

June 13, 2014

## **TG Therapeutics' TG-1101 (Ublituximab) in Combination With Ibrutinib Demonstrates Compelling Clinical Activity and Safety Profile in Patients With Previously Treated Chronic Lymphocytic Leukemia (CLL) and Mantle Cell Lymphoma (MCL)**

- 90% overall response rate (ORR) at first efficacy assessment for combination of TG-1101 and Ibrutinib
- No patients have progressed on the combination to date
- Combination appears well tolerated with few Grade 3/4 events reported to date
- Updated data on single agent TGR-1202 demonstrates 89% nodal response in CLL patients

NEW YORK, June 13, 2014 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), an innovative, clinical-stage biopharmaceutical company today announced preliminary clinical results from its ongoing Phase 2 study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with ibrutinib (IMBRUVICA™), the oral BTK inhibitor from Pharmacyclics/Janssen. Data from the Phase 2 study is being presented during the 19<sup>th</sup> Annual European Hematology Association (EHA) meeting being held in Milan, Italy.

The poster presentation includes data from 28 patients with relapsed and/or refractory CLL or MCL treated with TG-1101 at doses of 600 mg or 900 mg, in combination with ibrutinib at an oral daily dose of 420 mg for patients with CLL and 560 mg for patients with MCL.

### **Overview of the data presented on TG-1101 + ibrutinib:**

#### ***Safety and Tolerability***

TG-1101 in combination with ibrutinib was well tolerated in the 28 patients evaluable for safety, with Day 1 infusion related reactions (IRR) being the most frequently reported adverse event for TG-1101. All but one IRR were Grade 1 or 2 in severity and were manageable without dose reductions. Ibrutinib related adverse events included diarrhea and rash with one patient discontinuing treatment due to ibrutinib related diarrhea (only patient to discontinue from the study to date).

#### ***Clinical Activity***

The overall response rate (ORR) at the first planned efficacy assessment for the 10 evaluable patients was 90%. The breakdown of responses is as follows:

- CLL patients (including 4 with high risk cytogenetics such as 17p del and 11q del): 86% (6/7) achieved a partial response (PR) at the first assessment, with the remaining one patient achieving a 40% nodal reduction coupled with a > 50% reduction in ALC pending next response assessment; and
- MCL patients: 100% (3/3) achieved a response (1 CR and 2 PRs).

The addition of TG-1101 appears to abrogate ibrutinib related lymphocytosis in patients with CLL, with patients experiencing a median ~80% reduction in their absolute lymphocyte count (ALC) by month 4 following initiation of combination therapy.

Of the 28 patients enrolled on study to date, including patients with high risk CLL, no patients have progressed while on the combination, with patients on study now for upwards of 5 months.

Dr. Jeff Sharman, Medical Director of Hematology Research for the US Oncology Network, and Study Chair for the Phase 2 trial stated: "We are impressed with the clinical activity and safety profile seen with ublituximab in combination with ibrutinib to date. We believe there is an important role for combination therapy with the newer agents in CLL. Ublituximab is specifically designed to overcome specific weaknesses of traditional anti-CD20 therapy. This data shows ublituximab can safely be combined with ibrutinib and may both accelerate and deepen the response compared to prior trials of ibrutinib alone."

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "From the inception of TG Therapeutics, we have been focused on developing novel combination therapies with the goal of driving very high response rates without the toxicity associated with chemotherapy. We believe that today's data represent early evidence that we can achieve that goal. The rapid and deep responses seen in 9 out of 10 patients evaluable for response at the first assessment compares quite favorably to published data on ibrutinib monotherapy at early efficacy assessments. While still early, we are

very encouraged by the results seen thus far and look forward to presenting data on additional patients with longer-term follow-up at ASH at year's end."

