TG Therapeutics Provides Business Update and Reports First Quarter 2020 Financial Results

May 11, 2020

NEW YORK, May 11, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the first quarter ended March 31, 2020 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, “The first few months of 2020 have undoubtedly been the most impactful and exciting in our Company’s history. We kicked off the year with the initiation of our first rolling regulatory submission for umbralisib in both MZL and FL and most recently reported positive topline results from our UNITY-CLL Phase 3 trial evaluating our proprietary U2 combination in patients with CLL. This positive outcome marks a major step forward in our mission of developing the best possible combination treatment options for patients with B-cell diseases.” Mr. Weiss continued, “We now have three successful pivotal data sets which we believe have the potential to support regulatory approvals across MZL, FL and CLL. With more than $150 million proforma in cash on our balance sheet, we are well funded through and beyond our next set of key milestones, including the release of topline data from the ULTIMATE MS Phase 3 program, submission of an NDA/BLA for U2 in CLL, and hopefully, our first approval for umbralisib in MZL and FL, all of which are targeted to occur over approximately the next 9 months.”

Recent Developments and Highlights

Chronic Lymphocytic Leukemia:

- In May 2020, reported positive topline results from the Company’s UNITY-CLL Phase 3 trial evaluating U2 (the combination of umbralisib and ublituximab) in patients with previously untreated and relapsed/refractory chronic lymphocytic leukemia (CLL). The trial met its primary endpoint of improved progression-free survival (PFS) (p<.0001), as determined by an Independent Review Committee (IRC) and will be stopped early for superior efficacy. Regulatory submission and full data presentation targeted by year-end 2020.

Marginal Zone Lymphoma & Follicular Lymphoma:

- In January 2020, received guidance from the U.S. Food and Drug Administration (FDA) allowing submission of a single New Drug Application (NDA) for marginal zone lymphoma (MZL) and follicular lymphoma (FL) indications. A rolling NDA submission for umbralisib to treat adult patients with previously treated MZL and FL was initiated, with completion of submission targeted in the first half of 2020.
- In March 2020, received orphan drug designation for umbralisib from the FDA for the treatment of FL.

Multiple Sclerosis:

- In May 2020, announced the publication of results from the multicenter Phase 2 trial evaluating ublituximab in patients with relapsing forms of multiple sclerosis (RMS) in the *Multiple Sclerosis* Journal.
- Awaiting topline data from the Company’s Phase 3 ULTIMATE I & II trials evaluating ublituximab in patients with RMS, targeted in second half 2020.

Board of Directors & Management:

- In May 2020, appointed Sagar Lonial, MD, FACP, Professor and Chair of the Department of Hematology and Medical Oncology at the Emory University School of Medicine, as well as the Chief Medical Officer at Winship Cancer Institute of Emory University, to the Company’s Board of Directors.
- In May 2020, strengthened executive team with the addition of Owen A. O’Connor, MD, PhD as Chief Scientific Officer. Dr. O’Connor most recently served as a Professor of Medicine and Experimental Therapeutics, the Director of the Center for Lymphoid Malignancies, and Co-Program Director of the Lymphoid Development and Malignancy Program in the Herbert Irving Comprehensive Cancer Center at Columbia University Medical Center.

Bolstered Balance Sheet:

- In May 2020, strengthened balance sheet with more than $75 million in gross proceeds through the Company’s At-the-Market (ATM) facility, $40 million of which came from a longtime shareholder.

Key Objectives for 2020

- Complete rolling NDA submission for umbralisib in patients with previously treated MZL and FL, in the first half of 2020.

- Report topline results from the Phase 3 ULTIMATE I & II trials in RMS, in the second half of 2020.
- Present full data from the UNITY-CLL Phase 3 trial and present full data from the FL and MZL umbralisib monotherapy cohorts of the UNITY-NHL trial at a major medical meeting, by year-end 2020.
- Target an NDA/Biologics Licensing Application (BLA) submission of U2 for the treatment of patients with CLL (including both previously untreated and relapsed/refractory patients), by year end 2020.
- Continue to advance our early pipeline candidates including our anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), our covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, and our anti-CD47/CD19 bispecific antibody, TG-1801.

