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

August 10, 2020

NEW YORK, Aug. 10, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the second quarter ended June 30, 2020 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, “We are extremely pleased by the progress made thus far in 2020 and are looking forward to an impactful end of year and into 2021. Completing the NDA rolling submission this past June for umbralisib in previously treated Marginal Zone Lymphoma and Follicular Lymphoma was a major milestone for our Company.” Mr. Weiss continued, “With one completed NDA submission, positive topline data from our UNITY-CLL Phase 3 trial, and a healthy balance sheet with over $275 million in cash, we are well positioned to execute on our remaining milestones for this year as well as transition from a development stage company to a fully-integrated commercial organization. For the remainder of this year, we look forward to reporting topline data from our Phase 3 ULTIMATE program in Multiple Sclerosis, full data presentations from the UNITY-NHL FL and MZL single agent umbralisib cohorts, data presentation from the UNITY-CLL Phase 3 trial, as well as updated data from our triple combination trials, which we believe set the stage for the future of U2 in CLL and non-Hodgkin’s Lymphoma.”

Recent Developments and Highlights

- **Marginal Zone Lymphoma & Follicular Lymphoma:**
  ° In June 2020, completed rolling submission of New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for umbralisib as a treatment for patients with previously treated marginal zone lymphoma (MZL) and follicular lymphoma (FL).

- **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).
  ° In May 2020, reported final results from the GENUINE Phase 3 study evaluating the combination of ublituximab plus ibrutinib compared to ibrutinib alone in patients with relapsed/refractory CLL with high-risk cytogenetics. Results indicated the addition of ublituximab to ibrutinib as compared to ibrutinib alone improved PFS, overall response rate, complete response rate and the number of patients with undetectable minimal residual disease.

- **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.

- **Bolstered Balance Sheet:**
  ° In May 2020, strengthened balance sheet with more than $240 million in gross proceeds through a public offering and the Company’s At-the-Market (ATM) facility.

- **Publication:**
  ° In July 2020, published preclinical data describing the unique immunomodulatory effects of umbralisib, in Blood Advances, a Journal of the American Society of Hematology.

- **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.

Key Objectives for Remainder of 2020 and Early 2021

- Report topline results from the Phase 3 ULTIMATE I & II trials in Multiple Sclerosis.
- Present full data from the UNITY-CLL Phase 3 trial and present full data from the FL and MZL single agent umbralisib cohorts of the UNITY-NHL trial at a major medical meeting.
- 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)
- Continue to advance our early pipeline candidates including our anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), our Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, and our anti-CD47/CD19 bispecific antibody, TG-1801.

Financial Results for the Three and Six Months Ended June 30, 2020

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation) was $34.9 million and $68.9 million for the three and six months ended June 30, 2020, respectively, compared to $31.4 million and $62.3 million for the three and six months ended June 30, 2019, respectively. The modest increase in R&D expense during the three and six month periods of 2020 is primarily attributable to our ongoing clinical development programs as well as preparations for regulatory filings and potential commercialization. We expect our R&D expenses to decrease during the remainder of 2020 as costs associated with our main pivotal clinical trials continue to decline, 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 $8.6 million and $13.8 million for the three and six months ended June 30 2020, respectively, as compared to $2.3 million and $4.3 million for the three and six months ended June 30, 2019, respectively. The increase in other G&A expenses is primarily due to increased personnel and other general and administrative costs, associated with preparations for a potential commercial launch. We expect G&A expenses to increase modestly during the remainder of 2020 in preparation for potential launch.

- **Net Loss:** Net loss was $52.9 million and $104.0 million for the three and six months ended June 30, 2020, respectively, compared to a net loss of $36.2 million and $71.4 million for the three and six months ended June 30, 2019, respectively. Excluding non-cash compensation, the net loss for the three and six months ended June 30, 2020 was approximately $45.5 million and $85.6 million, respectively, compared to a net loss of $34.5 million and $67.7 million for the three and six months ended June 30, 2019, respectively.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $275.6 million as of June 30, 2020. The Company believes its cash, cash equivalents and investment securities on hand as of June 30, 2020, 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 in late stage clinical development with two investigational therapies targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a 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. 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

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 positive, or if positive, may not be sufficient or acceptable to support regulatory submission or approval of ublituximab in relapsing forms of MS; the risk that achievement of the clinical development and regulatory milestones we project will be delayed due to a variety of factors, including, without limitation, the evolving and unpredictable COVID-19 pandemic, available resources, program reprioritization, and feedback from the FDA or foreign regulators; the risk that we are not able to successfully or cost effectively complete all the preclinical, clinical and CMC requirements necessary to support regulatory submissions; the risk that early clinical trial results that may have influenced our decision to proceed with additional clinical trials may not be replicated; 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; and the risk that we are unable to raise capital on acceptable terms. . 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 June 30,		Six months ended June 30,	
	2020	**2019**	**2020**	**2019**
License revenue	$38	$38	$76	$76
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	--	100	--	100
Noncash compensation	1,553	1,352	3,532	2,841
Other research and development	34,896	31,414	68,939	62,310
Total research and development	36,449	32,866	72,471	65,251
General and administrative:				
Noncash compensation	5,817	405	14,906	797
Other general and administrative	8,617	2,311	13,789	4,260
Total general and administrative	14,434	2,716	28,695	5,057
Total costs and expenses	50,883	35,582	101,166	70,308
Operating loss	(50,845)	(35,544)	(101,090)	(70,232)
Other expense (income):				
Interest expense	2,228	1,077	3,429	1,851
Other income	(189)	(408)	(519)	(715)
Total other expense (income), net	2,039	669	2,910	1,136
Net loss	$(52,884)	$(36,213)	$(104,000)	$(71,368)
Basic and diluted net loss per common share	$(0.47)	$(0.42)	$(0.95)	$(0.85)
Weighted average shares used in computing basic and diluted net loss per common share	112,353,414	86,800,017	108,926,690	84,002,700

Condensed Balance Sheet Information (in thousands):

	June 30, 2020 (Unaudited)	**December 31, 2019***

Cash, cash equivalents and investment securities	$275,570	$140,435
Total assets	294,621	163,014
Accumulated deficit	(805,215)	(701,216)
Total equity	194,227	38,615

* Condensed from audited financial statements

Source: TG Therapeutics, Inc.