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

November 9, 2020

NEW YORK, Nov. 09, 2020 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the third quarter ended September 30, 2020 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, “This has been a very exciting few months for TG especially sharing the first ever data from the UNITY-CLL Phase 3 trial last week showing that the trial met its primary endpoint of improvement in progression-free survival, as well as data from the UNITY-NHL trial which supported our NDA submission for umbralisib monotherapy. These data sets add to the growing body of evidence suggesting that umbralisib has a differentiated safety profile and support our long-term vision of U2 as a potential backbone for future combination therapies.” Mr. Weiss continued, “With PDUFA goal dates in February 2021 and June 2021 now set for our umbralisib NDA for the treatment of relapsed/refractory MZL and FL, respectively, our team is hard at work ensuring we are prepared for a successful launch in these indications. With a healthy balance sheet which includes a proforma cash position of approximately $325 million as of September 30, 2020, we are focused on preparing a BLA/NDA submission for U2 in CLL and importantly delivering on our remaining milestones for the year including topline results from our ULTIMATE I & II Phase 3 trials of ublituximab in MS.”

Recent Developments and Highlights

- **ASH 2020 Presentations:**
  • Four abstracts have been accepted for presentation at the upcoming 62nd American Society of Hematology (ASH) annual meeting, to be held virtually December 5 – 8, 2020, including:
  • Results from the UNITY-NHL Phase 2 marginal zone lymphoma (MZL) and follicular lymphoma (FL) umbralisib monotherapy cohorts
  • Results from the UNITY-CLL Phase 3 trial evaluating the combination of umbralisib and ublituximab (U2) in patients with treatment naïve and relapsed/refractory chronic lymphocytic leukemia (CLL)
  • Two triple therapy presentations, one evaluating the combination of U2 plus venetoclax in CLL, and a another evaluating the combination of U2 plus TG-1701, our BTK inhibitor, in patients with B-cell malignancies
  • Abstracts were made available last week and a call was held with leading investigators from our trials to review the data included in these abstracts. A replay from this call is available on our corporate website at https://ir.tgtherapeutics.com/events.

- **UNITY-NHL: Umbralisib Monotherapy Marginal Zone Lymphoma & Follicular Lymphoma Cohorts**
  • In July 2020, we announced the publication of preclinical data describing the unique immunomodulatory effects of umbralisib in Blood Advances, a Journal of the American Society of Hematology.
  • In August 2020, the U.S Food and Drug Administration (FDA) accepted the Company’s New Drug Application (NDA) for umbralisib as a treatment for patients with previously treated MZL and FL. The NDA was based primarily on data from the umbralisib monotherapy MZL and FL cohorts of the UNITY-NHL Phase 2b trial. The MZL indication, under Breakthrough Therapy Designation (BTD), has been accepted for Priority Review and has a Prescription Drug User Fee Act (PDUFA) goal date of February 15, 2021. The FL indication has been accepted for standard review with a PDUFA goal date of June 15, 2021.

- **UNITY-CLL: Ublituximab and Umbralisib (U2) in Chronic Lymphocytic Leukemia**
  • In October, the FDA granted Fast Track Designation to the combination of ublituximab and umbralisib (U2) for the treatment of adult patients with CLL, which could potentially expedite the development and regulatory review of U2. The application for Fast Track was based on data from the UNITY-CLL Phase 3 Study.

