TG Therapeutics Announces Initiation of Phase I First-in-Human Clinical Trial of its Anti-CD47/CD19 Bispecific Antibody, TG-1801, in Patients with Relapsed or Refractory B-cell Lymphoma

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NEW YORK, Feb. 26, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company dedicated to developing medicines for patients with B-cell mediated diseases, today announced the commencement of a Phase I first-in-human trial of TG-1801, the Company's novel first-in-class anti-CD47/CD19 bispecific antibody, in patients with relapsed or refractory B-cell lymphoma.

TG-1801 is the first therapy to target both CD19, a B-cell specific marker widely expressed across B-cell malignancies, and CD47, the "don't eat me" signal used by both healthy and tumor cells to evade macrophage mediated phagocytosis. CD47 is expressed ubiquitously on normal cells, including red blood cells and platelets. By co-targeting both CD47 and CD19, TG-1801 has the potential to overcome the limitations of existing CD47 targeted therapies by avoiding the side effects caused by indiscriminate blockade of CD47 on healthy cells.

This Phase I open label, multi-center trial is designed to assess the safety, pharmacokinetics, efficacy and recommended Phase 2 dose of TG-1801. The primary objective of the study is to determine the Maximum Tolerated Dose (MTD) and characterize the safety profile of TG-1801, with secondary endpoints including characterization of pharmacokinetics and preliminary anti-cancer activity.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased to announce the commencement of clinical development for TG-1801, our proprietary first-in-class anti-CD47/CD19 bispecific antibody which we licensed from Novimmune last year." Mr. Weiss continued, "CD47 targeted therapy has yielded promising early clinical results, and we look forward to exploring the potential of this dual targeted immunotherapy with a long-term goal of combining TG-1801 with our other in-house immunotherapies and targeted agents to create novel treatment options for patients with B-cell cancers."

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing two therapies targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) 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 umbralisib (TGR-1202), an oral, once-daily inhibitor of PI3K-delta. Umbralisib uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K-delta inhibitors. Both ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody, TG-1501, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801, into Phase 1 development. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release or in the abstracts mentioned in this press release 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 preclinical and clinical trials; the risk that early clinical trial results (both safety and efficacy), that may have supported or influenced our decision to proceed with additional clinical trials will not be reproduced in future studies or in the final presentations; the risk that we will not initiate future single agent or combination trials with TG-1801 or that if we do, the results of such clinical trials will not be promising to support further development of TG-1801 alone or in combination; the risk that TG-1801 will suffer the same safety and toxicity of existing CD47 targeted agents or will carry its own toxicity that will prohibit it from further development; the risk that we are unable to manage cash in line with our expectations and meet our development milestones and/or continue our operations without raising capital; the risk that we are unable to raise capital on acceptable terms; 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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