



TG Therapeutics to Present Results from the ULTIMATE I & II Phase 3 Trials Evaluating Ublituximab in Multiple Sclerosis at the Upcoming American Academy of Neurology 73rd Annual Meeting

March 4, 2021

NEW YORK, March 04, 2021 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that results of the ULTIMATE I & II Phase 3 trials evaluating ublituximab, the Company's novel, glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of multiple sclerosis (RMS) have been selected for presentation at the upcoming American Academy of Neurology (AAN) annual meeting, being held virtually April 17 – 22, 2021. The abstract is available online and can be accessed via the below link or on the AAN meeting website at www.aan.com.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are highly encouraged by the positive topline results from the ULTIMATE I & II Phase 3 trials announced this past December, showing both studies met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period. Importantly, ublituximab treatment resulted in an ARR of less than 0.10 in each of the studies." Mr. Weiss continued, "We look forward to presenting additional data from the ULTIMATE I & II Phase 3 trials during the AAN conference including safety and secondary endpoint analyses and to working towards a BLA submission targeted around mid-year 2021."

Presentation Details

Title: [Efficacy and safety of ublituximab versus teriflunomide in relapsing multiple sclerosis: Results of the Phase 3 ULTIMATE I and II trials](#)

- **Date & Time:** Available for viewing beginning Saturday April 17, 2021 at 8:00 AM ET
- **Abstract Number:** 4494
- **Lead Author:** Lawrence Steinman, MD, Zimmermann Professor of Neurology & Neurological Sciences, and Pediatrics at Stanford University

ABOUT THE ULTIMATE I & II 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). In December 2020, we announced that both studies met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period ($p < 0.005$ in each trial). Ublituximab treatment resulted in an ARR of < 0.10 in each of ULTIMATE I & II, with a relative reduction in ARR of approximately 60% and 50%, respectively, over teriflunomide. Data from these studies are intended to support a Biologics License Application (BLA) submission for ublituximab in RMS targeted in mid-year 2021. Additional information on these clinical trials can be found at www.clinicaltrials.gov (NCT03277261; NCT03277248).

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 two 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 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 Company's plans and timelines for submission of a Biologics License Application (BLA) for ublituximab for the treatment of relapsing forms of multiple sclerosis (RMS) and, if approved, commercialization, and the potential benefits of ublituximab in treating patients.

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 interim, top-line

and preliminary data from the ULTIMATE I & II trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed; the risk that safety issues or trends will be observed in the ULTIMATE I & II trials when the full safety dataset is available and analyzed; the risk that secondary endpoints from the ULTIMATE I & II will not be positive; our ability to complete the BLA submission for ublituximab in RMS within the timeline projected; the risk that the clinical results from the ULTIMATE I & II trials will not support regulatory approval of ublituximab to treat RMS or 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.

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