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TG Therapeutics, Inc. Announces Publication of Clinical Data from the Phase 1/2 Trial of TG-1101 (ublituximab) Monotherapy in the British Journal of Haematology

Single agent TG-1101 treatment resulted in 45% ORR in NHL and CLL patients previously exposed to rituximab, with a 31% ORR observed in rituximab-refractory patients

NEW YORK, Feb. 21, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) announced the publication of clinical data from a Phase 1/2 trial of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in patients with B-cell non-Hodgkin Lymphoma (NHL) or Chronic Lymphocytic Leukemia (CLL) previously exposed to rituximab. The data demonstrates single agent TG-1101 to be well tolerated with the most common adverse event observed being grade 1/2 infusion related reactions (IRR), with no grade 3/4 IRRs. TG-1101 monotherapy was active, with a 45% overall response rate (ORR) observed among heavily pretreated patients with NHL and CLL, including those who were refractory to prior anti-CD20 based therapy. These data are described further in the manuscript titled, "A phase 1/2 trial of ublituximab, a novel, glycoengineered anti-CD20 monoclonal antibody, in patients with B-cell non-Hodgkin lymphoma or chronic lymphocytic leukaemia previously exposed to rituximab," which was published online today in the *British Journal of Haematology*. The online version of the article can be accessed at http://onlinelibrary.wiley.com/doi/10.1111/bjh.14534/full.

"We want to thank Dr. Owen O'Connor, and the team from Columbia Presbyterian Medical Center and the Center for Lymphoid Malignancies for their work on this Phase 1/2 trial of single agent TG-1101 and congratulate them on the publication of these data. Since the inception of our Company, we have been focused on developing best-in-class agents with the goal of building novel combination therapies. This single agent data illustrates that TG-1101 is a safe and highly-active anti-CD20 monoclonal antibody on top of which additional treatments can be layered. The safety profile, speed of infusion, and response rates observed, with single agent TG-1101, especially in rituximab-refractory patients, serve as a foundation for our belief that TG-1101 is a best-in-class anti-CD20 monoclonal antibody," stated Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics. Mr. Weiss continued, "These Phase 1/2 data, as well as the combination data of TG-1101 plus ibrutinib published in the British Journal of Haematology late last year, further support our Phase 3 GENUINE trial of TG-1101 in combination with ibrutinib and we look forward to presenting top-line data from this study in the first half of this year."

"The addition of an anti-CD20 monoclonal antibody to other treatments, whether chemo-based or novel targeted therapies, has demonstrated to be an impactful way to enhance responses for patients with NHL and CLL. Acquired resistance to rituximab is a significant clinical issue for which many patients need an alternative effective agent to overcome the resistance. We are highly encouraged by the results we have seen in the clinic with ublituximab and believe the drug's safety profile, as well as shortened infusion times as compared to other anti-CD20s, can provide meaningful benefit to patients," stated Dr. Owen A. O'Connor, Professor of Medicine and Experimental Therapeutics, Director Lymphoid Malignancies at Columbia Presbyterian Medical Center.

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. 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, with TG-1101 recently entering clinical development for autoimmune disorders. The Company also has pre-clinical programs to develop IRAK4 inhibitors, BET inhibitors, and anti-PD-L1 and anti-GITR antibodies. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release, particularly those with respect to anticipating the timing of the completion of the GENUINE study, timing of top-line data for the GENUINE study, the usability of the results from GENUINE for accelerated approval, timing of initial data from the UNITY-DLBCL study, timing of the release of data and commencement of our MS pivotal program 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 the GENUINE, the UNITY-CLL or the UNITY-DLBCL trials; the risk that the clinical results from the GENUINE, UNITY-CLL and/or UNITY-DLBCL studies will be not positive and/or will not support regulatory approval of TG-1101 or TGR-1202; the risk that the FDA will not grant us a pre-BLA meeting to discuss the results of the GENUINE study; the risk that we will not file a BLA for TG-1101 or an NDA for TGR-1202 based on either the GENUINE or the UNITY-CLL; the risk that despite early positive trends in enrollment in the UNITY-CLL study that enrollment will be delayed beyond our projections; the risk that the planned interim analysis will not allow early closure of the single agent arms in the UNITY-CLL study, necessitating enrollment beyond the projected 450 patients, which would extend enrollment beyond our projections; the risk that safety issues or trends will be observed in the GENUINE study, the UNITY-CLL and/or the UNITY-DLBCL study that prevent approval of either TG-1101 and/or TGR-1202 or require us to terminate either the GENUINE study or the UNITY-CLL or the UNITY-DLBCL study prior to completion; 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 the GENUINE study, as amended or the UNITY-CLL or the UNITY-DLBCL studies, or any of our other registration-directed clinical trials as designed or amended may not be sufficient or acceptable to support regulatory approval; the risk that trials will take longer to enroll than expected; the risk that the projected cost savings to be realized by amending the GENUINE trial will not be realized; 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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