December 9, 2014

Preliminary Data From Ongoing Phase I/II Dose Escalation Study of TG-1101 (Ublituximab) in Combination With TGR-1202 in Heavily Pre-treated Relapsed/Refractory B-Cell Malignancies Demonstrates Encouraging Clinical Activity and Safety

- *100% of evaluable CLL/SLL patients (9/9) had nodal reductions, with 6 of 9 patients achieving a PR with the remaining 3 patients on study with nodal reductions ranging from 15% to 45% and a peripheral response (normalization or > 50% decrease in ALC) pending additional assessments*
- *83% (5/6) of patients with Non-Hodgkin's Lymphoma; 3/3 DLBCL and 2/3 Follicular Lymphoma (FL) responded to the combination at the highest dose tested, including 2 CR's in patients with DLBCL confirmed by independent review*
- *Collectively, 87 patients have been treated with TGR-1202, alone or in combination with TG-1101, without the observance of drug-related hepatic toxicity*
- *Dose escalation continues with TGR-1202 at 800mg micronized*
- *The combination of TG-1101, TGR-1202, and ibrutinib ("Triple Therapy") was safely administered to 5 patients with heavily pre-treated NHL, CLL, and Richter's transformation with no dose limiting toxicities observed, and no Grade 3 or 4 events observed to date*
- *2 of the first 3 evaluable patients responded to the Triple Therapy, including an ibrutinib-refractory, rituximab-refractory patient with Follicular Lymphoma*

SAN FRANCISCO, Dec. 9, 2014 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), an innovative, clinical-stage biopharmaceutical company today announced clinical results from its Phase 1/2 clinical study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with TGR-1202, the Company's novel once per day PI3K delta inhibitor. These data are being presented today in an oral presentation by Dr. Matthew Lunning from the University of Nebraska Medical Center at the 56th Annual American Society of Hematology (ASH) meeting being held in San Francisco, CA.

"We continue to be very impressed with the safety profile and activity observed to date in a heavily pre-treated population of patients with the combination of ublituximab and TGR-1202," said Dr. Matthew Lunning. "The activity seen to date has been impressive across all disease types, but of particular interest is the high level of activity seen in DLBCL, specifically the GCB subtype, a population of patients in dire need of effective therapies in the relapsed / refractory setting. We were also very excited to introduce a cohort into the study that explored the triple combination of ublituximab, TGR-1202, and ibrutinib, and have been very pleased with the early safety and activity profile of this combination."

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "We remain focused on developing the most efficacious, least toxic treatment options for patients with B-cell malignancies, and believe the data presented today by Dr. Lunning is a major step in that direction. We are very pleased with the early safety and activity profile of our proprietary combination, and look forward to additional follow-up and to seeing the effects of higher doses. Based on the safety and efficacy profile, we believe the combination has the potential to be the leading backbone for incremental combination therapy, as illustrated by the early triple combination data presented today." Mr. Weiss added, "We look forward to further dose escalations in this study while at the same time evaluating designs for our first registration trial for this proprietary combination, ideally to be announced in the first half of 2015."

OVERVIEW OF THE DATA:

The presentation includes data from 27 patients on the combination of TG-1101 and TGR-1202 with relapsed and/or refractory B-cell malignancies, with a median 3 prior lines of therapy, 65% of patients having seen 2 or more prior lines of rituximab, and 41% of patients refractory to prior therapy. The study has explored doses of 600mg and 900mg of TG-1101, and escalating doses of TGR-1202 beginning at 800mg (initial formulation) and escalating to 600mg of the micronized formulation. Five additional patients were treated in the triple combination cohort evaluating the combination of TG-1101, TGR-1202, and ibrutinib in which ibrutinib was dosed per its label in combination with TG-1101 at 900mg and TGR-1202 at 400mg and 600mg micronized. Based on recently reported safety and exposure-response relationship data for TGR-1202 as a single agent, the Company intends to continue dose escalation in this trial to 1200mg micronized with the potential for higher dose levels.

Safety and Tolerability - All Patients

The combination of TG-1101 and TGR-1202 was well tolerated in the 27 patients evaluable for safety, with day 1 infusion related reactions (IRR) being the most frequently reported adverse event. All IRR events were manageable without dose

reductions, and all but one event was Grade 1 or 2 in severity. Other adverse events included neutropenia, nausea, and diarrhea, with neutropenia being the only Grade 3/4 adverse event reported in > 10% of patients (33%). Consistent with the data observed to date in the ongoing TGR-1202 single agent Phase 1 study, no drug-related events of hepatic toxicity (ALT/AST elevations) were observed among the 27 patients treated to date with the combination of TG-1101 and TGR-1202. Additionally, no events of hepatic toxicity were observed amongst the 5 patients treated with the triple combination of TG-1101, TGR-1202, and ibrutinib. Collectively, with the results from the Phase 1 single agent study of TGR-1202, 87 patients have been treated with TGR-1202, alone or in combination with TG-1101, without the observance of drug-related hepatic toxicity. Additionally, in those 87 patients, there have been no events of colitis observed to date, with patients on the combination of TG-1101 and TGR-1202 for up to 9 months, and patients on single agent TGR-1202 upwards of 19+ months.

