June 1, 2015

TG Therapeutics Announces the Triple Combination of TG-1101, TGR-1202 and Ibrutinib is Safe and Highly Active in Patients With Advanced B-Cell Malignancies

Data presented this morning by Dr. Nathan Fowler, MD Anderson Cancer Center, at the 51st American Society of Clinical Oncology (ASCO) Annual Meeting, provides proof of concept that the chemotherapy-free triple combination of TG-1101, TGR-1202 and ibrutinib can be safely administered at active doses in patients with relapsed or refractory high-risk CLL and advanced NHL

Minimal adverse events reported to date with Grade 3 or 4 events seen in 6% of patients, with no patients discontinuing treatment due to an adverse event up through 800 mg micronized TGR-1202 and patients remaining on treatment now up to 9.5+ months

100% (4/4) ORR in patients with CLL/SLL with all CLL patients having high-risk features (17p del) and 75% ORR in iNHL (FL/MZL) with one ibrutinib refractory Follicular Lymphoma patient achieving a durable Partial Response

All responses were rapid and profound with a 76% median reduction in disease burden at first efficacy assessment, with all patients who had a subsequent efficacy assessment achieving a deeper response with a median 92% reduction

NEW YORK, June 1, 2015 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (Nasdaq:TGTX), today announced clinical results from its ongoing study with TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with the Company's oral, once-daily, PI3K delta inhibitor, TGR-1202 and ibrutinib, a BTK inhibitor. Data from this Phase I dose escalation study was presented today by Dr. Nathan Fowler, Director, Developmental Therapeutics, Department of Lymphoma, MD Anderson Cancer Center at the Lymphoma Oral Session during the 51st American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "The ability to safely combine these three agents highlights why we have been so focused on the importance of the safety profile of our proprietary combination of TG-1101 plus TGR-1202, which we refer to as "TG-1303". We firmly believe the future paradigm for the treatment of B-cell malignancies will consist of the combination of multiple novel non-chemotherapy agents, where the safety profile of the chosen backbone regimen, like TG-1303, will be critical. A favorable safety profile is critical to unlocking the potential to explore whether dramatic activity with these novel multiple drug combinations can be seen. We believe Dr. Fowler presented some intriguing evidence of significant activity across multiple B-cell malignancy sub-types using this novel chemotherapy-free triple combination made possible by the 1303 safety profile." Mr. Weiss continued, "We look forward to continuing to explore this and other novel triple combinations in the future as we drive to create best-in-class combinations that can materially and positively impact the lives of those living with B-cell malignancies."

The following summarizes the oral presentation:

Abstract Number 8501: Safety and activity of the chemotherapy-free triplet of ublituximab, TGR-1202, and ibrutinib in relapsed B-cell malignancies

Today's oral presentation includes data from 16 patients with advanced relapsed and refractory high-risk CLL and NHL patients treated with the combination of TG-1101, TGR-1202 and ibrutinib at doses up through 800 mg micronized QD with TGR-1202.

Safety and Tolerability

TG-1101 in combination with TGR-1202 and ibrutinib has been well tolerated in the 16 patients evaluable for safety, at dose levels up through 800 mg micronized, the highest dose level tested to date in the study. Three cohorts for each CLL and NHL were evaluated with TGR-1202 dose escalation starting with micronized doses of 400 mg (cohort 1), followed by 600 mg (cohort 2) and 800 mg (cohort 3), in combination with TG-1101 at 900 mg and ibrutinib daily at 420 mg (CLL) and 560 mg (NHL). Day 1 infusion related reactions (IRR) have been the most frequently reported adverse event in 25% of patients, with no Grade 3 or 4 events of IRR. Other adverse events were manageable, with Grade 3 and 4 events occurring in only 6% of patients. Of the 16 patients treated to date, no patients discontinued due to an adverse event. One patient in the CLL cohort at 400 mg had a reactivation of varicella zoster which delayed dosing and met the definition of a dose limiting toxicity requiring an additional 3 patients in the CLL cohort 1 (400 mg micronized), which are currently being recruited. No DLT's were observed

in the NHL cohorts up through 800 mg micronized.

Clinical Activity

Clinical activity was observed at all 3 dose levels with 13 of 16 patients evaluable for efficacy (1 patient was removed per investigator discretion and 2 were too early to evaluate). The following is a highlight of responses by CLL and NHL:

- In the CLL/SLL cohort, 100% of patients (4 of 4) achieved an objective response at the first efficacy assessment, with all CLL patients having 17p deletion. All 4 responding patients remain on study now up to 7+ months.
- In patients with heavily pre-treated (≥ 4 prior lines of therapy) Follicular or Marginal Zone lymphoma 75% (3 of 4) achieved an objective response including one ibrutinib refractory patient achieving a PR at the first efficacy assessment. The one patient who achieved stable disease (achieved a 39% nodal reduction) was duvelisib refractory. All FL and MZL patients remain on study awaiting further assessments, now up through 9.5+ months.
- Both Mantle Cell lymphoma (MCL) patients achieved an objective response with 1 patient who had previously relapsed after an autologous stem cell transplant subsequently achieving a complete response. As with the other responding patients, both MCL patients remain on study now through 9.5+ months.
- Of the 3 patients who progressed on study, 1 patient was a Richter's Transformation and 2 were Diffuse Large B-Cell who were both of ABC subtype.

Of importance, patients who responded to the triple combination at their first efficacy assessment (week 8) and were evaluable for a second efficacy assessment (week 20), had an improved response. All responses were rapid and profound with a 76% median reduction in disease burden at the first efficacy assessment, with all patients who had a second response assessment achieving a deeper response with a median 92% reduction.

Commenting on the triple combination data, Dr. Nathan Fowler stated: "Combining multiple targeted agent drugs has long been a goal for investigators but has proved to be a challenge as evidenced by recent studies combining PI3K Delta and SYK inhibitors, and PI3K delta inhibitors and immunomodulators. The fact that we are able to safely combine these 3 novel compounds, a PI3K delta inhibitor, a BTK inhibitor and a glycoengineered anti-CD20 antibody, is a great leap forward in bringing novel non-chemotherapy combinations to patients with advanced disease." Dr. Fowler added, "The triple combination of TG-1101 + TGR-1202 + ibrutinib was not only well tolerated but displayed significant activity in a heavily pretreated and high-risk patient population that has limited options at this stage of their disease. We look forward to continuing to build upon this data and evaluate the triple combination further."

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 pre-clinical programs to develop IRAK4 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, 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 data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior pre-clinical and clinical trials, particularly with respect to the incidence of colitis and liver toxicity; 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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