TG Therapeutics, Inc. Announces Publication of Clinical Data from the Phase I Triple Therapy Combination Trial of Ublituximab, Umbralisib, and Ibrutinib in The Lancet Haematology

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NEW YORK, Jan. 30, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced the publication of results from the multicenter Phase 1 triple combination trial of ublituximab (TG-1101), the Company's anti-CD20 monoclonal antibody, umbralisib (TGR-1202), the Company's oral once-daily PI3K delta inhibitor, and ibrutinib, the oral Bruton's tyrosine kinase (BTK) inhibitor, in The Lancet Haematology.

The paper includes safety and efficacy information from patients with relapsed or refractory B-cell malignancies, including 23 patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and 23 patients with non-Hodgkin lymphoma (NHL). Safety data was available from all 46 patients and the triple combination of ublituximab, umbralisib, and ibrutinib was well tolerated with a manageable adverse event profile, and no maximum tolerated dose achieved for the combination. Efficacy data was available from 44 patients and showed the triple combination to be highly active. The overall response rate (ORR) amongst all evaluable patients was 84%, with 100% (22 of 22) of patients with CLL/SLL achieving a response, including 36% achieving a Complete Response (CR). Among patients with NHL, 68% (15 of 22) achieved a response, including a 71% Overall Response Rate (ORR) in follicular lymphoma (FL) (n=7), a 100% ORR in marginal zone lymphoma (MZL) (n=3), and a 100% ORR in mantle cell lymphoma (MCL) (n=6).

These data are described further in the manuscript entitled, "Tolerability and activity of ublituximab, umbralisib, and ibrutinib in patients with chronic lymphocytic leukemia and non-Hodgkin lymphoma: a phase 1 dose escalation and expansion trial," which was featured as the cover article in the February issue of The Lancet Hematology published yesterday. The online version of the article can be accessed at https://www.thelancet.com/journals/lanhae/article/PIIS2352-3026(18)30216-3/fulltext

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated "We want to thank Dr. Loretta Nastoupil and the MD Anderson Cancer Center, as well as each of the participating trial sites and most importantly the patients who participated in this study. Umbralisib has demonstrated unique combinability with other targeted agents, and the data included in this publication further support our goal of developing a proprietary triple combination of ublituximab, umbralisib and our own BTK inhibitor, TG-1701, for which we target commencing clinical trials later this year."

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, as well as its covalently-bound Bruton Tyrosine Kinase (BTK) inhibitor, TG-1701, into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included 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. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, 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 preclinical and clinical trial results, that may have supported the acceptance of our data for publication or influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies or in future data presentations; the risk that umbralisib will not maintain its differentiated safety profile as patients continue to be treated on drug for longer durations and more patients are enrolled; the risk that the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2 and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations; the risk that we will not commence clinical trials of umbralisib plus TG-1701 or of U2 plus TG-1701; the risk that the early data seen with TG-1701 will not be reproduced in future trials. 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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