TG Therapeutics Announces Triple Combination Data Presentations at the at the 62nd American Society of Hematology Annual Meeting

December 7, 2020

U2 + Venetoclax: 100% ORR at cycle 12 (n=27), including 41% CR rate, and 96% of patients achieving undetectable MRD in the peripheral blood and 77% achieving undetectable MRD in bone marrow

U2 + TG-1701 (BTKi): Dose escalation cohort (n=14) resulted in 79% ORR, with 22% CR rate, including 100% ORR in patients WM, CLL, MZL and DLBCL (n=7)

NEW YORK, Dec. 07, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced two triple therapy combination data presentations. The first evaluated the investigational combination of umbralisib plus ublituximab (U2) plus venetoclax in patients with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL); and the second evaluated the investigational combination of U2 plus TG-1701, the Company's once daily, oral, BTK inhibitor, in patients with R/R CLL or B-cell lymphoma. Data from these trials were presented at the 62nd American Society of Hematology (ASH) annual meeting and exposition. Presentation highlights are included below.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased by the triple therapy data presented today demonstrating the potential of U2 with both venetoclax and our BTK inhibitor, TG-1701." Mr. Weiss continued, "Our mission continues to be to drive toward better outcomes for patients with B-cell malignancies by developing multi-drug combinations. We believe the data with these triple combinations highlights our approach of leveraging our portfolio and standard of care therapies to build on the U2 backbone with the goal of creating potentially best in class treatments for patients in need."

PRESENTATION HIGHLIGHTS:

Poster Presentation Title: A Phase 1/2 Study of Umbralisib, Ublituximab, and Venetoclax (U2-Ven) in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL)

- Regimen was administered with 3 cycles of U2 as induction in cycles 1 through 3, U2 plus venetoclax in cycles 4, 5 and 6, followed by umbralisib plus venetoclax in cycles 7 through 12 in patients with R/R CLL. Patients with centrally confirmed undetectable minimal residual disease (uMRD) in the bone marrow after cycle 12 were permitted to stop all therapy, while MRD detectable patients continued on single agent umbralisib.
- 43 patients have been treated as of the data cutoff with 58% of patients previously exposed to a BTK inhibitor
- Among evaluable patients, ORR was 77% (30/39) after cycle 3 (U2 only), 100% (31/31) after cycle 7, and 100% (27/27) after cycle 12
- Among the 27 patients who finished 12 cycles of therapy:
  - 41% achieved Complete Response (CR) by iwCLL criteria
  - 96% achieved undetectable MRD in the peripheral blood
  - 77% achieved undetectable MRD in the bone marrow
- At a median follow up of 15.6 months (n=43), only 1 patient has progressed 10 months after stopping treatment
- Grade 3/4 adverse events occurring in > 5% of patients were neutropenia (21%), leukopenia (12%), infusion related reactions (7%), anemia (5%), and diarrhea (5%). No TLS events were observed during venetoclax administration, with one TLS event occurring prior to venetoclax administration.

Poster Presentation Title: Clinical Activity of TG-1701, As Monotherapy and in Combination with Ublituximab and Umbralisib (U2), in Patients with B-Cell Malignancies

- A total of 102 patients with R/R CLL or b-cell lymphoma have been treated with TG-1701, with patients receiving monotherapy in the dose-escalation cohort (n=25) or in the 200 mg dose-expansion cohort (n=61), or TG-1701 in combination with U2 in the dose escalation cohort (n=16)
- TG-1701 monotherapy was well tolerated and the maximum tolerated dose was not reached up through 400 mg QD
- Grade 3/4 adverse events (AE) occurring in >10% of patients treated with TG-1701 monotherapy were limited and included ALT increase (12%), all of which were patients treated with 400 mg QD. At the target single-agent Phase 2 dose of 200mg (QD) (n=61), AEs of special interest included Grade 3 hypertension (1.6%), atrial fibrillation (1.6%), and no instances of major bleeding observed. Grade 3/4 AEs occurring in >10% of patients treated with U2+1701 were ALT increase (25%), AST increase (19%) and neutropenia (12%).
- At a median follow up of 7 months in the 200 mg QD monotherapy expansion cohorts, preliminary overall response rates (ORR) were: 95% (19/20) in CLL, 50% (6/12) in mantle cell lymphoma (MCL), and 95% (18/19) in Waldenstrom macroglobulinemia (WM)

- At a median follow up of 12 months, the 1701+U2 dose escalation (using doses of 100mg to 300 mg QD of TG-1701) resulted in 79% ORR, with 22% CR rate across patients with WM, CLL, marginal zone lymphoma (MZL), diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) (n=14)

Data presented at ASH 2020 will be available on the Publications page of the Company's website at https://www.tgtherapeutics.com/publications/.

CONFERENCE CALL REPLAY INFORMATION
The Company hosted a conference call on November 5, 2020, with leading investigators from the UNITY-NHL and UNITY-CLL trials to discuss the data included in the ASH 2020 abstracts. A recording of the conference call is available for replay at https://ir.tgtherapeutics.com/events.

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 in late stage clinical development with two investigational compounds, ublituximab and umbralisib, the combination of which is referred to as "U2", targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. Umbralisib (TGR-1202) is an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon. Umbralisib is currently under review by the U.S. Food and Drug Administration (FDA) for accelerated approval as a treatment for patients with previously treated marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen or follicular lymphoma (FL) who have received at least two prior systemic therapies. The Company also has a fully enrolled Phase 3 clinical trial evaluating U2 in patients with treatment naïve and relapsed/refractory chronic lymphocytic leukemia (CLL), and two fully enrolled identical Phase 3 trials evaluating ublituximab monotherapy in patients with relapsing forms of multiple sclerosis (RMS). 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 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. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, factors that could cause our actual results to differ materially include the following: the risk that we will not be able to meet the clinical trial or regulatory submission timelines that we project or achieve other anticipated milestones, including the risk that interim, top-line, or other early clinical trial results, 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 final data sets or in future studies; the risk that the safety profile observed with umbralisib, ublituximab or TG-1701, or combinations thereof, may change as additional patients are exposed for longer durations; the risk that the U2 combination will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations, including with venetoclax and TG-1701; and the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones. 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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