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TG Therapeutics, Inc. Announces Follow-Up Data for Combination of TGR-1202 (umbralisib) plus Ibrutinib in Patients with Relapsed or Refractory CLL and MCL at the 14th International Conference on Malignant Lymphoma

Combination of TGR-1202 (umbralisib) plus ibrutinib appears well tolerated with no Grade 3/4 transaminitis, pneumonitis, diarrhea, or colitis observed, with longest patients on study 29.5+ months

94% of the CLL patients achieved a CR, PR or PR-L, including 1 patient with a CR, and 3 additional patients with radiographic CR's

79% ORR in patients with MCL, including 1 patient with a CR and 1 additional patient with a radiographic CR

NEW YORK, June 14, 2017 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced updated clinical data from its ongoing Phase I/Ib trial of TGR-1202 (umbralisib), the Company's oral, next generation PI3K delta inhibitor, in combination with ibrutinib, a BTK inhibitor, in patients with Chronic Lymphocytic Leukemia (CLL) and Mantle Cell Lymphoma (MCL). This study is being run in collaboration with the Blood Cancer Research Partnership (BCRP) and Dana-Farber Cancer Institute (DFCI), in Boston, MA. Data from this trial were presented today by the Principal Investigator, Matthew S. Davids, MD, of Dana-Farber Cancer Institute, during an oral session at the 14th International Conference on Malignant Lymphoma (ICML), in Lugano, Switzerland.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We continue to be impressed with the safety, tolerability and activity of the combination of TGR-1202 and ibrutinib. With this all oral combination, we are seeing high response rates, including in those patients with prior PI3K inhibitor or ibrutinib exposure. Additionally, the combination was well tolerated with over 30 patients now treated and for durations upwards of 2.5 years in this independently run, investigator initiated study." Mr. Weiss continued, "We want to thank Dr. Davids and his collaborators at DFCI and the Leukemia & Lymphoma Society for leading this important investigator driven research. Dr. Davids' research provides another important piece of information as we try to identify the best way to use these drugs, alone or in combination. These data complement the recently reported results at ASCO from the triple combination of TGR-1202, ibrutinib and TG-1101, our anti-CD20 monoclonal antibody, which showed that the three-drug combination was also well-tolerated and appeared to induce even higher rates of response, with 100% ORR by iwCLL criteria and deeper responses with 26% of the CLL patients achieving a CR. We look forward to continuing to explore these combinations to drive better outcomes for patients."

Highlights from today's presentation include the following:

Oral Presentation: Updated results of a multicenter phase I/Ib study of TGR-1202 in combination with ibrutinib in patients with relapsed or refractory MCL or CLL (Abstract #040)

This oral presentation includes data from patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) or Mantle Cell Lymphoma (MCL) treated with TGR-1202 in combination with ibrutinib. 32 patients were evaluable for safety (18 CLL patients and 14 MCL patients), of which 31 patients were available for efficacy (17 CLL patients and 14 MCL patients). CLL patients had a median of 1.5 prior lines of therapy (range 1-6), with 2 patients receiving prior ibrutinib and 4 receiving prior PI3K inhibitors. MCL patients had a median of 3 prior lines of therapy (range 2-5), with 2 patients also receiving prior ibrutinib.

Highlights from this oral presentation include:

- 94% (16 of 17) of CLL patients achieved a Complete Response (CR), Partial Response (PR), or a Partial Response with lymphocytosis (PR-L), with 1 patient achieving a CR and 3 additional patients with radiographic CR
- All 3 patients with prior PI3K inhibitor therapy that were evaluable for efficacy, and 1 of the 2 patients with prior ibrutinib exposure responded
- 1-year progression free survival (PFS) for CLL is 88% and overall survival (OS) at 1-year is 94%, (n=17), with the longest patient on study 29.5+ months
- 79% (11/14) ORR in patients with MCL, including 1 CR and 1 additional radiographic CR, with marked clinical benefit observed in two additional patients

- Median PFS and OS for MCL is 8.4 and 11.6 months, respectively (n=11)
- The combination appears well tolerated across all patients with no grade 3/4 transaminitis (liver toxicity), diarrhea, colitis or pneumonitis observed

PRESENTATION DETAILS:

The above referenced presentation is now available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

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 and autoimmune diseases. 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 (umbralisib), 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, with TG-1101 also in clinical development for autoimmune disorders. The Company also has pre-clinical programs to develop IRAK4 inhibitors, BET 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 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. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, factors that could cause our actual results to differ materially are the following: our ability to successfully and cost effectively complete preclinical and clinical trials; the risk that early clinical trial results, including the safety and efficacy results seen with the combination of TGR-1202 plus ibrutinib that may have supported the acceptance of our data for presentation or influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 or as the U2 regimen and being studied in the chemo-free triple combination of TG-1101 plus TGR-1202 plus ibrutinib and in the UNITY clinical trials and other combination trials, will not prove to be safe and efficacious for any indication or as a backbone for current or future combination trials. 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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