March 6, 2017

TG Therapeutics Announces Positive Topline Data from Phase 3 GENUINE Study of TG-1101 in Combination with Ibrutinib in Patients with High Risk Chronic Lymphocytic Leukemia (CLL)

Study met its primary endpoint, with TG-1101 (ublituximab) plus ibrutinib increasing Overall Response Rate (ORR) by > 70% over ibrutinib alone

The combination was well tolerated with a safety profile consistent with the Phase 2 study of ublituximab plus ibrutinib recently published in the British Journal of Haematology

Targeting full data presentation at a medical meeting in 1H17 and meeting with FDA in 2H17 to discuss the results and filing for accelerated approval

Conference call to be held today, Monday March 6, 2017 at 8:30 am ET, with Dr. Anthony Mato from the University of Pennsylvania, a lead enroller in the GENUINE trial

NEW YORK, March 06, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics (NASDAQ:TGTX) today announced positive topline results from its Phase 3 GENUINE clinical trial of TG-1101 (ublituximab) plus ibrutinib in patients with previously treated high risk Chronic Lymphocytic Leukemia (CLL). For the study, high risk was defined as having any one or more of the following: 17p deletion, 11q deletion or p53 mutation.

The multicenter, randomized trial (NCT02301156), which assessed the efficacy and safety of TG-1101 plus ibrutinib, met its primary endpoint, demonstrating a statistically significant improvement in Overall Response Rate (ORR) compared to ibrutinib alone in both the Intent to Treat (ITT) population (p=0.001) and Treated population (p < 0.001). The ITT population includes all 126 randomized patients (64 in the TG-1101 + ibrutinib arm and 62 in the ibrutinib alone arm) while the Treated population includes all ITT patients that received at least one dose of either study drug (59 in the TG-1101 + ibrutinib arm and 58 in the ibrutinib alone arm).

Overall Response Rates

	TG-1101 plus Ibrutinib	Ibrutinib	P-value
Treated Population (n)	n=59	n=58	
Overall Response Rate	80%	47%	P < 0.001

All responses were assessed by independent blinded central review using the iwCLL 2008 guidelines. Per iwCLL guidelines, responders require confirmation of response for a minimum duration of 2 months. As of the date of the analysis, each arm had responders that were awaiting confirmation visits which are scheduled to occur over the next two months. During the study it was infrequent (less than 3% in the combination arm) for initial responses to fail to be confirmed. Median follow-up for the study was approximately 12 months.

The GENUINE study was designed to demonstrate the value of adding TG-1101, a highly potent next generation glycoengineered anti-CD20 monoclonal antibody to ibrutinib monotherapy in high risk CLL, and was powered to show a statistically significant improvement in ORR, with a minimal absolute detectable difference between the two arms of approximately 20%. The absolute difference between the arms was approximately 30% resulting in a p-value of ≤ 0.001. Results from registration directed studies included in the ibrutinib prescribing information demonstrate single agent ibrutinib response rates ranging from 43% to 58% in patients with previously treated CLL, with the findings from the GENUINE study of 47% ORR for ibrutinib fitting well within historical experience.

In addition to ORR, observed advantages were seen for the combination in a number of secondary and other efficacy measures, including radiographic Complete Response (CR) rate, Progression Free Survival and Time to Response. Sufficient data on MRD negative status and bone marrow confirmation of radiographic CRs were not available at the time of analysis. From a safety standpoint, the combination was well tolerated with a safety profile consistent with the Phase 2 study of ublituximab plus ibrutinib recently published in the *British Journal of Haematology.*

A full analysis of the Phase 3 GENUINE data along with detailed efficacy and safety results will be submitted for presentation at a medical meeting in the first half of 2017 and the Company plans to meet with the FDA as soon as possible thereafter to discuss the filing of the data for accelerated approval.

"TG-1101 is a highly potent next generation glycoengineered anti-CD20 monoclonal antibody. We believe the data today demonstrate that the addition of TG-1101 to ibrutinib enhances the therapeutic benefit of ibrutinib in patients with previously treated high risk CLL, the patient population with the poorest outcome on ibrutinib. We believe the results observed in the combination arm are extremely compelling and the regimen has the potential to become the standard of care for treating patients with high risk CLL that have progressed from other therapies," said Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics. Mr. Weiss continued, "We believe that using combination therapy to accelerate and deepen response in poor prognosis high risk CLL is critically important for patient outcomes and we look forward to sharing these data with the FDA in the coming months to discuss filing for accelerated approval. Most importantly, we would like to thank the investigators and their patients for participating in this significant research."

Dr. Jeffrey Sharman, the GENUINE Phase 3 Study Chair and the Medical Director for Hematology Research for the US Oncology Network, commenting on the results stated, "Ibrutinib has been a great addition to our CLL armamentarium, however we have long believed that ibrutinib alone may not be enough, particularly for patients with high-risk disease. This study demonstrates that the addition of ublituximab, can significantly enhance the response rates without compromising safety. We believe that the rapid responses seen in our Phase 2 study with ublituximab plus ibrutinib are validated here in our Phase 3 GENUINE study and are important markers of improved overall efficacy and patient outcomes. I look forward to the presentation of the results at an upcoming medical meeting."

ABOUT THE PHASE 3 GENUINE STUDY

The Phase 3 GENUINE study is a randomized, open label, multicenter clinical trial to evaluate the safety and efficacy of TG-1101 (ublituximab) plus ibrutinib compared to ibrutinib alone in adult patients with high risk Chronic Lymphocytic Leukemia (CLL) who received at least one prior therapy for their disease.

The study was conducted at 160 clinical trial sites in the US and Israel and randomized 126 patients. Patients received ibrutinib orally at 420 mg once daily in both arms and in the treatment arm those patients also received intravenous infusions of TG-1101 at 900 mg dosed on days 1, 8 and 15 of cycle 1 and day 1 of cycles 2-6. Patients in the treatment arm who had not progressed received quarterly infusions of TG-1101 maintenance at 900 mg.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, Monday March 6, 2017 at 8:30 am ET to discuss the Phase 3 GENUINE Trial Topline Data.

In order to participate in the conference call, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), Conference Title: TG Therapeutics Phase 3 GENUINE Topline Data Call. A live webcast of this presentation will be available on the Events page, located within the Investors & Media section, of the Company's website at www.tgtherapeutics.com. An audio recording of the conference call will also be available for replay at www.tgtherapeutics.com, for a period of 30 days after the call.

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 also in 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

Statements included in this press release, including without limitation those with respect to expected results and results to date of the GENUINE Phase 3 study, the potential efficacy of TG-1101 in combination with ibrutinib, anticipating the timing of and data to be included in the full presentation and analysis of the GENUINE Phase 3 data, the willingness of the FDA to review the data for approval and any likelihood of FDA approval or disapproval and the timing of filing of a BLA for TG-1101, if any 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 or the UNITY-CLL trials; the risk that the clinical results from the GENUINE or UNITY-CLL studies will be not positive and/or will not support regulatory approval of TG-1101 or TGR-1202; the risk that the pending GENUINE confirmation scans may have a negative effect on the topline data presented; 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 trial or the UNITY-CLL trial; 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 or the UNITY-CLL 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 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 study, 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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