TG Therapeutics Announces Publication of Ublituximab Phase 2 Clinical Trial Results in Multiple Sclerosis Journal

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Ublituximab was generally well tolerated across all cohorts including those patients receiving one-hour infusions for the 450mg dose currently being studied in the Phase 3 ULTIMATE MS program

Annualized Relapse Rate of 0.07 observed at week 48

NEW YORK, May 01, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced the publication of results from the multicenter Phase 2 trial evaluating ublituximab, the Company's investigational, glycoengineered, anti-CD20 monoclonal antibody, in patients with relapsing forms of multiple sclerosis (RMS), in the *Multiple Sclerosis Journal*.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased to see the ublituximab Phase 2 results published in *Multiple Sclerosis Journal*. Anti-CD20 therapy has quickly become a very important treatment option for patients with MS, and we believe our Phase 2 data highlight the potential therapeutic benefits for ublituximab delivered in a convenient one-hour infusion following day 1. Further, these Phase 2 data strengthen our confidence in the design of our fully enrolled Phase 3 ULTIMATE program for ublituximab in RMS, for which we are targeting topline data in the second half of this year." Mr. Weiss continued, "We want to thank Dr. Edward Fox as well as the investigators and staff at each of the participating trials sites, and most importantly the patients who participated in this study."

Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas at Central Texas Neurology Consultants, Clinical Associate Professor at the University of Texas Dell Medical School in Austin, TX and the Principal Investigator for this Phase 2 study stated, "The encouraging clinical data we have published illustrate the potential for ublituximab in the treatment of patients with relapsing forms of multiple sclerosis. The compelling efficacy findings and favorable tolerability profile reported in this Phase 2 study along with the one-hour infusion time are promising and support a differentiated profile for ublituximab." Dr. Fox continued, "I am encouraged that all patients who completed the 48-week Phase 2 trial entered the extension phase of the study and look forward to updates from the Phase 2 extension, as well as to topline data from the Phase 3 trials evaluating ublituximab later this year."

The manuscript includes safety and efficacy information from 48 patients with RMS. Patients received 3 ublituximab infusions in 6 dosing cohorts (150mg over 1-4 hours on day 1 and 450-600mg over 1-3 hours on day 15 and week 24) and were followed for a total of 48 weeks. The primary endpoint of the trial was responder rate, defined as the proportion of patients with >95% peripheral CD19+ B-cell depletion from baseline to week 4 (two weeks after the second ublituximab infusion). Secondary endpoints included the effects of ublituximab on gadolinium-enhancing T1-weighted lesions, T2-weighted lesion volume and number of new or enlarging T2 lesions on brain MRI, annualized relapse rate (ARR), and proportion of relapse-free patients.

Safety data was available from all 48 patients and demonstrated ublituximab was well generally tolerated with no patients discontinuing due to a drug-related adverse event (AE). One grade 3 AE, fatigue, was considered possibly related to ublituximab. No serious infections were reported, and no deaths occurred on-study. The most common ublituximab-related AE was infusion related reactions (IRRs) (58%) all of which were grade 1 or 2 in severity, including amongst those patients receiving 450mg ublituximab infusion in one hour.

Efficacy data were also available and include the following:

- The responder rate was 100%, with a median peripheral B-cell depletion of >99% from baseline to week 4. B-cell reductions were sustained pre-dose at week 24 and also at week 48.
- Annualized Relapse Rate (ARR) at week 48 was 0.07, with a mean follow-up of approximately 47 weeks.
- At study weeks 24 and 48, no patient had a new or persisting gadolinium-enhancing lesion on any brain MRI scan (100% reduction from baseline; *P*=0.003).

These data are described further in the manuscript entitled, "A Phase 2 Multicenter Study of Ublituximab, a Novel Glycoengineered Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis", which was published yesterday in *Multiple Sclerosis Journal*. The online version of the article can be accessed at https://www.tgtherapeutics.com/wp-content/uploads/2020/04/MS-Journal-4.29.20.pdf.

ABOUT THE ULTIMATE I & II TRIALS
ULTIMATE I and ULTIMATE II are two independent Phase 3 trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing ublituximab (TG-1101), to teriflunomide in subjects with relapsing forms of Multiple Sclerosis (RMS). The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment. These trials are being led by Lawrence Steinman, MD, George A. Zimmermann Professor and Professor of Pediatrics, Neurology and Neurological Sciences at Stanford University and are being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). Additional information on these clinical trials can be found at www.clinicaltrials.gov (NCT03277261; NCT03277248).

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 multiple 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 dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. 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 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 within the meaning of the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but may not be limited to, statements anticipating the benefit of the data reported in the Phase 2 MS trial program, the performance of ublituximab in the Phase 3 ULTIMATE clinical program, and the timing for topline data from the ULTIMATE clinical program. These forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to differ materially, including: the risk that early 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 additional patients in expansion cohorts, ongoing or future studies; the risk that the clinical results from the Phase 3 ULTIMATE clinical program will not be positive and/or will not support regulatory approval of ublituximab to treat RMS; our ability to successfully and cost-effectively complete the Phase 3 ULTIMATE clinical program; the risk that ublituximab will not have a differentiated profile from the other drugs in the class; our ability to achieve the milestones we project over the next year, including the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones; our ability to manage our cash in line with our projections, and other risk factors identified from time to time in our reports filed with the 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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