TG Therapeutics Announces Data Presentations at the 25th European Hematology Association (EHA) Annual Congress

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NEW YORK, June 12, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced data presentations at the 25th European Hematology Association (EHA) annual congress including data from a Phase 1 study evaluating TG-1701, the Company's once daily, selective, BTK inhibitor, as monotherapy and in combination with umbralisib and ublituximab (U2) in relapsed/refractory chronic lymphocytic leukemia (CLL) and lymphoma, as well as long term data from a Phase 1/1b study evaluating the combination of umbralisib and ibrutinib in relapsed/refractory CLL and mantle cell lymphoma (MCL).

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We have long been excited about the potential for dual BCR blockade by targeting both PI3K-delta and BTK in the treatment of hematologic malignancies, and these data presentations offer insight into the therapeutic potential for this dual targeted approach. We are extremely pleased to see that TG-1701 continues to exhibit an encouraging safety and efficacy profile, both as a monotherapy and in our proprietary triplet combination with U2, with additional patients now treated and with longer follow-up. We now have patients on TG-1701 for upwards of 1.5 years, with no patients having discontinued therapy due to toxicity and responses deepening over time. We were also excited to see long-term data for the all-oral combination of umbralisib and ibrutinib, which similarly demonstrated continued improvement in overall response rates, and importantly identified no long-term safety signals at over 3.5 years of follow-up, underscoring the potential combinability of umbralisib with BTK therapy." Mr. Weiss continued, "In striving towards our goal of developing novel combination treatments for patients with unmet medical needs, we are highly encouraged by the data presented today and look forward to continuing dose escalation for our proprietary triple combination of ublituximab, umbralisib and TG-1701."

Details of the data presentations are included below.

Presentation Title: Safety and activity of the once daily selective bruton tyrosine kinase (BTK) inhibitor TG-1701 in patients with chronic lymphocytic leukemia (CLL) and lymphoma

This presentation includes interim data from a Phase 1 parallel dose-escalation study of TG-1701 monotherapy and TG-1701 in combination with U2 in 82 patients with relapsed/refractory B-cell malignancies. Sixty-nine patients were treated with single agent TG-1701, of which 25 patients were treated in the monotherapy dose escalation portion of the study and received TG-1701 at doses that ranged from 100mg to 400mg once daily, and 44 patients were treated with 200mg of TG-1701 in the monotherapy dose expansion cohort. An additional 13 patients were treated in the TG-1701 plus U2 dose escalation portion of the study.

Safety and efficacy highlights include:

- TG-1701 monotherapy exhibited an encouraging preliminary safety profile across all dose levels evaluated with only 3% (2/69) of patients having a dose reduction due to treatment-related adverse events (AEs), with no treatment discontinuations due to AEs in the monotherapy cohorts
- In the monotherapy dose escalation cohort (n=25), TG-1701 produced partial responses at all dose levels evaluated (100mg to 400mg once daily) in CLL, MCL, Waldenström's macroglobulinemia (WM), and small lymphocytic lymphoma (SLL)
- In the monotherapy dose expansion cohort in which TG-1701 was administered at 200mg, 25 patients were evaluable for efficacy with a 92% overall response rate (ORR) observed in CLL patients (n=12), a 33% ORR in MCL patients (n=6), and a 86% ORR in WM patients (n=7)
- The combination of TG-1701 plus U2 has been well tolerated and demonstrated encouraging clinical activity with a 77% ORR across all disease types (n=13), including complete responses in three patients; dose escalation continues

Presentation Title: Long term results of a Phase I/Ib study of ibrutinib in combination with umbralisib in patients with relapsed/refractory CLL or MCL

This presentation includes updated long term data from a Phase 1/1b study of patients with relapsed or refractory CLL or MCL treated with umbralisib in combination with ibrutinib. Data from this trial were previously published in Lancet Haematology in December 2018 (Davids et.al.). As of the updated data cutoff, 42 patients were evaluable for safety and efficacy (21 CLL patients and 21 MCL patients).

Safety and efficacy highlights include:

- With long term follow up (median follow-up of 43.5 months (range 8.4-61), there were no cumulative or recurrent late onset toxicities observed
- In relapsed/refractory CLL, the overall response rate was 95% including a 29% complete response (CR) rate, and the 4-year Progression-free Survival (PFS) and Overall Survival (OS) were 78% and 90%, respectively
- In relapsed/refractory MCL, the ORR was 71% with a 24% CR rate, and median PFS and OS were 10.8 and 30.7 months, respectively

The data presented is 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 dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. 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 its anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801. TG Therapeutics is headquartered in New York City.

Cautionary Statement
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, including statements relating to the clinical development of our product candidates, our combinatorial approach, and the potential attributes and benefits of our products, either as monotherapy or in combination. For these statements, which are subject to a number of risks and uncertainties, 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 our ongoing and planned clinical trials; the risk that early clinical trial results (both safety and efficacy), which 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; our ability to achieve the milestones we project, including the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones; 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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