TG Therapeutics, Inc. Provides Business Update and Reports First Quarter 2018 Financial Results

May 8, 2018

Investor Conference Call to be Held Today, Tuesday, May 8, 2018 at 8:30am ET

NEW YORK, May 08, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the first quarter ended March 31, 2018 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "2018 is off to a great start as we continue to advance our major pivotal programs and bolster our product pipeline, most recently with the addition of a BTK inhibitor program. As we move into the second quarter and the remainder of the year, we look forward to the announcement of topline data from our UNITY-CLL trial, completion of enrollment into the current cohorts of the UNITY-NHL study, final MS Phase 2 data, significant enrollment in our MS phase 3 program as well as filing decisions related to the Company's first BLA/NDA later in the year." Mr. Weiss continued, "We believe 2018 will be a pivotal year for the Company as approval pathways across multiple indications become clearer and position us for future success."

First Quarter and Recent Highlights

- **BTK License:** Entered into an exclusive global license agreement with Jiangsu Hengrui Medicine Co., Ltd. (or "Hengrui") to obtain worldwide rights, excluding Asia but including Japan, for the development of Hengrui's Bruton's Tyrosine Kinase (BTK) inhibitor program, including the lead candidate, TG-1701.
- **Umbralisib Lancet Publication:** Results from the Phase 1 first-in-human study of umbralisib (TGR-1202), the Company's novel once-daily PI3K delta inhibitor, were published in The Lancet Oncology.
- **TG-1601 Preclinical Data:** Presented the first preclinical data from TG-1601, the Company's novel BET inhibitor, at the 2018 American Association for Cancer Research (AACR) annual meeting.
- **Ublituximab Data in Multiple Sclerosis:** Presented clinical and MRI data from the Phase 2 trial of ublituximab (TG-1101) in RMS at the 3rd Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2018 and the American Academy of Neurology (AAN) 70th Annual Meeting.

Remaining 2018 Milestones

- Present top-line overall response rate data from the UNITY-CLL Phase 3 trial of ublituximab plus umbralisib in front line and relapsed/refractory Chronic Lymphocytic Leukemia (CLL).
- Prepare and potentially file the Company's first BLA and/or NDA.
- Complete enrollment in the current arms of the UNITY-NHL trial, including the Follicular Lymphoma, Marginal Zone Lymphoma, and Diffuse Large B-Cell Lymphoma cohorts.
- Present updated clinical data from ongoing oncology trials and final results from the Phase 2 trial of ublituximab in Multiple Sclerosis (MS) at major medical meetings during 2018.

Financial Results for the First Quarter 2018

- **Cash Position:** Cash, cash equivalents, investment securities, and interest receivable were $109.2 million as of March 31, 2018. Pro-forma cash, cash equivalents, investment securities, and interest receivable as of March 31, 2018 (excluding our second quarter 2018 operations) are approximately $123.3 million, after giving effect to $14.1 million of net proceeds from the utilization of the Company's at-the-market ("ATM") sales facility during the second quarter of 2018.

- **Other R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation) was $32.2 million for the three months ended March 31, 2018 compared to $20.4 million for the three months ended March 31, 2017. Included in other research and development expense for the three months ended March 31, 2018 was $14.5 million of clinical trial expense and $9.6 million of manufacturing and CMC expenses for Phase 3 clinical trials and potential commercialization. The current period increase in Other R&D expenses is primarily due to the ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202.

- **Other G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was $2.1 million for the three months ended March 31, 2018 as compared to $1.3 million for the three months ended March 31, 2017. Other G&A expenses for the three months ended March 31, 2018 remained relatively flat compared to the first quarter of 2017, and we expect Other G&A expenses to increase modestly through the remainder of 2018.

- **Net Loss:** Net loss was $41.5 million for the three months ended March 31, 2018, compared to a net loss of $27.7 million

for the three months ended March 31, 2017. Excluding non-cash items the net loss for the three months ended March 31, 2018 was approximately $33.2 million.

- **Financial Guidance:** Net cash utilized for operating activities during the three months ended 2018 was approximately $28.0 million. The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of March 31, 2018, inclusive of the proceeds raised subsequent to the first quarter, will be sufficient to fund the Company's planned operations through mid-2019.

Conference Call Information

The Company will host an investor conference call today, May 8, 2018, at 8:30am ET, to discuss the Company's first quarter 2018 financial results and provide a business outlook for the remainder of 2018.

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 2018 Earnings 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 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 orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. 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 into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. 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; our ability to manage cash in line with our expectations; the risk that early clinical trial results, including early data that may have supported the acceptance of our data for presentation or publication or may have influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; 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. 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,	
	2018	**2017**
License revenue	$ 38	$ 38
Costs and expenses:		
Research and development:		
Noncash compensation	2,859	2,306
Other research and development	32,159	20,376

Total research and development	35,018	22,382
General and administrative:		
Noncash compensation	4,478	3,689
Other general and administrative	2,119	1,333
Total general and administrative	6,597	5,022
Total costs and expenses	41,615	27,704
Operating loss	(41,577)	(27,666)
Other (income) expense:		
Interest income	(144)	(45)
Other expense	96	106
Total other (income) expense	(48)	61
Net loss	$ (41,529)	$ (27,727)
Basic and diluted net loss per common share	$ (0.59)	$ (0.52)
Weighted average shares used in computing basic and diluted net loss per common share	70,636,970	53,157,851

Condensed Balance Sheet Information (in thousands):

	March 31, 2018 (unaudited)	December 31, 2017*
Cash, cash equivalents, investment securities and interest receivable	$ 109,156	$ 84,825
Total assets	120,994	97,382
Accumulated deficit	(396,392)	(354,863)
Total equity	85,232	66,993

* Condensed from audited financial statements.

Primary Logo

Source: TG Therapeutics, Inc.