



December 6, 2015

## **TG Therapeutics, Inc. Announces Data Presentations at the 57th American Society of Hematology Annual Meeting From Ongoing Clinical Studies in Patients With Non-Hodgkins Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL)**

*Combination of TG-1101 plus TGR-1202 ("TG-1303") continues to demonstrate a favorable safety profile, with only 8% of patients discontinuing due to an adverse event and no cases of colitis reported to date*

*80% (8 of 10) ORR in patients with relapsed refractory CLL/SLL treated in the higher dose cohort of TG-1303, including 1 CR and 7 PR's and the remaining 2 patients with stable disease, one still on study with significant reduction in tumor burden (CLL evaluated per iwCLL 2008 criteria)*

*71% (12 of 17) ORR, including 24% CRs, in patients with heavily pretreated relapsed/refractory Follicular Lymphoma (FL) & Marginal Zone Lymphoma (MZL) treated in the higher dose cohort of TG-1303*

*35% (6 of 17) ORR in patients with relapsed/refractory DLBCL and Richter's transformation (large cell lymphoma) treated in the higher dose cohort of TG-1303*

*TGR-1202 based combination therapy with the glycoengineered anti-CD20 mAb, obinutuzumab, plus chlorambucil achieved 100% (15 of 15) ORR in treatment naïve CLL patients, with 33% of patients achieving a CR, and 47% of patients achieving MRD negativity*

ORLANDO, Fla., Dec. 06, 2015 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), today announced updated clinical results from its ongoing Phase I proprietary combination study of TG-1101 (ublituximab), the Company's novel, glycoengineered monoclonal antibody and TGR-1202, the Company's oral, once-daily, PI3K delta inhibitor as well as data from the Phase I study of TGR-1202 in combination with obinutuzumab plus chlorambucil. Data from these Phase I studies were presented this weekend at poster sessions during the 57th American Society of Hematology (ASH) Annual Meeting and Exposition being held at the Orange County Convention Center in Orlando, FL.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "We and our clinical investigators continue to be impressed with the activity and safety profile of our proprietary TG-1303 regimen with almost all CLL patients responding and over 70% of heavily pre-treated patients with indolent lymphoma responding to 1303. We are also very excited by the data in patients with large cell lymphoma where we are seeing 35% response rates in heavily pre-treated patients. Collectively, we believe these data support advanced clinical studies for TG-1303 across CLL and NHL and, accordingly, we plan to expand our UNITY clinical program into NHL in 2016. Finally, we are excited to see the high level of activity of a TGR-1202 based regimen in front-line CLL. We believe the safety and efficacy profile observed in those front-line patients sets the stage for what we should expect to see from TG-1303 in front-line patients included in our UNITY-CLL Phase 3 trial, which should open for enrollment in the coming weeks." Mr. Weiss continued, "We appreciate the strong support of our clinical investigators and thank them and their patients for participating in these important clinical trials."

Dr. Matthew Lunning, Assistant Professor, Division of Hematology at the University of Nebraska Medical Center and lead author for the poster presentation stated, "The principal goal for any novel-novel combination study is to establish safety and combinability of two agents. With the combination of ublituximab and TGR-1202, patients were not only able to achieve high response rates and durable remissions, but most importantly, were able to stay on treatment with limited discontinuations due to adverse events, which has been commonly seen with other novel targeted agents in this class. Many of the patients enrolled onto this study have been heavily pre-treated with limited treatment options, especially patients with DLBCL, and the ability to offer patients a novel-novel combination which has the potential to extend and improve patient lives is of great excitement."

The following summarizes the posters presented this weekend:

### ***Ublituximab + TGR-1202 Demonstrates Activity and Favorable Safety Profile in Relapsed/Refractory B-Cell NHL and High-Risk CLL: Phase I Results (Abstract Number 1538)***

This poster was presented yesterday, Saturday December 5<sup>th</sup> during the ASH Annual Meeting and included data from patients with relapsed and refractory NHL and high-risk CLL treated with the combination of TG-1101 (ublituximab) and TGR-1202. The combination has been well tolerated in the 71 patients evaluable for safety at all dose levels up through 1200mg micronized.

This was a heavily pretreated population with high-risk features, including 58% refractory to last treatment with multiple previous lines of rituximab based therapy. Efficacy data was presented on patients treated at the higher doses of TGR-1202 (1200mg of the original formulation and 600mg or greater of the micronized formulation).

