TG Therapeutics Announces Data Presentations at the 15th International Conference on Malignant Lymphoma

June 20, 2019

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)

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, June 20, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced data from four presentations, including three oral presentations and one poster presentation, at the 15thInternational Conference on Malignant Lymphoma (ICML), being held in Lugano, Switzerland. Highlights from all presentations are included below.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, “We are excited by the data presented today evaluating umbralisib in patients intolerant to currently approved BTK or PI3K therapies. We believe the data presented continue to show that there are many patients in need of alternative treatment options for whom umbralisib can provide meaningful benefit.” Mr. Weiss continued, “We are also pleased to present data from the combination of ublituximab + umbralisib (“U2”) plus pembrolizumab in patients with relapsed/refractory CLL and Richter’s transformation. It was encouraging to see that 5 of 6 BTK refractory patients responded to therapy, with 4 of those responders achieving a rapid response to U2 alone at the patient’s first efficacy assessment prior to the addition of pembrolizumab. We are eager to initiate our clinical study of U2 plus TG-1501, our PDL1 inhibitor, in the same patient population and believe the triplet may offer the opportunity for time limited therapy in CLL.”

Highlights from the oral presentations include:

Oral 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. Fifty-one patients were evaluable for safety of which 50 were evaluable for Progression Free Survival (PFS).

Highlights:

- Umbralisib demonstrated a favorable safety profile in patients intolerant to prior BTK or PI3K delta 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
- In this relapsed/refractory 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
- Median overall survival (OS) has not been reached with a median follow-up of 14 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

Oral Presentation Title: ***Phase I/II Study of Umbralisib (TGR-1202) in Combination with Ublituximab (TG-1101) and Pembrolizumab in Patients with Relapsed/Refractory CLL and Richter’s Transformation (RT)***

This oral 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 relapsed post-transplant continuing on study in CR now 20+ months

Additionally, data from the UNITY-NHL MZL cohort and data from TG-1801, the Company’s first-in-class anti-CD47-CD19 bispecific antibody, will be presented during ICML. These presentations were recaps and have been previously presented. Links to full data presentations included below.

Oral Presentation Title: ***Umbralisib Monotherapy Demonstrates Efficacy and Safety in Patients with Relapsed/Refractory Marginal Zone***

Lymphoma: A Multicenter, Open-Label, Registration Directed Phase 2 Study

Poster Presentation Title: The novel bispecific CD47-CD19 antibody TG-1801 potentiates the activity of ublituximab-umbralisib (U2) drug combination in preclinical models of B-NHL

Full schedule of data being presented at ICML:

- Oral Presentation: 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
  -- Session Date & Time: Thursday, June 20, 2019 13:45 – 15:15 CEST
  - Presentation Time: 15:00 CEST
  -- Session Title: Session 3 - CLL
  -- Location: Palazzo dei Congressi, Room A – Main Hall
  -- Lead Author: Anthony R. Mato, MD, Memorial Sloan Kettering Cancer Center

- Oral Presentation: Phase I/II Study of Umbralisib (TGR-1202) in Combination with Ublituximab (TG-1101) and Pembrolizumab in Patients with Rel/Ref CLL and Richter's Transformation
  -- Session Date & Time: Thursday, June 20, 2019 17:05 – 18:05 CEST
  - Presentation Time: 17:05 CEST
  -- Session Title: Focus on Non-Clinical and Early Clinical Data with New Combinations
  -- Location: Palazzo dei Congressi, Cinema Corso
  -- Lead Author: Anthony R. Mato, MD, Memorial Sloan Kettering Cancer Center

- Oral Presentation: Umbralisib Monotherapy Demonstrates Efficacy and Safety in Patients with Relapsed/Refractory Marginal Zone Lymphoma: A Multicenter, Open-Label, Registration Directed Phase 2 Study
  -- Session Date & Time: Saturday, June 22, 2019 10:15 – 11:15 CEST
  - Presentation Time: 10:45 CEST
  -- Session Title: Focus on Indolent Non-Follicular Lymphoma
  -- Location: Palazzo dei Congressi, Room A and B
  -- Lead Author: Pierre-Luigi Zinzani, MD, University of Bologna, Institute of Hematology "L. e A. Seràgnoli"

- Poster Presentation: The novel bispecific CD47-CD19 antibody TG-1801 potentiates the activity of ublituximab-umbralisib (U2) drug combination in preclinical models of B-NHL
  -- Session Date & Time: Wednesday, June 19 (12:00-17:00 CEST), Thursday, 20 (9:00-17:00 CEST) and Friday, June 21 (9:00-18:30 CEST)
  -- Location: Palazzo dei Congressi, Marquee Parco Ciani
  -- Lead Author: Marcelo Lima Ribeiro, Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology (VHIO), Autonomous University of Barcelona, Barcelona, Spain

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; 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 interim data from the UNITY-NHL MZL cohort reported thus far will not be reproduced when the final analysis is conducted on all patients later this year, including the risk that the final results will demonstrate a lower ORR and/or enhanced toxicities, which may not support a filing for accelerated approval; the risk that even if the UNITY-NHL MZL interim results are reproduced in the final analysis of the UNITY-NHL MZL cohort or that the final results otherwise meet the Company's target ORR of 40-50%, that the final results will still be insufficient to support a filing for accelerated approval;

the risk that the PFS observed in TKI intolerant 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; the risk that the novel bispecific CD47-CD19 antibody, TG-1801, will not potentiate the activity of U2 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.

CONTACT:
Jenna A. Bosco
Senior Vice President,
Corporate Communications
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

Source: TG Therapeutics, Inc.