

June 5, 2017

# TG Therapeutics, Inc. Announces Follow-Up Data from the Chemo-Free Triple Combination of TG-1101, TGR-1202, and Ibrutinib at the 53rd Annual Meeting of the American Society of Clinical Oncology

100% ORR (19 of 19) observed in patients with CLL/SLL, including 32% CR rate

100% ORR (6 of 6) observed in patients with MZL and MCL, with 50% CR rate

80% ORR (4 of 5) observed in patients with FL, with 20% CR rate

Favorable safety profile observed in patients treated with the triple combination reinforcing that TG-1101 plus TGR-1202 is a well-tolerated and efficacious backbone for multi-drug combination regimens

CHICAGO, June 05, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced updated clinical data from its ongoing Phase I/lb trial of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with TGR-1202 (umbralisib), the Company's oral, next generation PI3K delta inhibitor, and ibrutinib, a BTK inhibitor, in patients with Chronic Lymphocytic Leukemia (CLL) and Non-Hodgkin's Lymphoma (NHL). Data from this trial was presented today during the 53rd American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. Additionally, a poster was presented describing the design of a study evaluating TGR-1202 in CLL patients who are intolerant to prior kinase inhibitor (KI) therapy, particularly ibrutinib and idelalisib.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "The triple data presented today provides a compelling case for combining our doublet, referred to as TG-1303, with ibrutinib across a number of b-cell malignancies for which ibrutinib is now approved. Importantly, the high rates of complete responses observed across these diseases with the triple therapy may enable some patients to discontinue treatment prior to becoming ibrutinib refractory, a population associated with very poor outcomes." Mr. Weiss continued, "Additionally, the data shown today strengthens our belief that TG-1303 is a safe and efficacious backbone upon which we can build triple and quad therapies, as we continue to strive towards identifying combinations that provide deeper remissions that can ideally avoid lifetime treatment. We look forward to further exploring multi-drug combination therapies both with currently approved agents as well as with our inhouse pipeline products."

Highlights from today's presentations include the following:

<u>Poster Presentation:</u> Tolerability and activity of chemo-free triplet combination of TGR-1202, ublituximab, and ibrutinib in patients with advanced CLL and NHL (Abstract #7511)

**Poster Viewing & Discussion Details:** Monday, June 5, 2017 8:00 AM-11:30 AM CT (Poster Viewing); 1:15 PM-2:30 PM CT (Poster Discussion)

This poster presentation includes data from patients with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) and Non-Hodgkin's Lymphoma (NHL) treated with the triple combination of TGR-1202, TG-1101 and ibrutinib. All patients were relapsed or refractory to prior therapy, except 3 CLL patients who were treatment naïve. Three cohorts for each CLL/SLL and NHL were evaluated with TGR-1202 dose escalation starting with doses of 400 mg (cohort 1), followed by 600 mg (cohort 2) and 800 mg (cohort 3), in combination with TG-1101 at 900 mg and ibrutinib daily at 420 mg (CLL) and 560 mg (NHL).

## Safety & Tolerability

Thirty Eight (38) patients were evaluable for safety (20 CLL/SLL patients, and 18 NHL patients). The triple combination appeared to be well tolerated in all patients, with neutropenia (32% all grades, 18% Grade 3/4) and pneumonia (18% all grades, 11% Grade 3/4), being the only Grade 3/4 AEs in > 10% of patients. Of the 38 patients treated to date, only two AEs (sepsis and pneumonia) led to treatment discontinuation. Median time on study was 11.1 months (range 0.4 - 30+ months) with 81% of patients on study > 6 months.

## **Clinical Activity**

Clinical activity was observed at all dose levels with 36 of 38 patients evaluable for efficacy (19 CLL/SLL patients, and 17

NHL patients), with 2 patients having discontinued prior to first efficacy assessment (1 pneumonia, and 1 investigator discretion).

## CLL/SLL Efficacy highlights include:

- 100% (19 of 19) Overall Response Rate (ORR), including a 32% Complete Response (CR) rate observed in patients with CLL/SLL (4 of 6 CR's pending marrow confirmation)
- 50% of the CLL patients had a 17p and/or 11g deletion
- 3 CLL patients had prior BTK and/or PI3Kδ inhibitor therapy, including one patient refractory to both idelalisib and ibrutinib who attained a complete response (ongoing for 1.5+ years)

#### NHL Efficacy highlights include:

- Response Rates observed in patients with NHL:
  - 100% (2 of 2) ORR, including one CR in patients with Marginal Zone Lymphoma (MZL)
  - i 100% (4 of 4) ORR, including 50% CR rate in patients with Mantle Cell Lymphoma (MCL)
  - 80% (4 of 5) ORR, including 20% CR rate in patients with Follicular Lymphoma (FL)
  - 17% (1 of 6) ORR in patients with Diffuse Large B-cell Lymphoma (DLBCL)
- FL patients were heavily pretreated including 2 with prior Autologous Stem Cell Transplant (ASCT), 1 refractory to prior ibrutinib, and 1 with 5 prior lines of rituximab based therapy
- DLBCL patients had a median of 4 prior therapies, and 4 of 6 were of non-GCB subtype

<u>Poster Presentation:</u> KI intolerance study: A phase 2 study to assess the safety and efficacy of TGR-1202 in pts with chronic lymphocytic leukemia (CLL) who are intolerant to prior BTK or PI3K-delta inhibitor therapy (Abstract: TPS7569)

This poster details the study design for an ongoing Phase II, multicenter, single-arm trial of TGR-1202 (umbralisib) in CLL patients requiring therapy who are intolerant to prior Kinase Inhibitor (KI) therapy. The study will enroll approximately 50 patients who have discontinued prior therapy with a BTK or Pl3K delta inhibitor due to intolerance and not disease progression. The primary objective of the study is to determine the progression free survival (PFS) of TGR-1202 in this patient population. Key secondary objectives such as overall response rate, duration of response, time to treatment failure and safety of TGR-1202 as compared to the prior KI therapy will also be evaluated.

## **PRESENTATION DETAILS:**

The above referenced presentations are now available on the Publications page, located within the Pipeline section, of the Company's website at <a href="https://www.tgtherapeutics.com/publications.cfm">www.tgtherapeutics.com/publications.cfm</a>.

#### TG THERAPEUTICS INVESTOR & ANALYST EVENT

TG Therapeutics will host a reception tonight, Monday, June 5, 2017 beginning at 7:00pm CT, with featured presentations beginning promptly at 7:05pm CT. The event will take place at the Peninsula Chicago Hotel in the Avenues Ballroom. This event will be webcast live and will be available on the Events page, located within the Investors & Media section of the Company's website at <a href="https://www.tgtherapeutics.com">www.tgtherapeutics.com</a>, 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 June 2017 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. TG-1101 (ublituximab) 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 TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies, with TG-1101 also in clinical development for autoimmune disorders. The Company also has pre-clinical programs to develop IRAK4 inhibitors, and anti-PD-L1 and anti-GITR antibodies. 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 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; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 and being studied in the chemo-free triple combination of TG-1101 plus TGR-1202 plus ibrutinib and in the UNITY clinical trials and other combination trials, will not prove to be safe and efficacious for any indication or as a backbone for current or future triple and/or quad therapies; the risk that even if the company is successful in developing its drugs through FDA approval and on to the market, that the cost efficiencies anticipated through proprietary combinations may not be realized in the marketplace. 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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