



December 6, 2016

## **TG Therapeutics, Inc. Announces Double & Triple Combination Therapy Data Presentations at the 58th American Society of Hematology Annual Meeting**

*Combination of TG-1101, TGR-1202 and bendamustine resulted in 71% ORR, including 43% complete response rate, in relapsed or refractory DLBCL*

*TGR-1202 continues to demonstrate a favorable and differentiated safety profile when combined with a variety of agents*

SAN DIEGO, Dec. 06, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), announced the presentation yesterday of data from three combination studies involving the Company's lead compounds, TGR-1202, the Company's once-daily PI3K delta inhibitor, and TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody at the 58<sup>th</sup> American Society of Hematology (ASH) Annual Meeting, in San Diego, California.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO stated, "We are very pleased to continue to see a highly differentiated safety profile for TGR-1202 across multiple double and triple combination studies with a high level of activity. Each of the four clinical studies presented at the ASH meeting, enhanced our overall understanding of the breadth of activity of TGR-1202. In addition to DLBCL, FL and CLL, where we have already shown data previously, it was nice to see the flexibility of TGR-1202 and its ability to be combined with brentuximab vedotin in relapsed or refractory Hodgkin's and with ruxolitinib in Myelofibrosis." Mr. Weiss continued, "We are also encouraged by the triple combination data of TG-1101, TGR-1202, and bendamustine in relapsed or refractory, difficult to treat, DLBCL and FL patients which showed no discontinuations for a treatment related adverse event, as well as an 80% overall response rate across both DLBCL and FL patients and a high level of CR's. We, and our investigators, believe this triplet combination is a promising regimen and plan to study it in this patient population in a registration-directed trial."

Highlights from yesterday's presentations include the following:

### ***Poster Presentation: Combination of Ublituximab, TGR-1202, and Bendamustine Demonstrates Significant Activity in Patients with Advanced DLBCL and Follicular Lymphoma (Abstract Number 4197)***

This poster presentation includes data from patients with relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL) or Follicular Lymphoma (FL) treated with the triple combination of TG-1101 (ublituximab), TGR-1202 and bendamustine. Nineteen patients were evaluable for safety of which 15 were evaluable for efficacy (3 patients were too early to evaluate and 1 patient had a non-related adverse event (AE) prior to efficacy assessment). The triple combination appears well tolerated with no discontinuations for a treatment related AE. Neutropenia and anemia were the only Grade 3/4 AE's occurring in more than 1 patient. Importantly, no Grade 3/4 transaminitis was reported, no events of pneumonia or pneumonitis, and only 1 transient event of Grade 3 diarrhea, with a duration of 1 day, was observed. Eleven patients (58%) were refractory to prior treatment. Median time on study at the data cut off was approximately 6 months with the majority of patients continuing on study and follow-up ongoing.

Efficacy highlights from this poster include:

- | 71% (5 of 7) Overall Response Rate (ORR), including a 43% Complete Response (CR) rate observed in patients with relapsed or refractory DLBCL
- | 88% (7 of 8) ORR, including a 37% CR rate observed in patients with relapsed or refractory FL 4/6 CR's that were achieved between the DLBCL and FL groups occurred at the first 8 week efficacy assessment
- | First response assessment occurred at Month 3 following initiation of therapy, with durable responses observed notably amongst DLBCL patients.

### ***Poster Presentation: A Phase I Trial of TGR-1202, a Next Generation Once-Daily PI3Kδ Inhibitor, in Combination with Brentuximab Vedotin, in Patients with Relapsed/Refractory Hodgkins Lymphoma (Abstract Number 4146)***

This poster presentation includes data from patients with relapsed and refractory Hodgkin's Lymphoma (HL) treated with TGR-1202 at either 400mg or 600mg dosed orally once daily in combination with brentuximab vedotin in continuous 21 day cycles. 14 patients were evaluable for safety, of which 11 were evaluable for efficacy (3 discontinued prior to disease evaluation (2 AE's and 1 withdrew consent)). 43% (6 of 14) of patients had prior exposure to brentuximab vedotin and all

were refractory to prior brentuximab vedotin therapy. The combination demonstrated tolerability with nausea, diarrhea, and neutropenia being the most prevalent adverse events. Notably all but one case of diarrhea was Grade 1 or 2 in severity.

Efficacy highlights from this poster include:

- | 60% (3 of 5) ORR, including a 40% CR rate observed across brentuximab vedotin refractory patients
- | 64% (7 of 11) ORR, including a 45% CR rate observed across all patients treated

**Oral Presentation: Preliminary Results from a Phase I Dose Escalation Trial of Ruxolitinib and the PI3K $\delta$  Inhibitor TGR-1202 in Myelofibrosis (Abstract Number 1125)**

This oral presentation includes data from patients with myelofibrosis treated with the combination of ruxolitinib, the JAK1/2 inhibitor and TGR-1202. The combination was well tolerated and efficacious in the twelve patients treated. The most prevalent adverse events deemed at least possibly related to TGR-1202 included anemia, thrombocytopenia, neutropenia, AST/ALT elevation and amylase/lipase elevation and diarrhea, all of which were notably Grade 1/2 with the exception of Grade 3 amylase/lipase elevation seen in 2 patients (16.7%), and Grade 3 diarrhea seen in 1 patient (8.3%). Presentation highlights included:

- | The patient population enrolled was advanced, with the majority having 2 or more prior mutations at baseline;
- | Per protocol, all enrolled patients were on a stable dose of ruxolitinib monotherapy with best response to ruxolitinib monotherapy achieved prior to enrollment;
- | Following the addition of TGR-1202, 11/12 patients experienced improvement in hemoglobin, many with a concomitant reduction in platelet counts indicating clinical benefit beyond ruxolitinib monotherapy; and
- | 83% of study participants experienced clinical benefit (hematologic improvement, reduced spleen size and/or improvement in symptoms) including one patient who achieved a CR and continues on study, now out 72 weeks

**PRESENTATION DETAILS:**

Copies of the above referenced presentations are available on the Company's website at [www.tgtherapeutics.com](http://www.tgtherapeutics.com), located on the Publications page.

**TG THERAPEUTICS INVESTOR & ANALYST EVENT:**

TG Therapeutics held an investor and analyst reception yesterday, at the Marriott Gaslamp, in San Diego, California. The audio file and slide presentation are available for review on the Events page, located within the Investors & Media section of the Company's website at [www.tgtherapeutics.com](http://www.tgtherapeutics.com).

**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, 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 recently entering clinical development for autoimmune disorders. The Company also has pre-clinical programs to develop IRAK4 inhibitors, BET 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, particularly those with respect to anticipating future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies 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. Among the 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 for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies; the risk that early preclinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies will not be reproduced in additional patients or in future studies; the risk that trends observed which underlie certain assumptions of future performance of TGR-1202 will not continue, the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase 1 study; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303, will not prove to be a safe and efficacious backbone for triple and quad combination therapies; the risk that the data (both safety and efficacy) from future clinical trials

will not coincide with the data produced from prior preclinical and clinical trials; the risk that trials will take longer to enroll than expected; our ability to achieve the milestones we project over the next year; our ability to manage our cash in line with our projections, 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](http://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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