TG Therapeutics Announces Data Presentations from the ULTIMATE I & II Phase 3 Trials of Ublituximab in Multiple Sclerosis to be Presented at the Americas Committee for Treatment and Research in Multiple Sclerosis Annual Forum

February 15, 2022

NEW YORK, Feb. 15, 2022 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced the schedule of data presentations highlighting data from the ULTIMATE I & II Phase 3 trials evaluating ublituximab in patients with relapsing forms of multiple sclerosis (RMS), at the upcoming Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) annual forum, being held February 24 – 26, 2022, in West Palm Beach, Florida. Abstracts are now available online and can be accessed on the ACTRIMS meeting website at www.forum.actrims.org. Highlights from the abstract and details of the presentations are outlined below.

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics stated, “We are pleased to have three abstracts accepted for presentation at the upcoming ACTRIMS forum, highlighting additional analyses from the ULTIMATE I & II Phase 3 trials. Each new analysis continues to be encouraging and we believe reinforces the utility of ublituximab as a potential treatment option for patients with RMS.” Mr. Weiss continued, “We look forward to sharing the full data sets at the upcoming ACTRIMS meeting.”

Poster Presentation Title: Reduction in T1 Hypointense Lesions With Ublituximab vs Teriflunomide in the Phase 3 ULTIMATE I and II Studies in Relapsing Multiple Sclerosis

- Presentation Date/Time: Thursday, February 24, 2022 at 5:30 PM ET
- Session: PS1. Poster Session 1
- Abstract Number/Poster Number: 386/P108
- Lead Author: Bruce A. C. Cree, MD, PhD, MAS, UCSF Weill Institute for Neurosciences, University of California San Francisco

Poster Presentation Title: Neutralizing Antibodies and Antidrug Antibodies in the Ublituximab Phase 3 ULTIMATE I and II Studies in Relapsing Multiple Sclerosis

- Presentation Date/Time: Thursday, February 24, 2022 at 5:30 PM ET
- Session: PS1. Poster Session 1
- Abstract Number/Poster Number: 594/P103
- Lead Author: Enrique Alvarez, MD, University of Colorado, Aurora, CO

Poster Presentation Title: Pharmacodynamics of B-Cell Depletion and Pharmacokinetics of the Novel Anti-CD20 Monoclonal Antibody Ublituximab in Patients With Relapsing Multiple Sclerosis

- Presentation Date/Time: Thursday, February 24, 2022 at 5:30 PM ET
- Session: PS1. Poster Session 1
- Abstract Number/Poster Number: 595/P105
- Lead Author: Edward J. Fox, MD PhD, Central Texas Neurology Consultants, Round Rock, TX

A copy of the above abstract can be found on the ACTRIMS meeting website. Following the presentation, the data presented will be available on the Publications page, located within the Pipeline section, of the Company’s website at www.tgtherapeutics.com/publications.cfm.

ABOUT THE ULTIMATE I & II PHASE 3 TRIALS
ULTIMATE I and ULTIMATE II are two independent Phase 3, randomized, double-blinded, active-controlled, global, multi-center studies evaluating the efficacy and safety/tolerability of ublituximab (450mg dose administered by one-hour intravenous infusion every 6 months, following a Day 1 infusion of 150mg over four hours and a Day 15 infusion of 450mg over one hour) versus teriflunomide (14mg oral tablets taken once daily) in subjects with relapsing forms of Multiple Sclerosis (RMS). The ULTIMATE I & II trials enrolled a total of 1,094 patients with RMS across 10 countries. These trials were led by Lawrence Steinman, MD, Zimmermann Professor of Neurology & Neurological Sciences, and Pediatrics at Stanford University and were conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). As previously announced, both studies met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) compared to teriflunomide over a 96-week period ($p<0.005$ in each trial). Additional information on these clinical trials can be found at www.clinicaltrials.gov (NCT03277261; NCT03277248).

