TG Therapeutics Announces Data Presentations at the Upcoming 62nd American Society of Hematology Annual Meeting and Exposition

November 2, 2020

Zoom conference call to be held November 5, 2020 at 8:45 AM ET

NEW YORK, Nov. 02, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that four abstracts have been accepted for presentation at the upcoming 62nd American Society of Hematology (ASH) annual meeting and exposition, to be held virtually December 5 – 8, 2020. Abstracts will be made publicly available online on November 5, 2020 at 9:00 AM ET via the ASH meeting website at www.hematology.org. The Company will also host a zoom conference call with leading investigators from the UNITY-NHL and UNITY-CLL trials on Thursday, November 5, 2020, beginning at 8:45 AM ET. Details about the ASH presentations and the conference call are outlined below.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, “We are excited to have four abstracts accepted for presentation at the upcoming ASH conference highlighting data from two registration directed trials, the UNITY-CLL Phase 3 trial of ublituximab in combination with umbralisib (U2) in CLL, and the UNITY-NHL MZL and FL/SLL umbralisib monotherapy cohorts. Our NDA for umbralisib monotherapy for previously treated MZL and FL is currently under review, and we are actively preparing a BLA/NDA submission for the U2 combination for CLL to be submitted in the coming months based on the results of the UNITY-CLL Phase 3 study. Demonstrating the potential to build upon these backbone regimens, there will also be two triple therapy datasets presented, one with U2 plus TG-1701, our BTK inhibitor; and one with U2 plus venetoclax in CLL. We look forward to the abstracts being released publicly on November 5 at 9 AM ET and to reviewing the exciting data on a conference call that morning.”

ASH 2020 PRESENTATION DETAILS:

- Oral Presentation Title: Umbralisib Plus Ublituximab (U2) Is Superior to Obinutuzumab Plus Chlorambucil (O+Chl) in Patients with Treatment Naïve (TN) and Relapsed/Refractory (R/R) Chronic Lymphocytic Leukemia (CLL): Results from the Phase 3 UNITY-CLL Study
  ° Publication Number: 543
  ° Oral Session: 642. CLL: Therapy, excluding Transplantation
  ° Session Date and Time: Monday, December 7, 2020; 7:00 AM – 8:30 AM (Pacific Time)
  - Presentation Time: 7:15 AM (Pacific Time)
  ° Presenter: John G. Gribben, D.Sc., F.R.C.P., F.R.C.Path., F.Med.Sci., North East London Cancer Research Network Centre, Barts and the London Cancer Center, UK

- Poster Presentation Title: Umbralisib, the Once Daily Dual Inhibitor of PI3Kδ and Casein Kinase-1ε Demonstrates Clinical Activity in Patients with Relapsed or Refractory Indolent Non-Hodgkin Lymphoma: Results from the Phase 2 Global UNITY-NHL Trial
  ° Publication Number: 2934
  ° Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster III
  ° Date and Time: Monday, December 7, 2020; 7:00 AM - 3:30 PM (Pacific Time)
  ° Presenter: Pier Luigi Zinzani, MD, Institute of Hematology, “L. e A. Seràgnoli”, University of Bologna, Italy

- Poster Presentation Title: A Phase 1/2 Study of Umbralisib, Ublituximab, and Venetoclax (U2-Ven) in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL) ° Publication Number: 3137
  ° Session: 642. CLL: Therapy, excluding Transplantation: Poster III
  ° Date and Time: Monday, December 7, 2020; 7:00 AM - 3:30 PM (Pacific Time)
  ° Presenter: Paul M. Barr, MD, Wilmot Cancer Institute, University of Rochester Medical Center, NY

- Poster Presentation Title: Clinical Activity of TG-1701, As Monotherapy and in Combination with Ublituximab and Umbralisib (U2), in Patients with B-Cell Malignancies
  ° Publication Number: 1130
  ° Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster I
  ° Date and Time: Saturday, December 5, 2020; 7:00 AM - 3:30 PM (Pacific Time)
  ° Presenter: Chan Cheah, MD, Sir Charles Gairdner Hospital, Hollywood Private Hospital, University of Western Australia, Blood Cancer Research Western Australia

Abstracts will be made publicly available online on November 5, 2020 at 9:00 AM ET via the ASH meeting website at www.hematology.org and will also be accessible via the publications page of TG corporate website at http://tgtxinc.com/publications.cfm. Following each presentation during ASH, the data presented will also be available on TG’s website.

ZOOM CONFERENCE CALL INFORMATION

The Company will host a zoom conference call November 5, 2020, at 8:45 AM ET.

In order to participate in the call, please join via the zoom webinar link: https://bit.ly/37XZai1, which will also be available on the Events page, located within the Investors & Media section, of the Company's website at https://ir.tgtherapeutics.com/events. Attendees may also join via phone by dialing 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), Conference Title: TG Therapeutics ASH Abstract Review Call. A recording of the conference call will also be available for replay at www.tgtherapeutics.com, for a period of 30 days after the call.

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 in late stage clinical development with two investigational compounds, ublituximab and umbralisib, the combination of which is referred to as “U2”, targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. Umbralisib (TGR-1202) is an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon. Umbralisib is currently under review by the U.S. Food and Drug Administration (FDA) for accelerated approval as a treatment for patients with previously treated marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen or follicular lymphoma (FL) who have received at least two prior systemic therapies. The Company also has a fully enrolled Phase 3 clinical trial evaluating U2 in patients with treatment naïve and relapsed/refractory chronic lymphocytic leukemia (CLL), and two fully enrolled identical Phase 3 trials evaluating ublituximab monotherapy in patients with relapsing forms of multiple sclerosis (RMS). Additionally, the Company has recently brought into Phase 1 clinical development its anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), its covalently-bound Bruton’s Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801. 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 include the following: the risk that the results of the UNITY-CLL trial will not be sufficient or acceptable to support regulatory submission of the combination of ublituximab (TG-1101) and umbralisib (TGR-1202) (U2) for the treatment of CLL; the risk that the results of the UNITY-NHL trial in previously treated FL and MZL will not be sufficient to support accelerated approval of our pending NDA for umbralisib; the risk that we will not be able to meet the regulatory submission timelines that we project or achieve other anticipated milestones, including the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones; the risk that interim, top-line, or other early clinical trial results, 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 final data sets or in future studies; and the risk that the U2 combination will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations, including with venetoclax and TG-1701. 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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