TG Therapeutics Announces Positive Results from the UNITY-NHL Phase 2b Pivotal Trial Evaluating Umbralisib Monotherapy in Patients with Relapsed/Refractory Follicular Lymphoma

October 28, 2019

Follicular lymphoma cohort met the primary endpoint of overall response rate (ORR)

Umbralisib monotherapy appeared to be well tolerated with a safety profile consistent with previous reports

TG plans to present the data at a future medical conference and discuss the results with the FDA

Conference call to be held today, Monday, October 28, 2019 at 8:30 AM ET

NEW YORK, Oct. 28, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX), a biopharmaceutical company developing medicines for patients with B-cell mediated diseases, today announced that the follicular lymphoma (FL) cohort of the UNITY-NHL Phase 2b pivotal trial evaluating single agent umbralisib, the Company's novel, once daily, PI3K delta inhibitor, met the primary endpoint of overall response rate (ORR) as determined by Independent Review Committee (IRC) for all treated patients (n=118) who have received at least two prior lines of therapy including an anti-CD20 monoclonal antibody and an alkylating agent. The results met the Company's prespecified ORR target of 40-50%. Importantly, umbralisib monotherapy appeared to be well tolerated with a safety profile consistent with previous reports.

The Company plans to present the data at a future medical conference as well as discuss the data with the U.S. Food and Drug Administration (FDA).

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are extremely pleased to announce that the UNITY-NHL follicular lymphoma cohort evaluating umbralisib monotherapy met the primary endpoint of ORR. There are no fully approved drugs for patients with follicular lymphoma that have progressed following two or more prior lines of therapy and we are excited by the potential to offer a novel treatment for this underserved population. We look forward to sharing these results with the FDA and discussing submission opportunities for accelerated approval of umbralisib in follicular lymphoma." Mr. Weiss continued, "These are very exciting times for TG and with two additional major events targeted to occur over the next several months, including commencing our first NDA filing for umbralisib in patients with relapsed/refractory marginal zone lymphoma and results from our UNITY-CLL Phase 3 trial, we expect that excitement to continue. Taken together, we see 2020 shaping up as a pivotal year where we transition from a development-stage company into a fully-integrated development and commercial organization."

ABOUT THE UNITY-NHL PHASE 2b STUDY—FOLLICULAR LYMPHOMA COHORT

The multicenter, open-label, UNITY-NHL Phase 2b study – Follicular Lymphoma cohort was designed to evaluate the safety and efficacy of single agent umbralisib, the Company's novel, once daily, PI3K delta inhibitor, 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. Secondary endpoints include safety, duration of response, and progression-free survival (PFS).

The positive ORR outcome announced today was based on 118 FL patients that received at least one dose of umbralisib and who previously had received at least two prior lines of therapy, including an anti-CD20 regimen and an alkylating agent.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, Monday, October 28, 2019 at 8:30 AM ET to discuss the UNITY-NHL FL news. In order to participate in the conference call, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), Conference Title: TG Therapeutics Update Call.

A live audio webcast of this call will be available on the Events page, located within the Investors & Media section, of the Company's website at www.tgtherapeutics.com. An audio recording of the conference call will also be available for replay at www.tgtherapeutics.com, for a period of 30 days after the call.

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 usually not considered to be 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[1], FL is the most common indolent lymphoma accounting for approximately 20 percent of all NHL cases[2].

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, 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 clinical trial results from the UNITY-NHL FL cohort will not be sufficient to support a filing for approval; the risk that the positive data from the UNITY-NHL FL cohort will not be reproduced in future studies or in other cohorts of the UNITY-NHL study; the risk that umbralisib will not receive accelerated approval based on data from the UNITY-NHL FL cohort; the risk that duration of response or progression free survival data from the UNITY-NHL FL cohort when available will not be positive or supportive of approval; the risk that safety issues will arise when the safety data is cleaned and analyzed for the UNITY-NHL 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 the Company will not commence an NDA filing for umbralisib in patients with relapsed/refractory FL or marginal zone lymphoma in the planned timeframe or at all; the risk that data from the UNITY-CLL Phase 3 trial will not be available in the planned timeframe or not be sufficient to support a regulatory filing. 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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[1] American Cancer Society "Key Statistics for Non-Hodgkin Lymphoma"

[2] Lymphoma Research Foundation "Follicular Lymphoma"

Source: TG Therapeutics, Inc.