCT02268851.

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is an innovative, clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for cancer and autoimmune diseases. 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, also for hematologic malignancies and autoimmune diseases. 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 and the 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 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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