TG Therapeutics Announces FDA Extension of BLA PDUFA Date for Ublituximab to Treat Patients with RMS

May 31, 2022

New PDUFA goal date of December 28, 2022

NEW YORK, May 31, 2022 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date to December 28, 2022, for the Biologics License Application (BLA) for ublituximab as a treatment for patients with relapsing forms of multiple sclerosis (RMS).

The FDA extended the PDUFA goal date to allow time to review a submission provided by the Company in response to an FDA information request, which the FDA deemed a major amendment. The submission comprised an integration and summary of certain clinical information that was previously provided to the FDA by the Company.

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics stated, “While we are disappointed with the extension of our PDUFA goal date for ublituximab, a delay of this duration is not unprecedented, with both of the currently marketed CD20s in MS experiencing a similar 3-month PDUFA extension prior to approval. As we were targeting a launch for late this year or early next, we do not believe this will impact our overall launch plans for ublituximab in RMS.” Mr. Weiss added, “We will continue to work with the FDA to complete the review of the ublituximab BLA and plan to be prepared and ready to launch upon approval. We believe ublituximab has the potential to offer RMS patients a valuable treatment option that can be administered in a one-hour infusion every six months following the first dose.”

The BLA submission was based on the results of the ULTIMATE I & II trials, two identical Phase 3, randomized, global, multi-center, double-blinded, active-controlled trials evaluating ublituximab compared to teriflunomide in patients with RMS.

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
TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline including several investigational medicines, TG has completed a Phase 3 program for ublituximab, an investigational glycoengineered monoclonal antibody that targets a unique epitope on CD20-expressing B-cells, to treat patients with relapsing forms of multiple sclerosis (RMS). For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and Linkedin.

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 FDA review of the Biologics License Application (BLA) for ublituximab for the treatment of relapsing forms of Multiple Sclerosis (RMS) and the commercial potential of ublituximab for the treatment of RMS if the BLA is approved.

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 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 ublituximab will not be commercially successful, if approved; 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 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; 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, 2021, our most recent Quarterly Report filed on Form 10-Q, and our other filings with the U.S. 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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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.