Highlights from this poster include:

- | 80% (8 of 10) ORR in patients with CLL/SLL, including 1 CR and 7 PRs
  - | Remaining 2 patients had stable disease, one of which remains on study and the other, an ibrutinib refractory patient, progressed after 2 cycles
  - | 75% of CLL patients had high-risk cytogenetics (17p and/or 11q del)
  - | Data supports the current Phase 3 UNITY-CLL Study of TG-1101 + TGR-1202 in CLL
- | 71% (12 of 17) ORR in heavily pretreated patients with indolent NHL (FL & MZL), including 4 CRs (24%) and 8 PRs, with 4 of the remaining 5 patients achieving stable disease
- | 35% (6 of 17) ORR in patients with DLBCL and Richter's Transformation, 3 of which achieved a CR, with 2 additional patients achieving stable disease
  - | 94% of DLBCL patients were refractory to prior therapy with 69% of patients rituximab refractory, including one patient with triple hit lymphoma
  - | Of the 16 DLBCL patients, 9 were GCB subtype, 3 were ABC subtype, and 4 patients' subtype was unknown, with notable activity (ORR and PFS) observed in patients with confirmed GCB subtype
- | Combination of 1303 was well tolerated, with only 8% of patients discontinuing due to an adverse event:
  - | Notably, the only Grade 3/4 adverse event occurring in > 5% of patients was neutropenia. Of the 71 patients available for safety, only 6 patients (8%) discontinued due to a TGR-1202 related event
  - | Twenty-six patients have been on the combination of TG-1101 plus TGR-1202 for 6+ months, with no events of colitis reported to date
  - | Safety profile supports multi-drug regimens

***A Phase I Trial of TGR-1202, a Next Generation Once Daily PI3K-Delta Inhibitor in Combination with Obinutuzumab Plus Chlorambucil, in Patients with Chronic Lymphocytic Leukemia (Abstract Number 2942)***

The poster was presented today, Sunday December 6<sup>th</sup> during the ASH Annual Meeting and includes data from patients with treatment naïve and previously treated CLL treated with TGR-1202 in combination with the glycoengineered anti-CD20 mAb, obinutuzumab, and chlorambucil. The study design evaluated escalating doses of TGR-1202 which was dosed orally once-daily starting at Day 1 of Cycle 1. Obinutuzumab and chlorambucil were administered according to their FDA labeled dosing regimen. The combination was dosed in 18 patients, of which 15 were treatment naïve and 3 were previously treated. All patients were evaluable for safety and efficacy.

Highlights from this poster include:

- | 100% (15 of 15) ORR in treatment naïve CLL patients, with 33% of patients achieving a CR, and 47% of patients achieving MRD negativity
- | 95% (17 of 18) ORR in treatment naïve and relapsed/refractory CLL patients, with 28% of patients achieving a CR
  - | Remaining patient achieved a 45% nodal reduction and remains on study, progression-free
  - | Notably, all previously treated CLL patients were refractory to a prior BTK inhibitor and had at least one high-risk cytogenetic abnormality
- | The combination demonstrated acceptable tolerability, which notably differed from that observed when TGR-1202 was combined with TG-1101 in patients with relapsed or refractory CLL, specifically regarding neutropenia (78% vs. 30%), thrombocytopenia (78% vs. < 10%), and transaminase elevations (39% vs. 8%)
- | The median PFS has not been reached, with the longest patient on study now 20+ months on TGR-1202 daily maintenance at 800mg

**POSTER Presentation details**

A copy of the poster presentations are available on the Company's website at [www.tgtherapeutics.com](http://www.tgtherapeutics.com), located on the Publications Page, within the Pipeline section.

**TG THERAPEUTICS INVESTOR & ANALYST EVENT DETAILS**

TG Therapeutics will also host a reception on Monday, December 7<sup>th</sup>, 2015 beginning at 7:45pm ET, with featured presentations beginning promptly at 8:00pm ET. The event will take place at the Hyatt Regency Orlando in the Bayhill 17/18 Room. 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 [www.tgtherapeutics.com](http://www.tgtherapeutics.com), as well as archived for future review. This event will also be broadcast via conference call. In order 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 2015 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. 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. The Company also has a pre-clinical program to develop IRAK4 inhibitors, as well as an antibody research program to develop 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, 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 pre-clinical and clinical trials for TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 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 pre-clinical 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.

TGTX-G

CONTACT: Jenna Bosco

Director- Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4351

Email: [ir@tgtxinc.com](mailto:ir@tgtxinc.com)

 Primary Logo

Source: TG Therapeutics, Inc.

News Provided by Acquire Media