TG Therapeutics Reports Second Quarter 2024 Financial Results and Raises BRIUMVI® (ublituximab-xiiy) Full Year Revenue Guidance

August 6, 2024

Second quarter 2024 U.S. BRIUMVI net revenue of $72.6 million

Raising full year 2024 U.S. BRIUMVI net revenue target to approximately $290 - $300 million

Cash flow positive for second quarter 2024

Establishes $250 million credit facility to repay existing debt and to buy back up to $100 million of common stock under a share repurchase program

Initiated phase 1 study in RMS patients for subcutaneous ublituximab and received FDA IND clearance to study azer-cel (allogeneic CD19 CAR-T) in patients with progressive MS

Conference call to be held today, August 6, 2024, at 8:30 AM ET

NEW YORK, Aug. 06, 2024 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) (the Company or TG Therapeutics) today announced its financial results for the second quarter of 2024, along with recent company developments and provided an update on 2024 revenue guidance.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer stated, "We are pleased to report another quarter of outperformance across all aspects of our business. From a financial standpoint, our second quarter U.S. BRIUMVI net revenues exceeded expectations, leading us to raise our full year guidance. On the R&D side, we also had an exciting quarter with the first patients now treated with subcutaneous ublituximab in a newly launched Phase 1 study and clearance of our IND for azer-cel, our allogeneic "off-the-shelf" CD19 CAR-T, for patients with progressive MS." Mr. Weiss continued, "We are also excited to announce our new $250 million credit facility with HealthCare Royalty and Blue Owl Capital that enables us to accelerate the initiation of a share repurchase program and pay down our current debt, while preserving our current cash to continue building our commercial infrastructure, ramping up our marketing efforts, and investing in our R&D programs. We look forward to continuing the positive momentum into the second half of 2024."

Recent Highlights & Developments

United States (U.S.) Commercialization of BRIUMVI® (ublituximab-xiiy)

- BRIUMVI U.S. net product revenue of $72.6 million for the second quarter of 2024, representing >350% growth over the second quarter of 2023
- Approximately 5,850 BRIUMVI new patient prescriptions received by the TG Therapeutics hub since launch, from approximately 950 healthcare providers at approximately 525 centers, including more than 1,400 prescriptions received in the second quarter of 2024
- Awarded a national contract with the Department of Veterans Affairs (VA) for BRIUMVI to be the preferred anti-CD20 agent listed on the VA National Formulary for patients with relapsing forms of multiple sclerosis (RMS)

Development Updates & General Business

- Initiated a phase 1 clinical trial evaluating subcutaneous ublituximab in RMS, with the first patients now dosed
- Received clearance by the U.S. Food and Drug Administration (FDA) of an Investigational New Drug (IND) application for azer-cel in progressive forms of multiple sclerosis (MS)
- Obtained three additional patents from the United States Patent and Trademark Office (USPTO) for BRIUMVI, extending patent protection through 2042

Corporate Finance Updates

- Established a new 5-year, $250 million credit facility with HealthCare Royalty and Blue Owl Capital, set to mature in 2029, primarily to repay $107 million in outstanding debt and accrued interest, which was set to mature in multiple tranches from mid-2025 to January 2026, and to fund the buyback of up to $100 million of currently outstanding shares of the Company's common stock. The remainder will be available for working capital purposes, providing the Company with additional operational flexibility.

2024 Updated Target U.S. BRIUMVI Guidance

- Updating BRIUMVI U.S. net product revenue target to approximately $290 to $300 million for the full year 2024 (prior guidance of $270 to $290 million for full year 2024)

Remaining 2024 Development Pipeline Anticipated Milestones

- Study BRIUMVI in an additional autoimmune disease outside of MS
- Commence a clinical trial evaluating azer-cel in autoimmune diseases, starting with progressive MS
- Present additional data from the ENHANCE Phase 3b CD20 switch trial

