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

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NEW YORK, June 17, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company developing medicines for patients with B-cell mediated diseases, today announced the completion of the 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 investigational once-daily, oral, 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 FDA previously granted umbralisib breakthrough therapy designation (BTD) for MZL and orphan drug designation (ODD) for MZL and FL.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "The completion of this NDA submission marks an important milestone in bringing us one step closer to providing umbralisib as a potential treatment option for patients with relapsed/refractory MZL and FL. As a company this is a very exciting moment for us, as it marks our very first NDA submission, and I commend our team for all their efforts to get to this point." Mr. Weiss continued, "Importantly, I also want to thank the patients, their families and the research teams who participated in these trials. This has been an incredibly impactful year for TG thus far, with several important milestones yet to come, including topline data from the ULTIMATE trials of ublitximab in multiple sclerosis, presentation of full data from the UNITY-NHL FL/MZL cohorts and from the UNITY-CLL Phase 3 trial of umbralisib plus ublituximab (U2), and a BLA/NDA submission for U2 in chronic lymphocytic leukemia targeted by the end of the year."

ABOUT THE UNITY-NHL PHASE 2b STUDY—MZL & FL COHORTS
The UNITY- NHL trial is a 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 (n=69). 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 have received 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 (n=118). The results met the Company's prespecified response target of 40-50% ORR.

ABOUT MARGINAL ZONE LYMPHOMA
Marginal zone lymphoma (MZL) comprises a group of indolent (slow growing) B-cell non-Hodgkin lymphomas (NHLs) that begin forming in the marginal zone of lymphoid tissue. 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 a slow-growing or indolent form of non-Hodgkin lymphoma (NHL) that arises from B-lymphocytes, making it a B-cell lymphoma. Follicular lymphoma is generally not curable and is a chronic disease. 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 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 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.

[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 within the meaning of the United States Private Securities Litigation Reform Act of 1995, including statements relating to the NDA submission of umbralisib, the clinical development of our product candidates, and anticipated milestones. For these statements, which are subject to a number of risks and uncertainties, 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 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; *our ability to commercially 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; 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; the risk that regulatory submissions will not be completed in the planned timeframe; and our ability to achieve the milestones we project, including the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones. 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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