TG Therapeutics Provides Business Update and Reports Second Quarter 2019 Financial Results

August 9, 2019

Conference call to be held today, Friday, August 9, 2019 at 8:30 AM ET

NEW YORK, Aug. 09, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the second quarter ended June 30, 2019 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "As we enter into the second half of the year, we are pleased with the progress made thus far and excited for the upcoming milestones. With a well-defined path to a regulatory submission for umbralisib in marginal zone lymphoma, we feel confident that we are at a pivotal point in our Company's lifecycle." Mr. Weiss continued, "As we prepare for our first filing in MZL, we are also building a top-notch commercial organization which will fuel the long-term success of TG. And with pivotal data readouts also expected in CLL and MS over the next 6-12 months, we believe we are at the beginning of an extremely exciting transformational period for our Company."

Recent Developments and Highlights

- **Marginal Zone Lymphoma - Confirmed Registration Path:** Announced confirmation of registration path to submit umbralisib for accelerated approval based on data from the marginal zone lymphoma (MZL) cohort of the UNITY-NHL Phase 2b trial.
- **Positive Interim Data from MZL Cohort of UNITY-NHL Trial:** Presented positive interim data from the MZL cohort of the UNITY-NHL trial during oral presentations at the 55thAmerican Society of Clinical Oncology (ASCO) annual meeting and the 2019 International Conference on Malignant Lymphoma (ICML).
- **Ublituximab Data in Multiple Sclerosis**: Presented long-term follow-up data from the Phase 2 trial of ublituximab in patients with relapsing forms of multiple sclerosis (RMS) at the 5th Congress of the European Academy of Neurology (EAN).
- **Umbralisib Data in CLL and RT**: Presented Phase 2 data of umbralisib in patients with chronic lymphocytic leukemia (CLL) who are intolerant to prior BTK or PI3k delta inhibitor therapy, and also presented data from patients with relapsed/refractory CLL or Richter's Transformation (RT) treated with the triple combination of ublituximab, umbralisib and pembrolizumab.
- **TG-1801 Preclinical Data:** Presented the first preclinical data of TG-1801, the Company's first-in-class anti-CD47/CD19 bispecific antibody, at the 24th European Hematology Association (EHA) annual congress.

Remaining 2019 and Early 2020 Milestones

- Initiate a rolling New Drug Application (NDA) submission for patients with previously treated MZL
- Present final data from the MZL cohort of the UNITY-NHL registration directed trial evaluating umbralisib in MZL
- Potential top-line progression free survival (PFS) results from the Phase 3 UNITY-CLL trial evaluating U2 in patients with CLL
- Present updated data from our pipeline products and combination studies at upcoming major medical conferences

Financial Results for the Three and Six Months Ended June 30, 2019

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation and non-cash in-licensing expense) was $31.4 million and $62.3 million for the three and sixth months ended June 30, 2019 compared to $34.8 million and $66.0 million for the three and six months ended June 30, 2018. The decrease in other R&D expense is primarily attributable to a decrease in clinical trial expenses of $9.7 million and $10.4 million, respectively during the three and six months ended June 30, 2019, as compared to prior periods, offset by an increase in manufacturing and CMC expenses for Phase 3 clinical trials and potential commercialization of $7.9 million and $4.7 million, respectively during the three and six months ended June 30, 2019, as compared to prior periods. The current period decrease in other R&D expenses is primarily due to full enrollment in our pivotal Phase III clinical development programs completed in the prior

period. We expect other R&D expenses to decrease through the remainder of 2019.

- **G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was $2.3 million and $4.3 million for the three and six months ended June 30, 2019 as compared to $2.3 million and $4.4 million for the three and six months ended June 30, 2018. Other G&A expenses remained relatively flat compared to the prior period, and we expect Other G&A expenses to increase modestly through the remainder of 2019.

- **Net Loss:** Net loss was $36.2 million and $71.4 million for the three and six months ended June 30, 2019, respectively, compared to a net loss of $44.1 million and $85.7 million for the three and six months ended June 30, 2018, respectively. Excluding non-cash items, the net loss for the three and six months ended June 30, 2019 was approximately $34.4 million and $67.6 million. We expect our quarterly net loss to decrease through the remainder of 2019.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $85.0 million as of June 30, 2019. Pro forma cash, cash equivalents and investment securities as of June 30, 2019 (excluding our third quarter 2019 operations) are approximately $96.6 million, after giving effect to $11.6 million of net proceeds from the utilization of the Company's at-the-market ("ATM") sales facility during the third quarter of 2019. The Company believes its cash, cash equivalents and investment securities on hand as of June 30, 2019, inclusive of the proceeds raised from the ATM facility subsequent to the second quarter, as well as future availability under the ATM facility, will be sufficient to fund the Company's planned operations through the third quarter of 2020.

Conference Call Information

The Company will host a conference call today, August 9, 2019, at 8:30 am ET, to discuss the Company's second quarter 2019 financial results and provide a business outlook for the remainder of 2019.

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 Second Quarter 2019 Business Update Call. A live audio webcast will be available on the Events page, located within the Investors & Media section, of the Company's website at http://ir.tgtherapeutics.com/events. 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 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 will not be reproduced when the final analysis is conducted on all patients, 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 be accepted for filing or 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 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 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 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 timeline for filing an NDA for accelerated approval for patients with MZL based on UNITY-NHL data and the timeline for data releases for UNITY-CLL and ULTIMATE-MS trials 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. the risk that we are unable to manage cash in line with our expectations and meet our development milestones and/or continue our operations without raising capital; the risk that we are unable to raise capital on acceptable terms; the risk that early clinical trial results that may have influenced our decision to proceed with additional clinical trials, and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. 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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TG Therapeutics, Inc.
Selected Consolidated Financial Data

Statements of Operations Information (in thousands, except share and per share amounts; unaudited):

	Three months ended June 30,		Six months ended June 30,	
	2019	**2018**	**2019**	**2018**
License revenue	$ 38	$ 38	$ 76	$ 76
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	100	3,000	100	4,000
Noncash compensation	1,352	888	2,841	3,747
Other research and development	31,414	34,812	62,310	65,971
Total research and development	32,866	38,700	65,251	73,718
General and administrative:				
Noncash compensation	405	3,375	797	7,854
Other general and administrative	2,311	2,308	4,260	4,426
Total general and administrative	2,716	5,683	5,057	12,280
Total costs and expenses	35,582	44,383	70,308	85,998
Operating loss	(35,544)	(44,345)	(70,232)	(85,922)
Other (income) expense:				
Interest expense	1,077	223	1,851	436
Other income	(408)	(426)	(715)	(687)
Total other (income) expense, net	669	(203)	1,136	(251)
Net loss	$ (36,213)	$ (44,142)	$ (71,368)	$ (85,671)
Basic and diluted net loss per common share	$ (0.42)	$ (0.59)	$ (0.85)	$ (1.18)
Weighted average shares used in computing basic and diluted net loss per common share	86,800,017	74,256,348	84,002,700	72,456,657

Condensed Balance Sheet Information (in thousands):

	June 30, 2019 (Unaudited)	December 31, 2018*
Cash, cash equivalents and investment securities	$ 84,976	$ 68,901
Total assets	106,585	83,616
Accumulated deficit	(599,713)	(528,345)

Total equity	13,205	24,036

* Condensed from audited financial statements

Source: TG Therapeutics, Inc.