TG Therapeutics Presents Positive Interim Data from UNITY-NHL Phase 2b Trial Evaluating Umbralisib Monotherapy in Patients with Marginal Zone Lymphoma at the 55th American Society of Clinical Oncology (ASCO) Annual Meeting

June 4, 2019

Overall response rate (ORR) of 52% (N=42), with complete response (CR) rate of 19%, by central independent review committee (IRC)

Umbralisib was well tolerated with a safety profile that appeared to be maintained with prolonged exposure

NEW YORK, June 04, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today presented positive interim data from the ongoing single-arm marginal zone lymphoma (MZL) cohort of its Phase 2b UNITY-NHL trial currently evaluating umbralisib as a single agent in patients with relapsed/refractory MZL. Umbralisib is an investigational, oral, once-daily PI3K delta inhibitor with unique inhibition of CK1 epsilon and is currently under development for the treatment of non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL).

The interim data were presented today in an oral session during the 55th American Society of Clinical Oncology (ASCO) Annual Meeting. The slides presented are available on the Company's corporate website at www.tgtherapeutics.com/publications.cfm.

Summary of Data Presented:

The MZL cohort of UNITY-NHL enrolled patients with relapsed or refractory MZL who had received prior treatment with one or more lines of therapy including at least one anti-CD20 regimen. In August 2018, the trial completed enrollment with 69 treated patients. The interim data reported included safety and tolerability data on all 69 treated patients (safety population) and efficacy data on 42 patients who were enrolled at least 9 cycles (28 day cycles) prior to the data cut-off date (interim efficacy population). The primary endpoint is overall response rate (ORR) as assessed by IRC using criteria adopted from the International Working Group for malignant lymphoma.

Efficacy

Analysis of the interim efficacy population (n=42) with a median follow-up of 12.5 months showed the following:

	Interim Efficacy Population (n=42)
Overall Response Rate by IRC (CR + PR), %	52%
Complete Response by IRC (CR), (%)	19%
Partial Response by IRC (PR), (%)	33%
Median duration of response, months	NR (95% CI: 8.4 – NE)

CI = confidence interval; NR = not reached; NE = not estimable; SD = stable disease

Additional Efficacy Highlights:

- 52% ORR, with 17% CR, by IRC assessment for patients who had received 2 or more prior lines of therapy, n=23
- 88% clinical benefit rate by IRC, n=42, (defined as patients obtaining Complete Response + Partial Response + Stable Disease)
- All patients achieving a Complete Response by IRC remain on study (range: 10.1+ to 15.7+ months)
- Median time to initial response was 2.7 months
- Kaplan-Meier (KM) estimate of progression-free survival (PFS) at 12 months was 66%, with the median PFS not reached

Safety

Interim safety data were presented for all 69 treated patients with a median duration of exposure of 6.9 months. No unexpected toxicities were observed. The most common adverse events were diarrhea, nausea, and fatigue, with the majority of events Grade 1 in severity. The most frequent grade 3 or higher adverse events were neutropenia, diarrhea and ALT/AST increase, observed in 13%, 10% and 10% of patients, respectively.

Key Safety Findings (n=69):

- No events of colitis were reported and only 1 event of Grade 3 pneumonitis was reported
- Grade 3 infections were limited, occurring in 3 patients (bronchitis, pneumonia, and influenza)
- Discontinuations due to umbralisib-related AEs were limited (14%) with no discontinuations after 6 months due to a treatment-related AE
- No deaths occurred on study

ABOUT THE UNITY-NHL PHASE 2b STUDY—Marginal Zone Lymphoma Cohort

The multicenter, open-label, UNITY-NHL Phase 2b study - Marginal Zone Lymphoma 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 for umbralisib for the treatment of adult patients with marginal zone lymphoma 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 released today will not be reproduced when the final analysis is conducted on all patients later this year, 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 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 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 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 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 timelines for data releases and potential filings for approval 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. 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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