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TG Therapeutics, Inc. Announces Data from TGR-1202 in Combination with Ibrutinib as well as Recaps Long-Term Safety and Efficacy Data of TGR-1202 in CLL and NHL at the 21st European Hematology Association Annual Congress

Combination of TGR-1202 + Ibrutinib appears well-tolerated and active in relapsed/refractory CLL patients treated with the combination

NEW YORK, June 10, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced data presented during the 21st Annual Congress of the European Hematology Association (EHA) being held in Copenhagen, Denmark. These presentations include long term follow-up data of TGR-1202, the Company's once daily PI3K delta inhibitor, both alone and in combination with TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, as well as data presented for the first time from a Phase I/Ib study of TGR-1202 in combination with ibrutinib in patients with relapsed/refractory CLL or MCL.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "EHA is a great opportunity to showcase to the European hematology community the exciting data for TGR-1202 and for the combination of TGR-1202 plus TG-1101 that we recently presented at ASCO. We were also excited to present for the first time, the safety and preliminary activity of the all oral combination of TGR-1202 and the BTK inhibitor, ibrutinib, by Dr. Matthew Davids and the team from Dana-Farber. We were pleased to report today that the data demonstrates that TGR-1202 at our Phase 3 dose of 800 mg plus full dose ibrutinib appears safe, well-tolerated and produced high response rates, especially in patients with advanced CLL, including one complete response, a depth of response not generally observed with either agent alone. We thank all the investigators involved and look forward to continued enrollment in the combination of TGR-1202 plus ibrutinib, as well as the ongoing triplet combinations with TGR-1202 and TG-1101 in combination with either ibrutinib, bendamustine or pembrolizumab."

The following summarizes the posters presented yesterday and today during the EHA meeting:

E-Poster Title: Preliminary results of a Phase I/Ib study of ibrutinib in combination with TGR-1202 in patients with relapsed/refractory CLL or MCL

This poster includes data from patients with relapsed or refractory CLL or mantle cell lymphoma (MCL), all of whom were treated with TGR-1202 in combination with ibrutinib. A total of 27 patients were evaluable for safety, 17 patients with CLL and 10 with MCL, and 21 evaluable for efficacy, 11 patients with CLL and 10 with MCL (6 CLL patients were too early for assessment). CLL patients had a median of 2 prior lines of therapy (range 1-6), with 2 patients receiving prior ibrutinib and 2 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 poster include:

- 82% (9/11) ORR in patients with CLL, with 1 patient achieving a CR confirmed by a negative bone marrow and several other patients approaching a CR radiographically
- 60% (6/10) ORR in patients with MCL, with clinical benefit observed in two additional patients
- The combination was well tolerated with no DLTs observed up to the highest dose tested (800 mg TGR-1202 + full dose ibrutinib) with the toxicity profile being comparable to the additive toxicity of the two agents given individually

In addition to the above E-Poster, the Company is also presenting integrated analysis data from 165 patients with relapsed or refractory hematologic malignancies, which has been previously presented during the ASCO conference earlier this week. The data has been separated into two posters evaluating patients with CLL and then patients with NHL.

Long-term follow-up of the next generation PI3K-delta inhibitor TGR-1202 demonstrates safety and high response rates in CLL: Integrated-analysis of TGR-1202 monotherapy and combined with ublituximab (Abstract P207)

Long-term follow-up of the next generation PI3Kδ inhibitor TGR-1202 demonstrates safety and high response rates in NHL: Integrated-analysis of TGR-1202 monotherapy and combined with ublituximab (Abstract P315)

Updated information from the presentations at ASCO earlier this week include:

- Median Progression Free Survival (PFS) for TGR-1202 monotherapy was 24 months, while median PFS and DOR were not reached for TGR-1202 plus TG-1101 with median follow-up of 10.5 months, supporting our ongoing UNITY-CLL registration Phase 3 trial
- Median DOR of 12.1 months observed in DLBCL patients treated with TGR-1202 plus TG-1101, providing a strong rationale for our UNITY-DLBCL registration program
- Median DOR not reached in iNHL patients treated with TGR-1202 plus TG-1102 with a median follow-up of 15.8 months, further supporting our UNITY-iNHL registration directed trial, planned to launch by YE 2016

POSTER PRESENTATION DETAILS

A copy of the above mentioned poster presentations are available on the Company's website at www.tgtherapeutics.com, located on the Publications Page, within the Pipeline section.

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, 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 recently entering 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, 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, the BET 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, the BET 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, the BET 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 combination of TG-1101 and TGR-1202, referred to as TG-1303, will not prove to be a safe and efficacious backbone for triple and quad combination therapies; 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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