TG Therapeutics, Inc. Announces Umbralisib Clinical Data Presentation at the 54th Annual Meeting of the American Society of Clinical Oncology

June 4, 2018

CHICAGO, June 04, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX), today announced updated clinical data from its ongoing Phase 2 study evaluating umbralisib (TGR-1202), the Company's PI3K delta inhibitor, in patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) who are intolerant to prior BTK or PI3K delta inhibitor therapy. Data from this trial are being presented today during the 54thAmerican Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased with the data presented today during the ASCO annual meeting. We believe there is a need for novel treatment options for patients who are intolerant to the currently approved BTK and PI3K therapies and believe the data shown today demonstrates that umbralisib can be used effectively in these patients." Mr. Weiss, continued, "We continue to be pleased with the safety and efficacy profile of umbralisib and believe umbralisib single agent, or umbralisib plus ublituximab referred to as 'U2', can become important treatment options across multiple b-cell malignancies. We also look forward to presenting updated umbralisib integrated safety data at the European Hematology Association (EHA) annual congress in a couple of weeks, as well as the topline response rate data from the UNITY-CLL Phase 3 trial by the end of summer 2018."

Highlights from today's presentation include the following:

Poster Presentation: KI Intolerance Study: A Phase 2 Study to Assess the Safety and Efficacy of Umbralisib (TGR-1202) In Patients with Chronic Lymphocytic Leukemia (CLL) Who Are Intolerant to Prior BTK or PI3K-delta Inhibitor Therapy (Abstract Number 4314)

This poster presentation includes data from patients with CLL who are intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent umbralisib (TGR-1202). To be eligible for the study patients had to have received prior treatment with a BTK inhibitor (ibrutinib, acalabrutinib) or a PI3K delta inhibitor (idelalisib, duvelisib) and discontinued therapy due to intolerance within 12 months of starting treatment on this study. Forty-seven patients were evaluable for safety of which 46 were evaluable for Progression Free Survival (PFS), (1 patient had a confirmed Richter's Transformation (RT) at enrollment which did not meet eligibility criteria).

Highlights from this poster include:

- Umbralisib demonstrated a favorable safety profile in patients intolerant to prior BTK or PI3K therapy
- Only 13% discontinued due to an adverse event, of which only one patient discontinued due to a recurrent adverse event (AE) also experienced with prior KI therapy
- Nodal reductions were seen in nearly all patients evaluable for response with 3 patients achieving complete resolution of nodal disease, of which 1 patient with 17p del achieved a bone marrow confirmed Complete Response (CR)
- Median progression free survival (PFS) has not been reached with a median follow-up of 9.5 months
- In this relapsed/refractory CLL population, of which 77% required treatment within 6 months of prior KI discontinuation, 68% had a high-risk molecular / genetic marker and 6% had an ibrutinib resistance mutation, significant clinical activity has been 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. Ublituximab (TG-1101) 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 umbralisib (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 ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release or in the abstracts mentioned 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. Among the 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 (both safety and efficacy), 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 or in the final presentations; the risk that the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2, and being studied in the UNITY clinical trials and other studies, will not prove to be safe and efficacious for any indication; the risk that the differentiated tolerability profile for umbralisib observed will not be reproduced in full presentations or later larger studies; the risk that umbralisib will not be proven to be effective in the treatment of patients intolerant to prior kinase inhibitors; the risk that the final data from either GENUINE or UNITY-CLL will not support a regulatory filing or approval or that the company will choose not to file a BLA/NDA or seek accelerated approval based on those studies 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.

CONTACT:

Jenna Bosco
SVP, Corporate Communications
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

Primary Logo

Source: TG Therapeutics, Inc.