



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

May 10, 2019

Conference Call to be held today, Friday, May 10, 2019 at 8:00 AM ET

NEW YORK, May 10, 2019 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the first quarter ended March 31, 2019 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "2019 has been an extremely productive year thus far with the achievement of many key milestones, the most important of which has been the significant progress made with our Marginal Zone Lymphoma program, including the release of positive top-line results and the receipt of breakthrough therapy designation and orphan drug designation. Moving forward, we believe further clarity on our potential MZL NDA filing by year-end along with the presentation of final MZL data later this year has the potential to unlock significant value for our shareholders." Mr. Weiss continued, "Between now and the middle of next year, we expect to have pivotal data readouts across three trials, including umbralisib in non-Hodgkin's lymphoma, umbralisib plus ublituximab (U2) in chronic lymphocytic leukemia and ublituximab in multiple sclerosis. This is an extremely exciting time for us and we look forward to an impactful remainder of 2019 and 2020."

Recent Developments and Highlights

- **Marginal Zone Lymphoma – Breakthrough Therapy and Orphan Drug Designations:** Received breakthrough therapy designation (BTD) and orphan drug designation for umbralisib (TGR-1202), for the treatment of patients with all three types of marginal zone lymphoma (MZL): nodal, extranodal and splenic MZL.
- **Positive Results from MZL Cohort of UNITY-NHL Trial:** Announced positive outcome from the MZL cohort of the UNITY-NHL trial, which met the primary endpoint of Overall Response Rate (ORR). Interim safety and efficacy data from this study were presented in an oral presentation at the American Association of Cancer Research (AACR) annual meeting in Atlanta.
- **DSMB Updates:** Meetings held by the independent Data Safety Monitoring Boards (DSMBs) for both the UNITY-CLL trial and the UNITY-NHL trial did not raise any safety concerns and recommended that both trials continue unmodified.
- **TG-1801 (Anti-CD47/CD19):** Commenced a Phase 1 first-in-human, dose-escalation study of TG-1801 in patients with relapsed or refractory B-cell lymphoma.
- **Multiple Sclerosis Data:** Presented long-term safety data from the open label extension (OLE) of the Phase 2 trial of ublituximab in multiple sclerosis, which demonstrated that ublituximab continues to be well tolerated.

Remaining 2019 Milestones

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

Financial Results for the First Quarter 2019

- **Cash Position:** Cash, cash equivalents and investment securities were \$92.5 million as of March 31, 2019. Pro-forma cash, cash equivalents and investment securities as of March 31, 2019 (excluding our second quarter 2019 operations) are approximately \$116.7 million, after giving effect to \$24.2 million of net proceeds from the utilization of the Company's at-the-market ("ATM") sales facility during the second quarter of 2019.
- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation) was \$30.9 million for the three months ended March 31, 2019 compared to \$32.2 million for the three months ended March 31, 2018. Included in other research and development expense for the three months ended March 31, 2019 was \$13.8 million of clinical trial expense and \$6.4 million of manufacturing and CMC expenses for Phase 3 clinical trials and potential

commercialization. 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 the decrease in other R&D expenses to continue over the next several quarters.

- **G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was \$1.9 million for the three months ended March 31, 2019 as compared to \$2.1 million for the three months ended March 31, 2018. Other G&A expenses for the three months ended March 31, 2019 remained relatively flat compared to the first quarter of 2018, and we expect Other G&A expenses to increase modestly through the remainder of 2019.
- **Net Loss:** Net loss was \$35.2 million for the three months ended March 31, 2019, compared to a net loss of \$41.5 million for the three months ended March 31, 2018. Excluding non-cash items, the net loss for the three months ended March 31, 2019 was approximately \$33.3 million.
- **Financial Guidance:** Net cash utilized for operating activities during the three months ended March 31, 2019 was approximately \$33.5 million. The Company believes its cash, cash equivalents and investment securities on hand as of March 31, 2019, inclusive of the proceeds raised subsequent to the first quarter, will be sufficient to fund the Company's planned operations through mid-2020.

Conference Call Information

The Company will host a conference call today, May 10, 2019, at 8:00 am ET, to discuss the Company's first 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 First 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: our ability to successfully and cost effectively complete preclinical and clinical trials; the risk that the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2 or formerly TG-1303, and being studied in the UNITY clinical trials and other studies, will not prove to be safe and efficacious for any indication or will not prove to be safe and effective for use as part of triple and quad treatment regimens; the risk that the early Phase 2 data of ublituximab in MS will not be reproduced in the Phase 3 MS trial; the risk that top-line data from the ULTIMATE Phase 3 trials will not be available within projected timelines, the risk that current or additional double or potential planned triple combination therapy trials will not commence as planned or at all; the risk that the UNITY-CLL study, or any of our other registration directed clinical trials as designed or amended may not be sufficient or acceptable to support regulatory submission or approval; the risk that a filing based on GENUINE, UNITY-CLL, UNITY-NHL, ULTIMATE clinical trials or any other registration directed trials cannot be made on schedule as targeted or at all; 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, will not be reproduced in the final data presented 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 March 31,	
	2019	2018
License revenue	\$ 38	\$ 38
Costs and expenses:		
Research and development:		
Noncash compensation	1,489	2,859
Other research and development	30,896	32,159
Total research and development	32,385	35,018
General and administrative:		
Noncash compensation	393	4,478
Other general and administrative	1,949	2,119
Total general and administrative	2,342	6,597
Total costs and expenses	34,727	41,615
Operating loss	(34,689)	(41,577)
Other (income) expense:		
Interest income	(149)	(144)
Other (income) expense	616	96
Total other income, net	467	(48)
Net loss	\$ (35,156)	\$ (41,529)
Basic and diluted net loss per common share	\$ (0.43)	\$ (0.59)
Weighted average shares used in computing basic and diluted net loss per common share	81,174,301	70,636,970

Condensed Balance Sheet Information (in thousands):

	March 31,		December
	2019		31, 2018*
	(Unaudited)		
Cash, cash equivalents and investment securities	\$ 92,474	\$	68,900
Total assets	117,538		83,616
Accumulated deficit	(563,501))	(528,345)
Total equity	19,254		24,036

* Condensed from audited financial statements



Source: TG Therapeutics, Inc.