TG Therapeutics Announces Positive Outcome from UNITY-NHL Phase 2b Pivotal Trial Evaluating Umbralisib in Patients with Relapsed/Refractory Marginal Zone Lymphoma

February 28, 2019

Study met the primary endpoint of Overall Response Rate (ORR)

Interim data to be presented in an oral presentation at the 2019 American Association of Cancer Research (AACR) annual meeting on April 1, 2019

Umbralisib was previously granted Breakthrough Therapy Designation based on interim data from the marginal zone lymphoma (MZL) cohort of the UNITY-NHL trial

Conference call to be held today, Thursday February 28, 2019 at 8:30 AM ET

NEW YORK, Feb. 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 Marginal Zone Lymphoma (MZL) cohort of the UNITY-NHL Phase 2b pivotal trial evaluating umbralisib (TGR-1202), our 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=69). The results met the Company's target guidance of 40-50% ORR.

Interim safety and efficacy data from this study will be presented in an oral presentation at the upcoming American Association of Cancer Research (AACR) annual meeting on April 1, 2019 and full data from this study are expected to be presented at a medical meeting later this year. The company plans to discuss the results with the U.S. Food and Drug Administration (FDA) regarding a potential new drug application (NDA) filing for accelerated approval. Umbralisib was recently granted Breakthrough Therapy Designation (BTD) by the FDA for the treatment of adult patients with MZL who have received at least one prior anti-CD20 regimen.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are extremely pleased to announce that the UNITY-NHL marginal zone lymphoma cohort evaluating umbralisib monotherapy met the primary endpoint of ORR. While this was an early look at the response data, we were excited to have already met the target ORR, which we previously stated was approximately 40%-50%. Importantly, with many patients still on study, we anticipate the ORR will continue to improve with additional follow-up, which will also provide us with critical information on duration of response, progression free survival and long-term safety and tolerability necessary to support an NDA filing."

Mr. Weiss continued, "There are no fully approved drugs for MZL, and thus remains an unmet medical need and we are excited by the potential to offer a novel treatment for this underserved population. We look forward to discussing the results with the FDA as soon as possible and if all goes well, we believe we could be in a position to file for accelerated approval for umbralisib by year-end."

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, the Company's novel, once daily, PI3K delta inhibitor, 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 Independent Review Committee (IRC) assessment. The primary analysis of ORR will be conducted once 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).

The MZL cohort completed enrollment in August 2018 with a total of 69 patients enrolled and receiving at least one dose of umbralisib. The positive ORR outcome announced today was based on all 69 enrolled and treated patients, however at this time all patients have not yet been followed for a minimum of 9 cycles as required for the primary analysis of ORR. Accordingly, the study is on-going and patients with benefit on therapy (stable disease or in response) remain on study. Safety data are currently being analyzed.

2019 AACR Oral Presentation Details

Abstract titles are now available online and can be accessed on the AACR meeting website at www.aacr.org. The complete text of the abstract will be available on the meeting website on Friday, March 29, 2019. The presentation is expected to include a subset of patients from the UNITY-NHL-Marginal Zone Cohort with long-term follow-up as of the data cut-off. Additional details regarding the presentation are included below.

- **Title:** Umbralisib monotherapy demonstrates efficacy and safety in patients with relapsed/refractory marginal zone lymphoma: A multicenter, open-label, registration directed Phase II study
  - **Session Date and Time:** Monday April 1, 20193:00 PM - 5:00 PM ET
  - **Session Title:** The Next Generation of Clinical Trials in Molecularly-driven Therapy
  - **Session Location:** Marcus Auditorium- Bldg A-GWCC
  - **Presenter:**Nathan Fowler, MD, Associate Professor, Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center, Houston, TX
  - **Abstract Number:** 7821

Following the presentation, the data presented will be available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, Thursday, February 28, 2019 at 8:30 AM ET to discuss the UNITY-NHL MZL results.

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 webcast of this presentation 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 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, MZL is the third most common B-cell NHL accounting for approximately eight percent of all NHL cases.[i] 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).

ABOUT BREAKTHROUGH THERAPY DESIGNATION

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 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 interim clinical trial results from the UNITY-NHL MZL cohort that supported Breakthrough Therapy Designation (BTD) or that were accepted for presentation at AACR will not be reproduced in the final data, or if positive, will not be sufficient to support a filing for approval; the risk that the positive data from the UNITY-NHL MZL cohort will not be reproduced in future studies or in other cohorts of the UNITY-NHL study; the risk that the ORR data from the UNITY-NHL MZL cohort will not improve over time; the risk that umbralisib will not receive accelerated approval based on data from the UNITY-NHL MZL cohort; the risk that duration of response or progression free survival data from the UNITY-NHL 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 MZL cohort; the risk that the differentiated tolerability profile for umbralisib previously observed thus far in clinical trials will not be reproduced in the UNITY-NHL study, the UNITY-CLL study or any other on-going studies. 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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[i] Denlinger NM, Epperla N, William BM. Management of relapsed/refractory marginal zone lymphoma: focus on ibrutinib. Cancer Manag Res. 2018 Mar 27;10:615-624. doi: 10.2147/CMAR.S133291. eCollection 2018

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