The triple combination of TG-1101, TGR-1202, and ibrutinib was well tolerated in the 5 patients evaluable for safety. No DLTs were observed and no Grade 3/4 events have been reported, with IRR, nausea, fatigue, and diarrhea being the most commonly reported Grade 1/2 adverse events. No dose reductions or dose delays have occurred.

Clinical Activity of TG-1101 + TGR-1202 in Chronic Lymphocytic Leukemia (CLL)

Of the 11 CLL/SLL patients enrolled to date, 9 were evaluable for efficacy. One patient was found to be ineligible prior to first efficacy assessment and one CLL patient is on the triple therapy and too early to evaluate. Patients in this group were heavily pre-treated with 67% (6/9) harboring a 17p del and/or 11q del.

A summary of the CLL/SLL data reported is as follows:

- All 9 evaluable patients exhibited nodal reductions with 6 of 9 achieving a Partial Response by the iwCLL (Hallek 2008) or Cheson criteria
- The remaining 3 patients achieved nodal reductions ranging from ~15% to 45% accompanied by either a normalization of ALC or a greater than 50% reduction of ALC, sometimes referred to as a "peripheral response"
- All evaluable CLL patients remain on study (durations of 3+ to 9+ months) pending further efficacy assessments and intra-patient dose escalation, which is permitted per protocol

The lymphocytosis generally observed in CLL patients treated with TGR-1202, similar to other PI3K delta and BTK inhibitors, appears to be mitigated by the addition of TG-1101.

Similar to the trend observed in the single agent study of TGR-1202, responses to the combination of TG-1101 and TGR-1202 have been shown to improve overtime and dose escalation continues now at 800mg micronized and up to 1200mg micronized, with the possibility of dosing higher.

Clinical Activity of TG-1101 + TGR-1202 in Hodgkin's Lymphoma (NHL) / Richter's Syndrome

Of the 17 NHL or Richter's patients enrolled to date, all were evaluable for efficacy (7 DLBCL, 9 FL and 1 Richter's). Patients in this group were heavily pre-treated, with 53% refractory to their prior treatment regimen. In the DLBCL group, patients had a median of 3 prior lines therapy and 5 of the 7 patients had the GCB subtype, with one patient classified as "triple-hit" (overexpression of BCL2, BCL6, and MYC rearrangements). In the Follicular Lymphoma group, patients had a median of 5 prior lines of therapy, with 56% being deemed rituximab refractory.

Among patients with Non-Hodgkin's Lymphoma treated at the highest doses tested, 83% (5/6) of the patients (3/3 of DLBCL and 2/3 of FL) responded to the combination. Of particular note was the potential signal in DLBCL, where an ORR of 43% (3/7) was observed with 2 patients (29%) achieving a Complete Response (CR), both of which were confirmed by independent radiologic review. Two of the three DLBCL responders were GCB subtype, which has historically been less responsive to BCR targeted agents. The 3 DLBCL patients who achieved a response remain on study, progression-free for greater than 7 months.

Additionally, despite the advanced disease and multiple lines of rituximab-based therapy, all of the FL patients treated to date with the combination were stable at first assessment and exhibited a reduction in tumor mass. Consistent with the exposure-response data recently reported in the single agent dose escalation trial of TGR-1202, 2 of 3 patients with FL treated at the highest dose of TGR-1202, 600mg micronized, responded at the first assessment (day 60). The remaining patient had a nodal reduction and remains on study pending further efficacy assessments. Dose escalation of the combination continues with TGR-1202 now at 800mg micronized and up to 1200mg micronized, with the possibility of dosing higher.

Clinical Activity - Triple Therapy: TG-1101 + TGR-1202 + Ibrutinib

Of the 5 patients enrolled to date on the triple combination of TG-1101, TGR-1202, and ibrutinib, 3 were evaluable for efficacy (1 FL, 1 MCL, and 1 patient with Richter's Transformation) and 2 were too early to evaluate. Of the 3 evaluable patients, 2 responded (MCL and FL). The MCL patient was diagnosed as Stage IV, and had previously progressed within one year of an autologous stem cell transplant, and achieved a PET negative CR at the first response assessment (day 60). The FL patient

had also been diagnosed as Stage IV, was refractory to both rituximab and ibrutinib, and achieved a PR at the first response assessment (day 60) with a 74% nodal reduction. Enrollment into the triple combination cohort continues, with TGR-1202 currently dosed at 600 mg, with additional dose escalations planned.

Presentation Details

The presentation, titled "Ublituximab, a Novel Glycoengineered Anti-CD20 mAb, in Combination with TGR-1202, a Next Generation Once Daily PI3K Delta Inhibitor, Demonstrates Activity in Heavily Pre-Treated and High Risk Chronic Lymphocytic Leukemia and B-Cell Lymphoma" was presented today, Tuesday, December 9, during the session titled "Lymphoma: Therapy with Biologic Agents, excluding Pre-Clinical Models: Indolent B-cell NHL and T-cell NHL", from 8:00 to 9:30am Pacific Time. The presentation is available on the Events page, located within the Investors & Media section of the Company's website at 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. 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, also for B-cell malignancies and autoimmune diseases. TG Therapeutics is headquartered in New York City.

CAUTIONARY STATEMENT

Some of the statements included in this press release, particularly those, anticipating results that might be achieved at higher doses of, and longer exposures to, TGR-1202, anticipating future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101 and TGR-1202 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 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 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. 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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Source: TG Therapeutics, Inc.