Financial Results for Second Quarter 2024

- **Product Revenue, net:** Product revenue, net was approximately $72.6 million and $123.1 million for the three and six months ended June 30, 2024, respectively, compared to $16.0 million and $23.8 million for the three and six months ended June 30, 2023, respectively. Product revenue, net for both the three and six months ended June 30, 2024 and 2023, consisted of net product sales of BRIUMVI in the United States.
- **License, milestone, royalty and other revenue:** License, milestone, royalty and other revenue was approximately $0.9 million and $13.9 million for the three and six months ended June 30, 2024, respectively, compared to less than $0.1 million for both the three and six months ended June 30, 2023, respectively. License, milestone, royalty and other revenue for the six months ended June 30, 2024 is predominantly comprised of a $12.5 million milestone payment under the Neuraxpharm Commercialization Agreement for the first key market commercial launch of BRIUMVI in the European Union (EU) which occurred in the first quarter of 2024.
- **R&D Expenses:** Total research and development (R&D) expense was approximately $17.6 million and $50.3 million for the three and six months ended June 30, 2024, respectively, compared to $28.1 million and $44.0 million for the three and six months ended June 30, 2023, respectively. The decrease in R&D expense during the three months ended June 30, 2024 was primarily attributable to reduced clinical trial related expense and license milestones incurred during the period ended June 30, 2024. The increase in R&D expense during the six months ended June 30, 2024 was primarily attributable to license and milestone expense related to the license agreement with Precision BioSciences, Inc., as well as additional manufacturing and development costs incurred in connection with our ublituximab subcutaneous development work during the period.
- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was approximately $38.8 million and $73.4 million for the three and six months ended June 30, 2024, respectively, compared to $30.7 million and $58.8 million for the three and six months ended June 30, 2023, respectively. The increase in both periods was primarily due to the scale-up of the BRIUMVI commercial launch, including personnel.
- **Net Income (Loss):** Net income (loss) was $6.9 million and $(3.8) million for the three and six months ended June 30, 2024, respectively, compared to a net loss of $(47.6) million and $(86.8) million for the three and six months ended June 30, 2023, respectively.
- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $217.3 million as of June 30, 2024, which excludes any increase in cash associated with the new $250 million credit facility. We anticipate that our cash, cash equivalents and investment securities as of June 30, 2024, combined with the projected revenues from BRIUMVI, will be sufficient to fund our business based on our current operating plan.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, August 6, 2024 at 8:30 AM ET to discuss the Company's financial results from the second quarter ended June 30, 2024.

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 a period of 30 days after the call.

ABOUT BRIUMVI® (ublituximab-xiiy) 150 mg/6 mL Injection for IV

BRIUMVI is a novel monoclonal antibody that targets a unique epitope on CD20-expressing B-cells. Targeting CD20 using monoclonal antibodies has proven to be an important therapeutic approach for the management of autoimmune disorders, such as RMS. BRIUMVI is uniquely designed to lack certain sugar molecules normally expressed on the antibody. Removal of these sugar molecules, a process called glycoengineering, allows for efficient B-cell depletion at low doses.

BRIUMVI is indicated in the U.S. for the treatment of adults with RMS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and in the EU and UK for the treatment of adult patients with RMS with active disease defined by clinical or imaging features.

A list of authorized specialty distributors can be found at www.briumvi.com.

IMPORTANT SAFETY INFORMATION

Contraindications: BRIUMVI is contraindicated in patients with:

- Active Hepatitis B Virus infection
- A history of life-threatening infusion reaction to BRIUMVI

WARNINGS AND PRECAUTIONS

Infusion Reactions: BRIUMVI can cause infusion reactions, which can include pyrexia, chills, headache, influenza-like illness, tachycardia, nausea, throat irritation, erythema, and an anaphylactic reaction. In MS clinical trials, the incidence of infusion reactions in BRIUMVI-treated patients who received infusion reaction-limiting premedication prior to each infusion was 48%, with the highest incidence within 24 hours of the first infusion. 0.6% of BRIUMVI-treated patients experienced infusion reactions that were serious, some requiring hospitalization.