ABOUT UBLITUXIMAB
Ublituximab is an investigational glycoengineered monoclonal antibody that targets a unique epitope on CD20-expressing B-cells. When ublituximab binds to the B-cell it triggers a series of immunological reactions, including antibody-dependent cellular cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC), leading to destruction of the cell. Additionally, ublituximab is uniquely designed, to lack certain sugar molecules normally expressed on the antibody. Removal of these sugar molecules, a process called glycoengineering, has been shown to enhance the potency of ublituximab, especially the ADCC activity. Targeting CD20 using monoclonal antibodies has proven to be an important therapeutic approach for the

management of B-cell malignancies and autoimmune disorders, both diseases driven by the abnormal growth or function of B-cells.

ABOUT MULTIPLE SCLEROSIS
Relapsing multiple sclerosis (RMS) is a chronic demyelinating disease of the central nervous system (CNS) and includes people with relapsing-remitting multiple sclerosis (RRMS) and people with secondary progressive multiple sclerosis (SPMS) who continue to experience relapses. RRMS is the most common form of multiple sclerosis (MS) and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. It is estimated that nearly 1 million people are living with MS in the United States and approximately 85% are initially diagnosed with RRMS.[1,2] The majority of people who are diagnosed with RRMS will eventually transition to SPMS, in which they experience steadily worsening disability over time. Worldwide, more than 2.3 million people have a diagnosis of MS.[1]

ABOUT TG THERAPEUTICS, INC.
TG Therapeutics is a fully-integrated, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. In addition to an active research pipeline including five investigational medicines across these therapeutic areas, TG has received accelerated approval from the U.S. FDA for UKONIQ® (umbralisib), for the treatment of adult patients with relapsed/refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen and relapsed/refractory follicular lymphoma who have received at least three prior lines of systemic therapies. Currently, the Company has three programs in Phase 3 development for the treatment of patients with relapsing forms of multiple sclerosis (RMS) and patients with chronic lymphocytic leukemia (CLL) and several investigational medicines in Phase 1 clinical development. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and Linkedin.

UKONIQ® is a registered trademark of TG Therapeutics, Inc.

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. Such forward-looking statements include but are not limited to statements regarding the results of the ULTIMATE I & II Phase 3 studies and ublituximab as a potential treatment for relapsing forms of Multiple Sclerosis (RMS).

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. In addition to the risk factors identified from time to time in our reports filed with the U.S. Securities and Exchange Commission (SEC), factors that could cause our actual results to differ materially include the following: the risk that the data from the ULTIMATE I & II trials that we announce or publish may change, or the perceived product profile may be impacted, as more data or additional endpoints are analyzed; the risk that data may emerge from future clinical studies or from adverse event reporting that may affect the perceived safety and tolerability profile and commercial potential of ublituximab; the risk that the clinical results from the ULTIMATE I & II trials will not support regulatory approval of ublituximab to treat RMS for efficacy, safety or other issues or, if approved, that we will not receive regulatory approval within the timeline projected; the risk that if approved, ublituximab will not be commercially successful; our ability to expand our commercial infrastructure, and successfully launch, market and sell ublituximab in RMS if approved; the Company's reliance on third parties for manufacturing, distribution and supply, and a range of other support functions for our commercial and clinical products, including ublituximab; the uncertainties inherent in research and development; and the risk that the ongoing COVID-19 pandemic and associated government control measures have an adverse impact on our research and development plans or commercialization efforts. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in our other filings with the SEC. 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:

Investor Relations
Email: ir@tgtxinc.com
Telephone: 1.877.575.TGTX (8489), Option 4

Media Relations:
Email: media@tgtxinc.com
Telephone: 1.877.575.TGTX (8489), Option 6

1. MS Prevalence. National Multiple Sclerosis Society website. https://www.nationalmssociety.org/About-the-Society/MS-Prevalence. Accessed October 26, 2020. **2.** Multiple Sclerosis International Federation, 2013 via Datamonitor p. 236.