TG Therapeutics Announces Oral Presentation of Umbralisib, Ublituximab and Venetoclax Triple Combination Phase I/II Data in Relapsed/Refractory CLL at the 61st American Society of Hematology Annual Meeting and Exposition

December 8, 2019

100% overall response rate (ORR) in relapsed/refractory CLL patients treated with U2 (umbralisib + ublituximab) plus venetoclax at cycle 7 (n=13)

100% of patients (n=9) achieved undetectable MRD in the peripheral blood after 12 months of therapy and 78% achieved undetectable MRD in bone marrow and have stopped all therapy

No patients have progressed to date

Investor and analyst event to be held on Monday, December 9, 2019 at 7:30 PM ET at the Hyatt Regency Orlando featuring a fireside chat with leading clinical investigators

NEW YORK, Dec. 08, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced triple therapy data from the Phase I/II study of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with umbralisib (TGR-1202), the Company's oral, dual inhibitor of PI3K delta and CK1 epsilon, and venetoclax, in patients with relapsed/refractory chronic lymphocytic leukemia (CLL). Data from this trial were presented this morning during an oral session at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased to share the first data from the triple combination of U2 (umbralisib and ublituximab) and venetoclax, which we believe has the potential to offer patients with CLL a highly active, time-limited, and generally well tolerated treatment option. It was exciting to see that for those patients followed for at least 12 months at the time of the presentation, there was a 100% ORR, and all of those patients achieved MRD negativity in the peripheral blood, with 7 of those 9 patients also achieving MRD negativity in the bone marrow. We look forward to updating these data at future conferences as more patients are followed for 12 months and longer." Mr. Weiss continued, "We were also excited to see that 87% of patients responded to the U2 combination after just three months of treatment prior to the introduction of venetoclax. We believe this further demonstrates the activity of the U2 combination that is being studied in our UNITY-CLL Phase 3 trial, which we expect data from in the coming weeks or months."

Below are highlights from the oral presentation.

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

This oral presentation includes data from patients with relapsed or refractory CLL treated with the triple combination of ublituximab, umbralisib, and venetoclax. Twenty-seven patients were evaluable for safety and 23 were evaluable for efficacy. Data highlights include:

- *Regimen was administered with 3 cycles of U2 induction/debulking to reduce the risk of tumor lysis syndrome (TLS), followed by the combination of umbralisib and venetoclax starting in cycle 4. Patients who were bone marrow MRD negative after cycle 12 stopped all therapy.*
- *Overall response rate (ORR) of 87% (20/23) after U2 induction period at cycle 3, prior to introduction of venetoclax, in relapsed/refractory CLL patients, including patients refractory to ibrutinib*
- *U2 induction appeared to reduce venetoclax TLS risk, with no patients remaining as TLS high-risk following 3 cycles of U2*
- *13 patients treated for >7 cycles and 9 patients for > 12 cycles:*
  - *100% ORR (13/13) after cycle 7 for the triple combination*
  - *100% ORR (9/9) including 44% Complete Response (CR) after cycle 12 for the combination*
  - *100% (9/9) of patients had undetectable minimal residual disease (MRD) (<0.01%) in peripheral blood after 12 cycles of therapy; and*
  - *78% (7/9) of patients who completed 12 cycles of therapy had undetectable MRD in bone marrow and have stopped therapy*
- *No patients (n = 27) have progressed to date with a median follow-up of 6.4 months*
- *Triple combination was generally well tolerated with no events of TLS observed*

An open-label, multicenter, Phase 2 study evaluating U2 plus venetoclax (ULTRA-V) in treatment naïve and previously treated CLL is now open for enrollment.

Remaining ASH Presentation Details

- Title: Phase 1 Study of TG-1701, a Selective Irreversible Inhibitor of Bruton's Tyrosine Kinase (BTK), in Patients with Relapsed/Refractory B-Cell Malignancies

- Publication Number: 4001
- Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster III
- Date and Time: Monday, December 9, 2019; 6:00 PM - 8:00 PM ET
- Location: Orange County Convention Center, Hall B
- Presenter: Chan Cheah, MD, Sir Charles Gairdner Hospital, Hollywood Private Hospital, University of Western Australia, Blood Cancer Research Western Australia

Following the presentation, the data presented will be available on the Publications page of the Company's website at https://www.tgtherapeutics.com/publications/.

TG THERAPEUTICS INVESTOR & ANALYST EVENT

TG Therapeutics will host an event on Monday, December 9, 2019 beginning at 7:30 PM ET with a featured fireside chat beginning promptly at 8:00 PM ET. The event will take place at the Hyatt Regency Orlando, in the Plaza International Ballroom I. A live webcast will be available on the Events page, located within the Investors & Media section of the Company's website at http://ir.tgtherapeutics.com/events, as well as archived for future review. This event will also be broadcast via conference call. To access the conference line, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), and reference Conference Title: TG Therapeutics December 2019 Investor & Analyst Event.

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. 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 its anti-PD-L1 monoclonal antibody, TG-1501, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801, into Phase 1 development. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included 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. 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 are the following: our ability to successfully and cost effectively complete preclinical and clinical trials; the risk that data from the UNITY-CLL Phase 3 trial will not be available in the planned timeframe or not be sufficient to support a regulatory filing; the risk that the highlighted 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 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, will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations; the risk that the combination of U2 plus venetoclax will not prove to be a safe or efficacious treatment and will not warrant further testing; the risk that the combination of U2 plus venetoclax will not ultimately result in a time limited therapy; the risk that the combination of U2 plus venetoclax, if approved, will not be utilized broadly or at all by academic or community physicians. 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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