TG Therapeutics Announces Publication in Blood Advances Describing Unique Immunomodulatory Effects on CLL T cells by Umbralisib

July 8, 2020

NEW YORK, July 08, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced the publication of preclinical data describing the unique immunomodulatory effects of umbralisib, the Company's investigational oral once-daily dual inhibitor of PI3K-delta and CK1-epsilon, in *Blood Advances,* a Journal of the American Society of Hematology.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated "We want to thank Dr. Javier Pinilla-Ibarz, and the team at the H. Lee Moffitt Cancer Center & Research Institute for their important preclinical work examining the unique effect of umbralisib on T cells compared to other PI3K inhibitors. We have been encouraged by the safety profile reported in umbralisib clinical trials, and this preclinical data helps us to better understand the potential mechanistic rationale for the differentiated safety profile observed to date."

Dr. Javier Pinilla-Ibarz, Lymphoma Section Head, Director of Immunotherapy, Malignant Hematology Division at the H. Lee Moffitt Cancer Center in Tampa, Florida, and the senior author on the publication stated, "We have long been intrigued by the unique properties umbralisib has exhibited as a PI3K inhibitor. It is evident from the non-clinical work published today and from the clinical data seen thus far, that umbralisib is a novel molecule with differentiated effects on the T cell repertoire. We are pleased to contribute to elucidating the mechanisms of umbralisib and look forward to continuing our research."

The manuscript included preclinical data describing the effects of idelalisib, duvelisib and umbralisib on regulatory T cells (Tregs) on normal human T cells, T cells from CLL patients and T cells in an Eμ-TCL1 adoptive transfer mouse CLL model. While all three inhibitors exhibited anti-tumor efficacy in the Eμ-TCL1 CLL model, idelalisib or duvelisib-treated mice displayed increased immune-mediated toxicities, impaired function and reduced numbers of Tregs, whereas Treg number and function was more sustained in umbralisib-treated, CLL bearing mice. In addition, the manuscript also explored the effects of inhibition of CK1-epsilon on improvements in CLL Treg number and function and suggested the differentiated safety profile of umbralisib may be due to its role as a dual PI3K-delta/CK1-epsilon inhibitor.

These data are described further in the manuscript entitled, "The dual PI3K delta/CK1 epsilon inhibitor umbralisib exhibits unique immunomodulatory effects on CLL T cells," which was published online in the First Edition section of *Blood Advances*, the Journal of the American Society of Hematology. The online version of the article can be accessed at https://ashpublications.org/bloodadvances.

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 oral, once-daily inhibitor of PI3K-delta and CK1-epsilon. 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, TG-1501, as well as its covalently-bound Bruton Tyrosine Kinase (BTK) inhibitor, TG-1701, 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
This press release contains 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 preclinical and clinical trial results, that may have supported the acceptance of our data for publication or influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies or in future data presentations or will not support regulatory approval; and the risk that umbralisib will not maintain its differentiated safety profile as patients continue to be treated on drug for longer durations and more patients are enrolled. 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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Source: TG Therapeutics, Inc.