Financial Results for the Three Months Ended March 31, 2020

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation) was $34.0 million for the three months ended March 31, 2020, compared to $30.9 million for the three months ended March 31, 2019. The modest increase in R&D expense is primarily attributable to costs associated with the preparation of the Company's NDA filing for umbralisib in MZL and FL. We expect our R&D expenses to decrease during 2020 as costs associated with our main pivotal clinical trials continue to decline over the remainder of the year, partially offset by expenses associated with the expected NDA/BLA filing for U2 in CLL.

- **G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was $5.2 million for the three months ended March 31, 2020, as compared to $1.9 million for the three months ended March 31, 2019. The increase in other G&A expenses is primarily due to the build out of our commercial team and infrastructure in anticipation of the potential commercialization of umbralisib and ublituximab. We expect G&A expenses to increase modestly during the remainder of 2020.

- **Net Loss:** Net loss was $51.1 million for the three months ended March 31, 2020, compared to a net loss of $35.2 million for the three months ended March 31, 2019. Excluding non-cash compensation, the net loss for the three months ended March 31, 2020 was approximately $40.0 million, compared to a net loss of $33.3 million for the three months ended March 31, 2019.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $78.3 million as of March 31, 2020. Pro forma cash, cash equivalents and investment securities as of March 31, 2020 are approximately $154.3 million, after giving effect to $76.0 million of net proceeds from the utilization of the Company's ATM sales facility during the second quarter of 2020 at an average price of $17.07. The Company believes its cash, cash equivalents and investment securities on hand as of March 31, 2020, inclusive of the proceeds raised from the ATM facility, as well as future availability under the Company's debt and ATM facility, will be sufficient to fund the Company's planned operations through the end of 2021.

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 dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. 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 its anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801. TG Therapeutics is headquartered in New York City.

Cautionary Statement

This press release includes 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 final analysis of the UNITY-NHL MZL or FL cohorts will be insufficient to support FDA approval of umbralisib, or, if supportive of approval, will not be supportive of a differentiated profile; the risk that we are unable to successfully deliver the complete data set from the UNITY-CLL trial or prepare a regulatory submission on schedule as planned; the risk that the final analysis of the UNITY-CLL study will be insufficient to support FDA approval of the combination regimen of umbralisib and ublituximab in CLL or, if supportive of approval, will not be supportive of a differentiated profile; the risk that any of our other registration-directed clinical trials, including the ULTIMATE I & II trials, as designed or amended may not be sufficient or acceptable to support regulatory submission or approval; the risk that achievement of the milestones we project, including anticipated regulatory submissions based on UNITY-NHL and UNITY-CLL, preparation of the full data set from UNITY-CLL, the completion of the ULTIMATE I & II trials, and advancements of our early pipeline will be delayed due to a variety of factors, including, without limitation, the evolving and unpredictable COVID-19 pandemic, available resources, program reprioritization, and 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 regulatory

submissions; 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 may not be replicated; 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 Condensed Consolidated Financial Data

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

	Three Months Ended	
	March 31, 2020	**March 31, 2019**
License revenue	$ 38	$ 38
Costs and expenses:		
Research and development		
Non-cash compensation	1,979	1,489
Other research and development	34,043	30,896
Total research and development	36,022	32,385
General and administrative		
Non-cash compensation	9,089	393
Other general and administrative	5,172	1,949
Total general and administrative	14,261	2,342
Total operating expenses	50,283	34,727
Operating loss	(50,245)	(34,689)
Other (income) expense:		
Interest expense	1,201	774
Other income	(330)	(307)
Total other (income) expense	871	467
Consolidated net loss	$ (51,116)	$ (35,156)
Net income (loss) per common share:		
Basic and diluted	$ (0.48)	$ (0.43)
Weighted average shares of common stock outstanding:		
Basic and diluted	105,461,892	81,174,301

Condensed Balance Sheet Information (in thousands):

	March 31, 2020 (Unaudited)	December 31, 2019*
Cash, cash equivalents and investment securities	$ 78,335	$ 140,435
Total assets	101,849	163,014
Accumulated deficit	(752,332)	(701,216)
Total (deficit) equity	(1,353)	38,615

* Condensed from audited financial statements



Source: TG Therapeutics, Inc.