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 from the FL and MZL single agent umbralisib cohorts of the UNITY-NHL trial at ASH 2020 as well as data from our triple therapy combinations of U2 plus venetoclax and U2 plus 1701, our BTK inhibitor
- 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)
- Complete enrollment in ULTRA-V Phase 2b trial
- 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 and Nine Months Ended September 30, 2020

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation) was $45.8 million and $114.8 million for the three and nine months ended September 30, 2020, respectively, compared to $56.5 million and $118.8 million for the three and nine months ended September 30, 2019, respectively. The decrease in R&D is primarily attributable to a decrease in manufacturing costs for ublituximab and umbralisib, offset by an increase in milestone payments made during the three and nine months ended September 30, 2020. 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 $11.6 million and $25.4 million for the three and nine months ended September 30 2020, respectively, as compared to $2.3 million and $6.6 million for the three and nine months ended September 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 $87.2 million and $191.2 million for the three and nine months ended September 30, 2020, respectively, compared to a net loss of $61.9 million and $133.3 million for the three and nine months ended September 30, 2019, respectively. The net loss for the nine months ended September 30, 2020 included approximately $15 million of one-time milestone expenses related to our license agreements. Excluding non-cash compensation, the net loss for the three and nine months ended September 30, 2020 was approximately $58.8 million and $144.4 million, respectively, compared to a net loss of $59.9 million and $127.6 million for the three and nine months ended September 30, 2019, respectively.

- **Cash Position and Financial Guidance:** Cash and cash equivalents were $254.2 million as of September 30, 2020. Pro forma cash, cash equivalents and investment securities as of September 30, 2020 are approximately $328 million, after giving effect to $74.0 million of net proceeds from the utilization of the Company's ATM sales facility during the fourth quarter of 2020. The Company believes its cash and cash equivalents on hand as of September 30, 2020, along with the additional capital raised in the fourth quarter of 2020, will be sufficient to fund the Company's planned operations well into 2022.

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 compounds, ublituximab and umbralisib, the combination of which is referred to as "U2", 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. Umbralisib (TGR-1202) is an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon. Umbralisib is currently under review by the U.S. Food and Drug Administration (FDA) for accelerated approval as a treatment for patients with previously treated marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen or follicular lymphoma (FL) who have received at least two prior systemic therapies. The Company also has a fully enrolled Phase 3 clinical trial evaluating U2 in patients with treatment naïve and relapsed/refractory chronic lymphocytic leukemia (CLL), and two fully enrolled identical Phase 3 trials evaluating ublituximab monotherapy in patients with relapsing forms of multiple sclerosis (RMS). 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 positive, or if positive, may not be sufficient or acceptable to support regulatory submission or approval of ublituximab in relapsing forms of Multiple Sclerosis; the risk that we are not able to successfully and cost effectively complete all the preclinical, clinical and manufacturing requirements necessary to support our anticipated regulatory submissions; 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, or feedback from the FDA or foreign regulators; 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 September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
License revenue	$38	$38	$114	$114
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	--	--	--	100
Noncash compensation	4,618	1,482	8,150	4,323
Other research and development	45,846	56,503	114,785	118,814
Total research and development	50,464	57,985	122,935	123,237
General and administrative:				
Noncash compensation	23,712	593	38,618	1,391
Other general and administrative	11,584	2,321	25,373	6,580
Total general and administrative	35,296	2,914	63,991	7,971
Total costs and expenses	85,760	60,899	186,926	131,208
Operating loss	(85,722)	(60,861)	(186,812)	(131,094)
Other expense (income):				
Interest expense	1,610	1,537	5,038	3,388
Other income	(169)	(468)	(687)	(1,183)
Total other expense (income), net	1,441	1,069	4,351	2,205
Net loss	$(87,163)	$(61,930)	$(191,163)	$(133,299)
Basic and diluted net loss per common share	$(0.73)	$(0.69)	$(1.70)	$(1.55)
Weighted average shares used in computing basic and diluted net loss per common share	119,176,336	89,667,979	112,380,784	85,911,878

Condensed Balance Sheet Information (in thousands):

	September 30, 2020 (Unaudited)	December 31, 2019*
Cash, cash equivalents and investment securities	$254,154	$140,435
Total assets	273,856	163,014
Accumulated deficit	(892,379)	(701,216)
Total equity	170,658	38,615

* Condensed from audited financial statements



Source: TG Therapeutics, Inc.