TG Therapeutics Announces Triple Combination Data Presentations at the Upcoming 61st American Society of Hematology Annual Meeting and Exposition

November 6, 2019

100% overall response rate (ORR) in relapsed/refractory CLL patients (n=9) treated with U2 (umbralisib + ublituximab) plus venetoclax, with all patients at 12 months achieving MRD negativity (n=5)

Proprietary triplet of U2 plus TG-1701 (BTK inhibitor) induced 100% ORR (n=3) in patients with relapsed/refractory marginal zone lymphoma and follicular lymphoma at the lowest dose of TG-1701 tested

Additional patients and updated data will be presented at the conference

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, Nov. 06, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that data for the triple combination of U2 (umbralisib and ublituximab) plus venetoclax has been accepted for oral presentation, and Phase 1 data for TG-1701, the Company's novel BTK inhibitor, monotherapy and in combination with U2, has been accepted for poster presentation, at the upcoming 61st American Society of Hematology (ASH) annual meeting and exposition, to be held December 7 – 10, 2019, at the Orange County Convention Center in Orlando, FL. Abstracts are now available online and can be accessed on the ASH meeting website at www.hematology.org. Abstract highlights and presentation details are outlined below.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, “We are looking forward to an exciting ASH conference as we continue to present data highlighting the unique combinability of the U2 doublet as the backbone for triple therapy combinations. We believe the combination of U2 plus venetoclax offers a well-tolerated, highly-active, treatment option potentially offering CLL patients an opportunity to achieve bone marrow MRD negativity and cease treatment after 12 months.” Mr. Weiss continued, “We are also extremely pleased to see the preliminary results for our BTK inhibitor, TG-1701, both as a single agent and in combination with U2. We have previously presented compelling results from the combination of U2 plus ibrutinib and believe a proprietary triplet can offer a better outcome for patients than U2 or a BTK alone, across multiple B-cell cancers. We look forward to sharing these data at the upcoming meeting as we continue to drive towards the initiation of our first NDA filing for umbralisib monotherapy, as well as the PFS readout for U2 from our UNITY-CLL Phase 3 trial.”

Abstract Highlights

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

- *Regimen was administered with 3 cycles of U2 induction to reduce risk of tumor lysis syndrome (TLS) followed by addition of venetoclax in cycle 4. Patients that were bone marrow MRD negative after cycle 12 were permitted to stop all therapy.*
- *Overall response rate (ORR) of 85% (11/13) after U2 induction period, prior to introduction of venetoclax, in relapsed/refractory CLL patients, including patients refractory to ibrutinib*
- *At the time of the abstract, 9 patients had been treated for >7 cycles and 5 patients for > 12 cycles:*
  - *100% ORR (9/9) after cycle 7 for the triple combination*
  - *100% (5/5) of patients who reached 12 cycles of therapy had undetectable minimal residual disease (MRD) (<0.01%) in peripheral blood; and*
  - *80% (4/5) of patients who reached 12 cycles of therapy had undetectable MRD in bone marrow and have stopped therapy*
- *Triple combination was well tolerated with no events of TLS observed*
- *Preliminary results suggest that the chemotherapy-free triple regimen of U2 plus venetoclax can provide undetectable MRD after only 12 cycles, representing an effective treatment plan for these heavily pre-treated CLL patients*

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

- *TG-1701, a once daily BTK inhibitor, has an encouraging preliminary safety profile, with clinical and pharmacodynamic activity at all dose levels evaluated*
- *19 patients have been treated with TG-1701: 3 patients at 100 mg QD, 9 patients at 200 mg QD (expansion before opening combination), 3 patients at 300 mg QD single agent arm, and 4 patients at 100 mg QD combination arm*
- *All 3 patients treated with 100 mg TG-1701 plus U2 have achieved a response at the first response assessment: 1 Complete Response (CR) in a follicular lymphoma (FL) patient and 2 Partial Responses (PR), a FL patient with 88% reduction in tumor burden, and a marginal zone lymphoma (MZL) patient with 65% reduction in tumor burden*

Presentation Details

- Title: A Phase 1/2 Study of Umbralisib, Ublituximab and Venetoclax in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL)
  - Publication Number: 360
  - Oral Session: 642. CLL: Therapy, excluding Transplantation: Combination and Novel Treatment
  - Session Date and Time: Sunday, December 8, 2019; 7:30 AM - 9:00 AM ET
    - Presentation Time: 8:45 AM ET
  - Location: Orange County Convention Center, Hall E1
  - Presenter: Paul M. Barr, MD, Wilmot Cancer Institute, University of Rochester Medical Center, Rochester, NY

- 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 each presentation, the data presented will be available on the Publications page of the Company's website at http://tgtxinc.com/publications.cfm.

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. 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 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 hor at all by academic or community physicians; the risk that the preliminary results for TG-1701 will not be reproduced in additional data sets; and the risk that future results from the combination of U2 plus TG-1701 will not be comparable in safety, efficacy, or both, to those results previously seen with the combination of U2 plus ibrutinib. 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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