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TG Therapeutics, Inc. Initiates First-In-Human, Phase I Clinical Trial for Its Novel, Highly Specific PI3K-Delta Inhibitor, TGR-1202, in Patients With Hematologic Malignancies

NEW YORK, Jan. 8, 2013 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (TGTX) today announced that it has initiated a Phase I, open label, multi-center, first-in-human clinical trial of its novel PI3K delta inhibitor, TGR-1202, in patients with hematologic malignancies.

The study, entitled "A Phase I Dose Escalation Study Evaluating the Safety and Efficacy of TGR-1202 in Patients with Relapsed or Refractory Hematologic Malignancies," is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN, and will enroll approximately 30 patients during the initial dose escalation phase, followed by up to an additional 30 patients in an expansion phase once the optimal dose has been determined. Enrollment is open to patients with relapsed or refractory Non-Hodgkin's Lymphoma ("NHL"), Chronic Lymphocytic Leukemia ("CLL"), and Peripheral T-Cell Lymphoma ("PTCL"). Michael R. Savona, MD, Director of Leukemic Research, Sarah Cannon Research Institute, will act as Study Chair for the Phase I study.

"Having received FDA clearance of our IND only last week, the launch of this first-in-human Phase I study of TGR-1202 demonstrates our team's commitment to rapidly initiating and executing our clinical programs," stated Michael S. Weiss, Executive Chairman and Interim CEO of TG Therapeutics. "Inhibition of PI3K delta has demonstrated remarkable potential as a therapeutic strategy for the treatment of patients with hematologic malignancies and we are excited to begin working with Dr. Savona and the research team at Sarah Cannon and other centers across the United States to begin assessing the clinical potential of TGR-1202."

The commencement of this Phase I study of TGR-1202 marks the third clinical trial for TG Therapeutics, following the initiation of two Phase I/II clinical trials last year for TG-1101 (ublituximab), the Company's novel anti-CD20 monoclonal antibody, also under development for hematologic malignancies.

ABOUT TGR-1202

TGR-1202 is a highly specific, orally available, PI3K delta inhibitor, targeting the delta isoform with nanomolar potency and several fold selectivity over the alpha, beta, and gamma isoforms of PI3K. Inhibition of PI3K delta signaling with TGR-1202 has demonstrated activity in numerous pre-clinical models and primary cells from patients with hematologic malignancies. TG Therapeutics, Inc. and Rhizen Pharmaceuticals, SA are jointly developing TGR-1202 on a worldwide basis, excluding India.

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 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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CONTACT: Jenna Bosco

Director - Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4484

Email: ir@tgtxinc.com

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