TG Therapeutics Announces Presentation of Long-term Follow-up Data from the Phase 2 Trial of Ublituximab in Patients with Multiple Sclerosis During an Oral Session at the 5th Congress of the European Academy of Neurology

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Ublituximab treatment continues to be well tolerated with a median duration of follow-up of 97.5 weeks

NEW YORK, July 02, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company dedicated to developing medicines for patients with B-cell mediated diseases, today announced the presentation of long-term follow-up data from the Phase 2 and Open Label Extension (OLE) trial of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS). The data were presented during an oral session today at the 5thCongress of the European Academy of Neurology (EAN), in Oslo, Norway. These data were previously presented at the American Academy of Neurology 71st Annual Meeting.

Today's presentation included long-term follow-up data for 45 patients from the Phase 2 trial that enrolled into the OLE trial and recaps the final efficacy data on patients enrolled in the Phase 2 study through 48 weeks of treatment.

Presentation Highlights:

- Ublituximab continues to be well tolerated, with a median duration of follow-up of 97.5 weeks.
- No subjects discontinued due to an Adverse Event (AE) related to ublituximab on the Phase 2 or during the OLE.
- AEs deemed at least possibly related to ublituximab were infrequent during the OLE with all patients dosed 450mg of ublituximab administered in a one-hour infusion (Phase 3 dose).
- Infusion Related Reactions (IRRs) were rare during the OLE, occurring in only 4 patients (9%), all Grade 1 or 2.

These long-term safety data, and the Phase 2 efficacy data support the ongoing, fully enrolled, international Phase 3 program evaluating ublituximab (administered in a rapid one-hour infusion) for the treatment of RMS. The Phase 3 trials, entitled ULTIMATE I and ULTIMATE II, are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and are being led by Lawrence Steinman, MD, of Stanford University.

The data presented today are available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

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 two 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 inhibitor of PI3K-delta. Umbralisib uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K-delta inhibitors. 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 its anti-PD-L1 monoclonal antibody, TG-1501, as well as its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801, into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Statements included in this press release, particularly those with respect to anticipating the benefit of the data seen in the Phase 2 and OLE MS program and performance in of ublituximab in the Phase 3 ULTIMATE clinical program may be 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. Among the factors that could cause our actual results to differ materially are the following: the risk that early clinical results that supported our decision to move forward will not be reproduced in additional patients in expansion cohorts, with longer term follow-up, or in the MS Phase 3 program; the risk that ublituximab will not have a differentiated safety or efficacy profile from the other drugs in the class; the risk that the long-term safety profile presented today will not be replicated in the Phase 3 ULTIMATE program; the risk that the clinical results from the MS Phase 3 ULTIMATE program, will not be positive and/or will not support regulatory approval of ublituximab to treat MS; our ability to successfully and cost-effectively complete the MS Phase 3 trials; our ability to achieve the milestones we project over the next year; 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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