TG Therapeutics Provides Business Update and Reports Third Quarter 2022 Financial Results

November 10, 2022

Conference call to be held today, November 10, 2022 at 8:30 AM ET

NEW YORK, Nov. 10, 2022 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the third quarter ended September 30, 2022 and recent company developments, along with a business outlook for the remainder of 2022.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, "Over the course of the third quarter we focused on preparing for the potential launch of ublituximab to treat patients with RMS in early 2023. This will continue to be our primary focus for the remainder of 2022 as we head toward the ublituximab PDUFA goal date of December 28, 2022." Mr. Weiss continued, "If approved, we believe ublituximab has the potential to be a meaningful treatment option for patients with relapsing forms of multiple sclerosis."

Business Highlights

Ublituximab in Multiple Sclerosis

- A Biologics License Application (BLA) for ublituximab, to treat patients with relapsing forms of multiple sclerosis (RMS) has been accepted by the Food and Drug Administration (FDA) and has a Prescription Drug User Fee Act (PDUFA) goal date of December 28, 2022.
- Most recently, at the 2022 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting, new exploratory analyses from the ULTIMATE I and II Phase 3 trials were presented. As previously reported, both trials met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period compared to teriflunomide in patients with RMS.

Key Objectives for 2022

- Obtain FDA approval of ublituximab to treat relapsing forms of multiple sclerosis by the PDUFA goal date of December 28, 2022
- Strengthen our commercial infrastructure to support the potential launch of ublituximab

Financial Results for the Three and Nine Months Ended September 30, 2022

- **Net Loss:** Net loss was $35.8 million and $145.3 million for the three and nine months ended September 30, 2022, respectively, compared to $85.6 million and $254.8 million for the three and nine months ended September 30, 2021. The decrease in net loss in both periods is primarily the result of our cost-savings measures implemented and the withdrawal of UKONIQ from the market.

- **R&D Expenses:** Total research and development (R&D) expense was $20.8 million and $95.7 million for the three and nine months ended September 30, 2022, respectively, compared to $52.0 million and $159.9 million for the three and nine months ended September 30, 2021, respectively. The prior period had higher costs associated with the submission of our BLA for ublituximab in RMS, increased manufacturing and clinical trial related expenses, as well as an increased non-cash compensation R&D expenses during the three and nine months ended September 30, 2021.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $14.3 million and $47.5 million for the three and nine months ended September 30, 2022, respectively, compared to $34.9 million and $95.7 million for the three and nine months ended September 30, 2021, respectively. The decrease was due primarily to decreased selling, general and administrative costs, including personnel, associated with the withdrawal of UKONIQ during the three and nine months ended September 30, 2022. We expect our selling, general and administrative expenses to increase for the remainder of 2022 as we prepare for the potential launch of ublituximab in RMS.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $197.7 million as of September 30, 2022. The Company believes its current cash, cash equivalents, investment securities and capital available under its debt facility on ublituximab's approval will be sufficient to fund our planned operations into 2024.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, November 10, 2022, at 8:30 AM ET, to discuss the Company's third quarter 2022 financial results.

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. 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

TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline including several investigational medicines, TG has completed a Phase 3 program for ublituximab, an investigational glycoengineered monoclonal antibody that targets a unique epitope on CD20-expressing B-cells, to treat patients with relapsing forms of multiple sclerosis (RMS). For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and on LinkedIn.

Cautionary Statement

This press release contains 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. Such forward looking statements include but are not limited to statements regarding the Company's plans, goals, strategies, timelines, anticipated milestones, and expectations for our current or future approved drugs and drug candidates, including; plans and timelines for potential approval of ublituximab monotherapy in RMS and, if approved, plans and timelines for commercializing ublituximab in RMS; the timing of initiation of clinical trials or the results of ongoing and planned clinical trials; the potential benefits of ublituximab in RMS or any of the Company's drug candidates in treating patients; and financial guidance regarding the period in which we will have sufficient capital resources to fund our operations.

All forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks and uncertainties. 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 from those expressed or implied by any forward-looking statements contained in this press release include the following: our ability to, if approved, establish, maintain and enhance our commercial infrastructure, to market and sell ublituximab; the potential for variation from the Company's projections and estimates about the potential market for ublituximab due to a number of factors, including for example, limitations that regulators may impose on the required labeling for the product; our ability to reach certain regulatory milestones at all or within the timelines projected; our ability to obtain, or to obtain within the timeline projected or for the indications sought, marketing authorization for our product candidates, including ublituximab monotherapy in RMS; our ability to successfully complete analyses of our clinical study results and present data within the timeframes projected; the risk that the interim, top-line and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed; the risk that regulatory authorities disagree with the conclusions we have reached or data we have publicly disclosed and we are unable to obtain approval for, or successfully commercialize, our product candidates; the risk that preclinical and clinical results for the Company's drug candidates may not support further development of such drug candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; the Company's reliance on third parties to perform manufacturing, distribution and supply services, and a range of other support functions for its clinical products; the risk that the ongoing COVID-19 pandemic and associated government control measures or other global issues such as the ongoing conflict in the Ukraine have an adverse impact on our clinical trials and other research and development plans or our regulatory filings and commercialization efforts; the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our financial performance; and the sufficiency of our existing capital resources to fund our future operating expenses for the timelines projected. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in our other filings with the U.S. Securities and Exchange Commission, including the most recent quarterly report on Form 10-Q for the third quarter ended September 30, 2022.

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,	
	2022	**2021**	**2022**	**2021**
Revenue				
Product revenue, net	$56	$1,992	2,591	$4,254
License revenue	38	38	114	114

Total revenue	94	2,030	2,705	4,368
Costs and expenses:				
Cost of product revenue	2	292	262	580
Research and development:				
Noncash compensation	3,249	4,534	7,471	19,061
Other research and development	17,552	47,433	88,246	140,872
Total research and development	20,801	51,967	95,717	159,933
Selling, general and administrative:				
Noncash compensation	3,740	9,463	663	27,857
Other selling, general and administrative	10,514	25,436	46,840	67,821
Total selling, general and administrative	14,254	34,899	47,503	95,678
Total operating expenses	35,057	87,158	143,482	256,191
Operating loss	(34,963)	(85,128)	(140,777)	(251,823)
Other expense (income):				
Interest expense	1,648	1,038	7,329	4,559
Other income	(793)	(529)	(2,765)	(1,619)
Total other expense (income), net	855	509	4,564	2,940
Consolidated net loss	$(35,818)	$(85,637)	$(145,341)	$(254,763)
Net loss per common share:				
Basic and diluted	$(0.26)	$(0.65)	$(1.08)	$(1.93)
Weighted average shares used in computing basic and diluted net loss per common share	135,327,035	132,353,119	134,839,207	132,109,912

Condensed Balance Sheet Information (in thousands):

	September 30, 2022 (Unaudited)	December 31, 2021*
Cash, cash equivalents and investment securities	197,708	350,296
Total assets	217,891	379,629
Accumulated deficit	(1,474,039)	(1,328,698)
Total equity	100,481	237,153

* Condensed from audited financial statements