TG Therapeutics Initiates Rolling Submission of New Drug Application (NDA) to U.S. Food and Drug Administration for Umbralisib as a Treatment for Patients with Previously Treated Marginal Zone Lymphoma or Follicular Lymphoma

January 16, 2020

TG received guidance from the FDA allowing submission of a single NDA for Marginal Zone Lymphoma (MZL) and Follicular Lymphoma indications

Completion of rolling submission for the MZL/FL NDA expected in 1H20

NEW YORK, Jan. 16, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company developing medicines for patients with B-cell mediated diseases, announced that the Company has initiated a rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting accelerated approval of umbralisib, the Company's oral, once-daily, dual inhibitor of PI3K-delta and CK1-epsilon, as a treatment for patients with previously treated marginal zone lymphoma (MZL) and follicular lymphoma (FL). The Company has received guidance from the FDA that submission of a single NDA for both the MZL and FL indications is acceptable. Umbralisib has previously been granted both orphan drug designation and breakthrough therapy designation by the FDA for MZL. The Company expects to complete the NDA rolling submission in the first half of 2020.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are extremely pleased to have initiated our first NDA submission for umbralisib and to have received guidance from the FDA to include both MZL and FL in a single NDA. This is an extremely important milestone for us, as it brings us one step closer to potentially offering a novel treatment option to patients with previously treated MZL and FL." Mr. Weiss continued, "I want to thank the patients, their families and the research teams who participated in these important trials and helped advance umbralisib, and the TG team for working tirelessly to initiate this NDA submission. This is the beginning of an impactful 2020 as we look forward to topline Phase 3 data from both the UNITY-CLL trial and the ULTIMATE I & II trials in multiple sclerosis, as well as potential regulatory submissions based off these data."

ABOUT THE UNITY-NHL PHASE 2b STUDY—MARGINAL ZONE LYMPHOMA AND FOLLICULAR LYMPHOMA COHORTS

The UNITY- NHL trial is a multicenter, open-label Phase 2b trial.

The Marginal Zone Lymphoma (MZL) cohort was designed to evaluate the safety and efficacy of single agent umbralisib, in patients with MZL who have received at least one prior anti-CD20 regimen. The primary endpoint is overall response rate (ORR) as determined by central Independent Review Committee (IRC) assessment.

The Follicular Lymphoma (FL) cohort was designed to evaluate the safety and efficacy of single agent umbralisib in patients with FL who have received at least two prior lines of therapy, including an anti-CD20 regimen and an alkylating agent. The primary endpoint is overall response rate (ORR) as determined by Independent Review Committee (IRC) assessment.

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 dual inhibitor of PI3K-delta and CK1-epsilon, which may 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, 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. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release 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. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, factors that could cause our actual results to differ materially are the following: our ability to successfully and cost effectively complete preclinical and clinical trials; the risk that the Company will not complete an NDA submission for umbralisib in patients with previously treated MZL or FL in the planned timeframe or at all; the risk that the FDA will not accept the NDA submission of umbralisib in patients with previously treated MZL or FL; the risk that the clinical trial results from the UNITY-NHL MZL or FL cohorts will not be sufficient to support accelerated approval or any regulatory approval of umbralisib for previously treated MZL or FL; the risk that the FDA may delay approval of the umbralisib NDA or grant approval that is more restrictive than anticipated; the risk that the positive data from the UNITY-NHL MZL or FL cohorts will not be reproduced in future studies or in other cohorts of the UNITY-NHL study; the risk that duration of response or progression free survival data from the UNITY-NHL MZL or FL cohorts when available will not be supportive of approval or be perceived to be clinically meaningful by physicians; the risk that safety issues will arise when the safety data is fully cleaned and analyzed for the UNITY-NHL MZL or FL cohort; the risk that the differentiated tolerability profile for umbralisib previously observed in clinical trials will not be reproduced in the UNITY-NHL study, the UNITY-CLL study or any other on-going studies; the risk that patients with relapsed/refractory FL or MZL as

studied in UNITY-NHL will not be considered an unmet medical need by regulatory authorities; the risk that the Company's target ORR will not be considered sufficient to establish clinical efficacy in the opinion of any regulatory authority; the risk that data from the UNITY-CLL Phase 3 trial or the Ultimate I&II trials will not be available in the planned timeframe or not be sufficient to support a regulatory submission. 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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