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TG Therapeutics' Novel Combination of TG-1101 (Ublituximab) and TGR-1202 Demonstrates Compelling Early Activity and Safety Profile in Patients With Previously Treated High-Risk Chronic Lymphocytic Leukemia (CLL) and Aggressive Lymphomas

- *100% of CLL/SLL patients had significant nodal reduction with either a normalization of or ≥80% reduction in Blood Lymphocyte Count*
- *4 of 5 CLL/SLL patients achieved a partial response at first assessment, including a patient relapsed from a prior BTK-inhibitor, and the 5th patient with stable disease achieved a 44% nodal reduction pending next assessment*
- *2 of 5 heavily pretreated DLBCL patients achieved a PR, including one patient with GCB subtype refractory to prior therapy*
- *Combination appears well tolerated with no dose-related increases in toxicity observed among patients treated to date*

NEW YORK, July 21, 2014 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), an innovative, clinical-stage biopharmaceutical company, today announced preliminary clinical results from its ongoing Phase I study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with TGR-1202, the Company's novel, once-daily PI3K delta inhibitor in patients with advanced CLL and non-Hodgkin's lymphoma. Data from the Phase 1 study is being presented by Dr. Matthew Lunning from the University of Nebraska Medical Center in Omaha, Nebraska during the 2014 Pan Pacific Lymphoma conference being held in Hawaii.

The poster presentation includes data from patients with advanced CLL, including 17p/11q del and a patient with Richter's Transformation, as well as heavily pre-treated, relapsed and/or refractory patients with Diffuse Large B-cell Lymphoma (DLBCL) and Follicular Lymphoma (FL). In an effort to utilize this study to potentially identify patient populations with unmet medical needs that could benefit from this combination, the study was designed to enroll heavily pre-treated and high risk patients, including those with aggressive lymphomas, with no limit on prior therapies, including patients relapsed or refractory to prior treatment with other PI3K delta and BTK inhibitors.

This is a dose escalation study. Patients treated to date and included in the presentation utilized escalating doses of TGR-1202 with a fixed dose of 900mg of TG-1101 for patients with NHL and 600mg for patients with CLL. As of July 1, 2014, enrollment in the study is now utilizing escalating doses of the micronized formulation of TGR-1202 starting at 400mg in combination with a fixed dose of TG-1101 at 900 mg for all patients. As of data cutoff, 21 patients were evaluable for safety with 15 evaluable for efficacy (6 were too early for assessment).

Overview of the data presented on TG-1101 + TGR-1202:

Safety and Tolerability

TG-1101 in combination with TGR-1202 was well tolerated in the 21 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 observed adverse events included neutropenia, nausea, and diarrhea, with neutropenia being the only Grade 3/4 adverse event reported in > 10% of patients (24%). One CLL patient required a dose delay for neutropenia in Cycle 1, which met the criteria for a dose-limiting toxicity (DLT) necessitating additional patients to be enrolled into the CLL Cohort 1. No additional DLT's have been observed with full enrollment completed in Cohorts 1 and 2. Consistent with the data observed to date in the ongoing TGR-1202 single agent Phase 1 (presented at EHA 2014), no drug-related events of AST/ALT elevations were observed among the 21 patients treated to date in this combination study with TG-1101.

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

Of the 8 CLL patients enrolled to date, 5 were evaluable for efficacy:

- Of the 5 CLL/SLL patients evaluable, 4 achieved a PR per the IWCLL (Hallek, et. al.) or Cheson criteria (SLL) at first efficacy assessment. The remaining patient, a CLL patient with both 17p and 11q del, achieved SD with a 44% nodal reduction at first assessment and > 50% reduction in ALC and remains on study.
- All 5 patients (100%) achieved a > 50% reduction in ALC by the first efficacy assessment with one patient achieving complete normalization of ALC (< 4000/uL) and the other 4 patients achieving a ≥80% reduction by the first efficacy

assessment (see chart below).

A chart accompanying this release is available at http://media.globenewswire.com/cache/8790/file/27712.pdf

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.

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

Of the 13 NHL or Richter's patients enrolled to date, 10 were evaluable for efficacy (5 DLBCL, 4 FL and 1 Richter's). Patients in this group were heavily pre-treated, with 50% refractory to their prior treatment regimen. In the DLBCL group, patients had a median of 3 prior lines and 3 of the 5 patients had the GCB subtype, with one patient classified as "triple-hit" lymphoma (overexpression of BCL2, BCL6 and MYC rearrangements). In the Follicular Lymphoma group, patients had a median of 6 prior lines of therapy and for the entire study population patients had a median of 2 prior lines of Rituxan-based therapy with a high of 7 prior lines of Rituxan-based therapy.

The disease control rate (Stable Disease or better) at first efficacy assessment was 90% (9 of 10), in this hard to treat population of high risk relapsed/refractory patients. Of particular note was the potential signal in DLBCL, where 2 of 5 patients with DLBCL had a partial response, including one GCB-subtype that was refractory to prior therapy. Both of these responses occurred at the higher dose of TGR-1202. Interestingly, in the single agent Phase 1 study of TGR-1202 a patient with GCB subtype DLBCL had a > 40% reduction in tumor mass and was stable for over 6 months.

Additionally, despite the advanced disease and multiple lines of Rituxan-based therapy, all of the FL patients were stable at first assessment and exhibited reduction in tumor mass, including one patient with ~45% nodal reduction, all pending subsequent assessments.

Dr. Susan O'Brien, Professor in the Department of Leukemia at MD Anderson Cancer Center and Study Chair for the CLL patient group stated, "We have been very impressed with the safety profile and the level of activity observed to date in all patient groups with TGR-1202 in combination with ublituximab, particularly given the advanced stage of disease, including the difficult-to-treat CLL patients with 17p and 11q deletion, and the GCB subtype DLBCL patients. Of particular interest is the absence of observed elevations in AST/ALT with TGR-1202, which is a known adverse event associated with other PI3K delta inhibitors. We look forward to continuing enrollment at all trial centers of this exciting combination and presenting data on more patients at upcoming medical meetings."

"Our corporate mission is to develop novel, proprietary combination therapies that provide a high level of activity without the toxic side effects of chemotherapy or chemotherapy-like drugs. Today's data presentation marks an exciting milestone for TG Therapeutics as it is the first data presented from our proprietary combination program. Our goal with this study was to establish that the combination could be delivered safely, to confirm our baseline assumption of a high level of activity in CLL and finally, to look for signals of activity in areas of unmet medical need. We are all very pleased with the preliminary results and despite the early look at the data, which we believe will only improve as it matures, we feel the study has already met our objectives," stated Michael S. Weiss, the Company's Executive Chairman and Interim CEO. Mr. Weiss continued, "We are looking forward to an exciting second half of this year as we continue to aggressively enroll into this study to expand our understanding of the safety, tolerability and activity of this combination in multiple diseases and settings as well as continue enrollment into our 1101 ibrutinib combination study. Additionally, we hope to launch additional combination trials as well, hopefully pushing the field toward better outcomes for patients with the least possible toxicity. Finally, if all goes as planned, the year will culminate with robust data presentations at ASH followed quickly by the launch of one or more registration trials."

The link to the full poster from the Pan Pacific Lymphoma Conference can be found at: www.tgtxinc.com/EPPLC2014-Poster2014.PDF.

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is an innovative, clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for cancer 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. 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. 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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