TG Therapeutics Announces Data Presentations at the XVIII International Workshop on Chronic Lymphocytic Leukemia (iwCLL)

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Phase 2 study of umbralisib monotherapy in BTK/PI3K-delta intolerant CLL reports an estimated median progression-free survival (PFS) of 23.5 months (n=50) with 58% of patients on umbralisib longer than their prior kinase inhibitor therapy

Phase 1/2 study of U2 + Pembrolizumab reports 83% (5 of 6) ORR in BTK refractory CLL patients, with 4 of 5 responders achieving a response to U2 alone prior to introduction of pembrolizumab

NEW YORK, Sept. 23, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that data from two Phase 1/2 trials were presented at the XVIII International Workshop on Chronic Lymphocytic Leukemia (iwCLL), currently being held in Edinburgh, Scotland. These data were previously presented earlier this year at the 15th International Conference on Malignant Lymphoma (ICML), held in Lugano, Switzerland. Highlights from the presentations are included below.

***Presentation Title:** A Phase 2 Study to Assess the Safety and Efficacy of Umbralisib in Patients with Chronic Lymphocytic Leukemia (CLL) Who Are Intolerant to Prior BTK or PI3K Delta Inhibitor Therapy*

This presentation includes data from patients with CLL who are intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent umbralisib. To be eligible for the study patients had to have received prior treatment with a BTK inhibitor or a PI3K delta inhibitor and discontinued therapy due to intolerance and were in need of subsequent therapy. Fifty-one patients were evaluable for safety of which 50 were evaluable for Progression Free Survival (PFS).

Data highlights include:

- Umbralisib demonstrated a favorable safety profile in patients intolerant to prior BTK (ibrutinib or acalabrutinib) or PI3K delta (idelalisib) therapy
- Only 12% discontinued due to an umbralisib adverse event, of which only one patient discontinued due to a recurrent adverse event (AE) previously experienced with prior kinase inhibitor therapy (ibrutinib)
- In this previously treated CLL population, 67% had a high-risk molecular / genetic marker and 6% had an ibrutinib resistance mutation, the estimated median progression free survival (PFS) was 23.5 months and overall survival (OS) not reached at a median follow-up of 15.7 months
- As of the cut-off date, 58% of patients have been on umbralisib for a duration longer than their prior BTK or PI3k inhibitor

***Presentation Title:** Phase I/II Triple Therapy Study of Umbralisib and Ublituximab (U2) Combined with Checkpoint Inhibition in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia (CLL) and Richter's Transformation (RT)*

This presentation includes data from patients with relapsed or refractory CLL or RT treated with the triple combination of ublituximab, umbralisib, and pembrolizumab. Patients with CLL received 2 cycles of the U2 regimen before pembrolizumab was added for an additional 4 cycles, followed by umbralisib maintenance. Patients with RT received U2 + pembrolizumab for the first 4 cycles, followed by U2 maintenance. Twenty patients were evaluable for safety (11 CLL patients and 9 RT patients) and 19 were evaluable for efficacy (11 CLL and 8 RT).

Data highlights include:

- The triple combination was well tolerated, with immune mediated toxicities not appearing above what would be expected with either umbralisib or pembrolizumab alone
- In this heavily pre-treated cohort with a median of 2 (1-9) prior lines of therapy:

- 91% (10 of 11) Overall Response Rate (ORR) in patients with relapsed/refractory CLL
- 83% (5 of 6) ORR in BTK refractory CLL patients, with 4 of 5 responders achieving a response to U2 alone at the patient's first efficacy assessment, prior to the addition of pembrolizumab
- 38% (3 of 8) ORR in RT, with two durable complete responses; 1 subject relapsed post-CAR-T in CR for 12 months and 1 subject progressed post-transplant continuing on study in CR now 20+ months. Two additional subjects were in stable disease, one with a 49% reduction in tumor burden.

The data presentations are now available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

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 multiple 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 into Phase 1 clinical development, TG-1501, its anti-PD-L1 monoclonal antibody, TG-1701, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor and TG-1801, its anti-CD47/CD19 bispecific antibody. 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 the acceptance of our data for presentation 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 the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2, and being studied in the UNITY clinical trials and other studies, will not prove to be safe and efficacious for any indication or for use as the backbone in a triple therapy regimen; the risk that the differentiated tolerability profile for umbralisib observed thus far will not be reproduced in full presentations or later larger studies; the risk that the PFS observed in BTK refractory CLL patients treated with umbralisib monotherapy will not be reproducible; the risk that the Company will not initiate a combination trial of U2 plus TG-1501, the Company's PDL1 inhibitor 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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