TG Therapeutics Announces FDA Acceptance of New Drug Application for Umbralisib as a Treatment for Patients with Previously Treated Marginal Zone Lymphoma and Follicular Lymphoma

August 13, 2020

NEW YORK, Aug. 13, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for umbralisib, the Company's investigational once-daily, oral, dual inhibitor of PI3K-delta and CK1-epsilon, as a treatment for patients with previously treated marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen and follicular lymphoma (FL) who have received at least two prior systemic therapies. The MZL indication, under Breakthrough Therapy Designation (BTD), has been accepted for Priority Review and has a Prescription Drug User Fee Act (PDUFA) goal date of February 15, 2021. The FL indication has been accepted for standard review with a PDUFA goal date of June 15, 2021. The FDA also notified the Company that it is not currently planning to hold an advisory committee meeting to discuss this application.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are extremely pleased with the FDA's acceptance of our first NDA submission and look forward to working with the FDA during the review process. This is a significant achievement in our path towards accomplishing our goal of developing novel treatments for patients with B-cell diseases." Mr. Weiss continued, "If approved, we believe umbralisib could become an important treatment option for patients with previously treated MZL and FL. We look forward to presenting the data from the UNITY-NHL trial that supported this NDA submission by year end."

The NDA for umbralisib was based primarily on data from the umbralisib monotherapy MZL and FL cohorts of the UNITY-NHL Phase 2b trial evaluating patients with relapsed/refractory MZL or FL. The Company has previously announced that each cohort met its primary endpoint of overall response rate (ORR), meeting the Company's target guidance of 40-50% ORR, as confirmed by an Independent Review Committee (IRC). The FDA has also previously granted umbralisib Breakthrough Therapy Designation (BTD) for MZL and orphan drug designation (ODD) for MZL and FL.

ABOUT THE UNITY-NHL PHASE 2b STUDY—MZL & FL COHORTS
The UNITY- NHL trial is a global multicenter, open-label Phase 2b trial.

The 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. In February of 2019, the Company announced that the primary endpoint of overall response rate (ORR) as determined by Independent Review Committee (IRC) was met for all treated MZL patients. The results met the Company's target guidance of 40-50% ORR. Interim safety and efficacy data from the MZL cohort were presented in oral presentations in 2019 at the American Association for Cancer Research (AACR) annual meeting, the American Society of Clinical Oncology (ASCO) annual meeting and the International Conference on Malignant Lymphoma (ICML).

The FL cohort was designed to evaluate the safety and efficacy of single agent umbralisib in patients with FL who were relapsed or refractory following at least two prior lines of therapy, including an anti-CD20 regimen and an alkylating agent. In October of 2019, the Company announced that the primary endpoint of ORR as determined by IRC was met for all treated FL patients. The results met the Company's prespecified response target of 40-50% ORR.

On June 15, 2020, the Company announced the completion of the rolling submission of a NDA to the FDA requesting accelerated approval of umbralisib as a treatment for patients with previously treated MZL and FL.

On August 12, 2020, the Company received notification from the FDA of its acceptance of the Company's NDA for umbralisib as a treatment for patients with previously treated MZL and FL.

ABOUT MARGINAL ZONE LYMPHOMA
Marginal zone lymphoma (MZL) comprises a group of indolent (slow growing) mature B-cell non-Hodgkin lymphomas (NHLs). MZL is generally considered a chronic and incurable disease. With an annual incidence of approximately 7,500 newly diagnosed patients in the United States[1], MZL is the third most common B-cell NHL, accounting for approximately eight percent of all NHL cases. MZL consists of three different subtypes: extranodal MZL of the mucosal-associated lymphoid tissue (MALT), nodal marginal zone lymphoma (NMZL), and splenic marginal zone lymphoma (SMZL)[2].

ABOUT FOLLICULAR LYMPHOMA
Follicular lymphoma (FL) is typically an indolent form of non-Hodgkin lymphoma (NHL) that arises from B-lymphocytes. It is the second most common form of NHL. FL is generally not curable and is considered a chronic disease, as patients can live for many years with this form of lymphoma. With an annual incidence in the United States of approximately 15,000 newly diagnosed patients[3], FL is the most common indolent lymphoma accounting for approximately 20 percent of all NHL cases[4].

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 in late stage clinical development with two investigational compounds, ublituximab and umbralisib, the combination of which is referred to as "U2", targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. Umbralisib (TGR-1202) is an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon. Umbralisib is currently under review by the U.S. Food and Drug Administration (FDA) for accelerated approval as a treatment for patients with previously treated marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen or follicular lymphoma (FL) who have received at least two prior systemic therapies. The Company also has a fully enrolled Phase 3 clinical trial evaluating U2 in patients with treatment naïve and relapsed/refractory chronic lymphocytic

leukemia (CLL), and two fully enrolled identical Phase 3 trials evaluating ublituximab monotherapy in patients with relapsing forms of multiple sclerosis (RMS). 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.

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[1]2016 Lymphoid Malignancy Statistics by World Health Organization Subtypes VOLUME 66 _ NUMBER 6 _ NOVEMBER/DECEMBER 2016 https://onlinelibrary.wiley.com/doi/pdf/10.3322/caac.21357

[2] Lymphoma Research Foundation: Marginal Zone Lymphoma https://lymphoma.org/aboutlymphoma/nhl/mzl/

[3] American Cancer Society "Key Statistics for Non-Hodgkin Lymphoma"

[4] Lymphoma Research Foundation "Follicular Lymphoma"

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. 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 include the following: the risk that umbralisib may not receive regulatory approval for previously treated MZL or FL in the currently anticipated timeline or at all; the risk that the FDA may grant approval that is more restrictive than anticipated; *our ability to successfully launch umbralisib for previously treated MZL or FL, if those indications are approved by the FDA;* our ability to successfully and cost-effectively complete our ongoing and planned clinical trials; the risk that early clinical trial results (both safety and efficacy), which may have influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; and the risk that the COVID-19 pandemic causes unforeseen delays in the FDA timelines we have outlined or in our ability to achieve other milestones we project. 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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