### **Overview of other data presented on TG-1101 and TGR-1202:**

In addition to the data from the ongoing TG-1101 plus ibrutinib combination study, the Company is also presenting data from ongoing single agent studies of TG-1101 and TGR-1202, the Company's novel, oral PI3K delta inhibitor, both of which, as previously reported at ASCO, were well tolerated and demonstrated significant single agent response rates in patients with relapsed and/or refractory B-cell malignancies. The Company's presentation for TGR-1202 includes updates from the ASCO data cutoff, where it was previously reported that 78% (7/9) CLL patients treated at 800 mg QD or higher had achieved a nodal partial response or a partial response. Updated data presented at the EHA meeting demonstrates an 89% nodal response rate with 8/9 CLL patients now achieving a nodal or partial response on TGR-1202 monotherapy at doses  $\geq$  800 mg.

Mr. Weiss added "We are also excited to note the evolving responses seen in our Phase 1 single-agent study of TGR-1202, with an additional CLL patient achieving a nodal PR, bringing our nodal response rate in CLL patients treated at 800mg or higher to nearly 90%. These encouraging results, coupled with the ibrutinib combination data, drive our confidence in our proprietary combination of TG-1101 and TGR-1202, which we will report data for at the Pan Pacific Lymphoma Conference in July 2014."

Presentation details for all posters presented at EHA are as follows:

Title: Ublituximab (TG-1101) a novel glycoengineered anti-CD20 monoclonal antibody in combination with ibrutinib in patients with CLL and MCL; Results of an ongoing Phase 2 trial

- Abstract Number: P880
- Presentation Date & Time: Saturday, June 14 2014, 5:45 PM - 7:00 PM CEST
- Poster Session: Chronic lymphocytic leukemia and related disorders - Clinical 2
- Poster Display: Poster Area (NW - Level 0)
- Lead Author: Jeff Sharman, MD, Willamette Valley Cancer Institute/US Oncology Research
- Link to Poster: [www.tgtherapeutics.com/EHA2014-PosterP880.pdf](http://www.tgtherapeutics.com/EHA2014-PosterP880.pdf)

Title: Ublituximab (TG-1101), a novel anti-CD20 monoclonal for rituximab relapsed/refractory B-cell malignancies

- Abstract Number: P444
- Presentation Date & Time: Friday, June 13, 2014, 5:45 PM - 7:00 PM CEST
- Poster Session: Indolent Non-Hodgkin lymphoma - Clinical
- Poster Display: Poster Area (NW - Level 0)
- Lead Author: Owen A. O'Connor, MD, PhD, Columbia University Medical Center, New York, NY
- Link to Poster: [www.tgtherapeutics.com/EHA2014-PosterP444.pdf](http://www.tgtherapeutics.com/EHA2014-PosterP444.pdf)

Title: TGR-1202, a novel once-daily PI3K delta inhibitor, demonstrates promising clinical activity with a favorable safety profile in patients with relapsed or refractory hematologic malignancies

- Abstract Number: P250
- Presentation Date & Time: Friday, June 13, 2014, 5:45 PM - 7:00 PM CEST
- Poster Session: Chronic lymphocytic leukemia and related disorders - Clinical 1
- Poster Display: Poster Area (NW - Level 0)
- Lead Author: Howard A. Burris, MD, Sarah Cannon Research Institute, Nashville, TN
- Link to Poster: [www.tgtherapeutics.com/EHA2014-PosterP250.pdf](http://www.tgtherapeutics.com/EHA2014-PosterP250.pdf)

### **ABOUT TG THERAPEUTICS, INC.**

TG Therapeutics is an innovative, clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. 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. TG Therapeutics is headquartered in New York City.

### **Cautionary Statement**

Some of the statements included in this press release, particularly those anticipating future clinical trials, the timing of commencing, completing or reporting such trials, the business prospects for TG-1101 and TGR-1202, the potential benefits of combining TG-1101 and TGR-1202 and the potential benefits that might be achieved with the micronized formulation and fed-state dosing 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 and TGR-1202; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101 and TGR-1202 will not be reproduced in additional patients or in future studies; the risk that the enhanced absorption seen in the healthy human volunteer bioequivalence studies will not be seen in whole or in part when the modified formulation and fed-state dosing are studied in patients with B-cell malignancies; 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 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.

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