



## **TG Therapeutics Confirms Registration Path for Umbralisib in Marginal Zone Lymphoma Following FDA Meeting**

June 11, 2019

### **New Drug Application (NDA) submission based on UNITY-NHL targeted for later this year**

NEW YORK, June 11, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that the Company has confirmed its path to submit umbralisib for accelerated approval based on data from the marginal zone lymphoma (MZL) cohort of the UNITY-NHL Phase 2b trial. The Company recently had a productive Breakthrough Therapy Designation (BTD) meeting with the U.S. Food and Drug Administration (FDA) to discuss the MZL submission strategy. Based on this meeting, the Company anticipates initiating a New Drug Application (NDA) submission for patients with previously treated MZL by year-end 2019.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "Marginal zone lymphoma is an incurable disease for which there are limited available therapies. As a non-chemotherapy, orally active, once daily medication, we believe umbralisib could represent a meaningful new treatment option for patients with MZL. Defining a path to a regulatory submission for umbralisib for this patient population marks an important step forward for the Company and we appreciate the guidance we have received from the FDA. We look forward to beginning the NDA process later this year, as we work expeditiously to bring umbralisib to the patients who need it." Mr. Weiss continued, "With our MZL NDA moving forward, and Phase 3 read-outs for CLL and MS targeted over approximately the next six to twelve months, we believe TG is well positioned for success."

#### **ABOUT THE UNITY-NHL PHASE 2b STUDY—MARGINAL ZONE LYMPHOMA COHORT**

The multicenter, open-label, UNITY-NHL Phase 2b study - 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 MZL cohort completed enrollment in August 2018 with a total of 69 patients enrolled and receiving at least one dose of umbralisib. In February of 2019, the Company announced that the MZL cohort met its primary endpoint of ORR as determined by central IRC for all treated patients (n=69). While the study has already met the Company's target guidance of 40-50% ORR, the final analysis of ORR will be conducted when all treated patients have had at least 9 cycles (cycle = 28 days) of follow-up. Secondary endpoints include safety, duration of response, and progression-free survival (PFS).

#### **ABOUT BREAKTHROUGH THERAPY DESIGNATION**

The Company announced in January of 2019 that the U. S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) for umbralisib for the treatment of adult patients with MZL who have received at least one prior anti-CD20 regimen.

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a drug candidate that is planned to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies.

#### **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 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 into Phase 1 clinical development, TG-1501, its anti-PD-L1 monoclonal antibody, TG-1701, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor and TG-1801, its anti-CD47/CD19 bispecific antibody. 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: the risk that the interim data (the "Interim Results") from the UNITY-NHL MZL cohort will not be reproduced when the final analysis is conducted on all patients, including the risk that the final results will demonstrate a lower ORR and/or enhanced toxicities, which may not support a filing for accelerated approval; the risk that even if the Interim Results are reproduced in the final analysis of the UNITY-NHL MZL cohort or that the final results otherwise meet the Company's target ORR of 40-50%, that the final results will still be insufficient to support a filing for accelerated approval; the risk that umbralisib will not be accepted for filing or receive accelerated approval based on data from the UNITY-NHL MZL cohort even if the final results are deemed positive by the Company and support a filing for accelerated approval; the risk that duration of response or progression free survival data from the UNITY-NHL cohort when available for all patients will not be positive or supportive of accelerated approval; the risk that safety issues will arise when the final safety data are cleaned and analyzed for all patients in the UNITY-NHL MZL cohort; the risk that the positive Interim Results from the UNITY-NHL MZL cohort will not be reproduced in other cohorts of the UNITY-NHL study or in other studies being conducted by the Company; the risk that our belief that umbralisib has a differentiated safety profile will not be shared by

physicians or the FDA or will not be reproduced in the final analysis of the UNITY-NHL MZL cohort, in other cohorts of the UNITY-NHL study, in the UNITY-CLL study or in any other of our on-going studies; the risk that the anticipated timeline for filing an NDA for accelerated approval for patients with MZL based on UNITY-NHL data and the timeline for data releases for UNITY-CLL and ULTIMATE-MS trials will be delayed due to a variety of factors, including, without limitation, available resources, program reprioritization, slower than expected event rates for UNITY-CLL and/or requests from FDA or foreign regulators; the risk that we are not able to successfully and cost effectively complete all the preclinical, clinical and CMC requirements necessary to support accelerated approval. 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](http://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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