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

November 12, 2019

Conference call to be held today, Tuesday, November 12, 2019 at 8:30 AM ET

NEW YORK, Nov. 12, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the third quarter ended September 30, 2019 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "In the third quarter our team continued to execute on our core mission of developing combination therapies for patients with B-cell diseases. With the announcement of positive marginal zone lymphoma data earlier this year, and positive follicular lymphoma data only a few weeks ago, we have our first two foundational datasets for which we believe approval is in our reach. Adding on top of this, will be our UNITY-CLL Phase 3 study, which we are targeting a PFS readout around year-end or into the first quarter of next year. With these core pieces in place, our broader combination approach should come into focus, as we execute on a strategy to position U2 as an important stand-alone treatment as well as one that can improve outcomes when combined with other available therapies. We believe our recent ASH abstracts contain some initial insights into the future of U2." Mr. Weiss continued, "With a pro forma cash position of approximately $100 million at the end of the third quarter, we believe we have sufficient capital resources through our next two major pivotal data releases including UNITY-CLL and the ULTIMATE MS Phase 3 trials."

Recent Developments and Highlights

- **ASH Presentations:** Two triple therapy data abstracts were accepted for presentation at the upcoming 61st American Society of Hematology (ASH) annual meeting, including an oral presentation for the triple combination of U2 (umbralisib and ublituximab) plus venetoclax, and Phase 1 data for TG-1701, the Company's novel BTK inhibitor, monotherapy and in combination with U2.
- **Positive Interim Data from FL Cohort of UNITY-NHL Trial:** Positive interim data from the follicular lymphoma (FL) cohort of the UNITY-NHL trial was announced, with results meeting the Company's prespecified ORR target. 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).
- **GENUINE Progression Free Survival (PFS):** Final long-term results from the Phase 3 GENUINE study demonstrated that ublituximab in combination with ibrutinib improved progression-free survival (PFS), as determined by Independent Review Committee (IRC).
- **U2 Published in Blood:** Phase I/Ib combination trial of U2 was published in *Blood*, the Journal of the American Society of Hematology.
- **Ublituximab Data in Multiple Sclerosis:** Updated Phase 2 extension trial data for ublituximab in relapsing forms of multiple sclerosis (RMS), as well as the ULTIMATE I & II Phase 3 RMS program study design and demographic data was presented at the 35th Annual Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

Remaining 2019 and Early 2020 Milestones

- Initiate a rolling New Drug Application (NDA) submission for umbralisib to treat adult patients with previously treated marginal zone lymphoma (MZL).
- Report potential top-line PFS results from the Phase 3 UNITY-CLL trial evaluating U2 in patients with frontline and previously treated CLL.
- Share results from the Phase 2b UNITY-NHL FL cohort with the FDA to determine potential filing opportunities.

Financial Results for the Three and Nine Months Ended September 30, 2019

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation and non-cash in-licensing expense) was $56.5 million and $118.8 million for the three and nine months ended September 30, 2019, respectively, compared to $32.8 million and $98.7 million for the three and nine months ended September 30, 2018, respectively. The increase in R&D expense is primarily attributable to an increase in manufacturing expenses for Phase 3 clinical trials and potential commercialization (incurred during 2019) of $27 million and $31.6 million during the three and nine months ended September 30, 2019, respectively, as compared to prior periods. This was partially offset by a decrease in clinical trial expense of $3.8 million and $14.2 million for the three and nine months ended September 30, 2019, respectively, as compared to prior periods. We expect our other R&D expenses to decrease during the remainder of 2019 and into 2020 as our clinical trial expenses continue to decrease and the bulk of our CMC expenditures have been incurred during 2019.

- **G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was $2.3 million and $6.6 million for the three and nine months ended September 30, 2019, respectively, as compared to $1.8 million and $6.2 million for the three and nine months ended September 30, 2018, respectively. Other G&A expenses remained consistent with the prior period, and we expect Other G&A expenses to increase modestly through the remainder of 2019.

- **Net Loss:** Net loss was $61.9 million and $133.3 million for the three and nine months ended September 30, 2019, respectively, compared to a net loss of $34.0 million and $119.6 million for the three and nine months ended September 30, 2018, respectively. Excluding non-cash items, the net loss for the three and nine months ended September 30, 2019 was approximately $59.9 million and $127.5 million. Cash used in operations for the three months ended September 30, 2019 was approximately $33 million, as the payments of much of the increase in manufacturing expenses were deferred 12 months, having little impact on the quarter's cash utilization.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $72.5 million as of September 30, 2019. Pro forma cash, cash equivalents and investment securities as of September 30, 2019 (excluding our fourth quarter 2019 operations) are approximately $96.3 million, after giving effect to $23.8 million of net proceeds from the utilization of the Company's at-the-market ("ATM") sales facility during the fourth quarter of 2019. The Company believes its cash, cash equivalents and investment securities on hand as of September 30, 2019, inclusive of the proceeds raised from the ATM facility subsequent to the third quarter, as well as future availability under the ATM facility, will be sufficient to fund the Company's planned operations into the fourth quarter of 2020.

Conference Call Information

The Company will host a conference call today, November 12, 2019, at 8:30 am ET, to discuss the Company's third 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 Third 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 or FL cohorts 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 or FL cohorts 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 or FL cohorts; the risk that the positive Interim Results from the UNITY-NHL MZL or FL cohorts 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 or FL cohorts, 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 or approval of an NDA for accelerated approval for patients with MZL or FL 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 the data contained in the recent ASH abstracts will not be reproduced in the final presentations at ASH; 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 September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
License revenue	$38	$38	$114	$114
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	--	--	100	4,000
Noncash compensation	1,482	644	4,323	4,391
Other research and development	56,503	32,754	118,814	98,724
Total research and development	57,985	33,398	123,237	107,115
General and administrative:				
Noncash compensation	593	(817)	1,391	7,037
Other general and administrative	2,321	1,785	6,580	6,212
Total general and administrative	2,914	968	7,971	13,249
Total costs and expenses	60,899	34,366	131,208	120,364
Operating loss	(60,861)	(34,328)	(131,094)	(120,250)
Other expense (income):				
Interest expense	1,537	221	3,388	657
Other income	(468)	(598)	(1,183)	(1,285)
Total other expense (income), net	1,069	(377)	2,205	(628)
Net loss	$(61,930)	$(33,951)	$(133,299)	$(119,622)
Basic and diluted net loss per common share	$(0.69)	$(0.43)	$(1.55)	$(1.61)
Weighted average shares used in computing basic and diluted net loss per common share	89,667,979	78,221,069	85,911,878	74,399,243

Condensed Balance Sheet Information (in thousands):

	September 30, 2019 (Unaudited)	**December 31, 2018***
Cash, cash equivalents and investment securities	$ 72,451	$ 68,901

Total assets	93,327	83,616
Accumulated deficit	(661,643)	(528,345)
Total (deficit) equity	(25,791)	24,036

* Condensed from audited financial statements

Source: TG Therapeutics, Inc.