Observe treated patients for infusion reactions during the infusion and for at least one hour after the completion of the first two infusions unless infusion reaction and/or hypersensitivity has been observed in association with the current or any prior infusion. Inform patients that infusion reactions can occur up to 24 hours after the infusion. Administer the recommended pre-medication to reduce the frequency and severity of infusion reactions. If life-threatening, stop the infusion immediately, permanently discontinue BRIUMVI, and administer appropriate supportive treatment. Less severe infusion reactions may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

Infections: Serious, life-threatening or fatal, bacterial and viral infections have been reported in BRIUMVI-treated patients. In MS clinical trials, the overall rate of infections in BRIUMVI-treated patients was 56%, compared to 54% in teriflunomide-treated patients. The rate of serious infections was 5% compared to 3%, respectively. There were 3 infection-related deaths in BRIUMVI-treated patients. The most common infections in BRIUMVI-treated patients included upper respiratory tract infection (45%) and urinary tract infection (10%). Delay BRIUMVI administration in patients with an active infection until the infection is resolved.

Consider the potential for increased immunosuppressive effects when initiating BRIUMVI after immunosuppressive therapy or initiating an immunosuppressive therapy after BRIUMVI.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation occurred in an MS patient treated with BRIUMVI in clinical trials. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with anti-CD20 antibodies. Perform HBV screening in all patients before initiation of treatment with BRIUMVI. Do not start treatment with BRIUMVI in patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consult a liver disease expert before starting and during treatment.

Progressive Multifocal Leukoencephalopathy (PML): Although no cases of PML have occurred in BRIUMVI-treated MS patients, JC virus infection resulting in PML has been observed in patients treated with other anti-CD20 antibodies and other MS therapies.

If PML is suspected, withhold BRIUMVI and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

MRI findings may be apparent before clinical signs or symptoms; monitoring for signs consistent with PML may be useful. Further investigate suspicious findings to allow for an early diagnosis of PML, if present. Following discontinuation of another MS medication associated with PML, lower PML-related mortality and morbidity have been reported in patients who were initially asymptomatic at diagnosis compared to patients who had characteristic clinical signs and symptoms at diagnosis.

If PML is confirmed, treatment with BRIUMVI should be discontinued.

Vaccinations: Administer all immunizations according to immunization guidelines: for live or live-attenuated vaccines, at least 4 weeks and, whenever possible, at least 2 weeks prior to initiation of BRIUMVI for non-live vaccines. BRIUMVI may interfere with the effectiveness of non-live vaccines. The safety of immunization with live or live-attenuated vaccines during or following administration of BRIUMVI has not been studied. Vaccination with live virus vaccines is not recommended during treatment and until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with BRIUMVI During Pregnancy: In infants of mothers exposed to BRIUMVI during pregnancy, assess B-cell counts prior to administration of live or live-attenuated vaccines as measured by $CD19^+$ B-cells. Depletion of B-cells in these infants may increase the risks from live or live-attenuated vaccines. Inactivated or non-live vaccines may be administered prior to B-cell recovery. Assessment of vaccine immune responses, including consultation with a qualified specialist, should be considered to determine whether a protective immune response was mounted.

Fetal Risk: Based on data from animal studies, BRIUMVI may cause fetal harm when administered to a pregnant woman. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. A pregnancy test is recommended in females of reproductive potential prior to each infusion. Advise females of reproductive potential to use effective contraception during BRIUMVI treatment and for 6 months after the last dose.

Reduction in Immunoglobulins: As expected with any B-cell depleting therapy, decreased immunoglobulin levels were observed. Decrease in immunoglobulin M (IgM) was reported in 0.6% of BRIUMVI-treated patients, compared to none of the patients treated with teriflunomide in RMS clinical trials. Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections, and after discontinuation of therapy, until B-cell repletion. Consider discontinuing BRIUMVI therapy if a patient with low immunoglobulins develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

Most Common Adverse Reactions: The most common adverse reactions in RMS trials (incidence of at least 10%) were infusion reactions and upper respiratory tract infections.

Physicians, pharmacists, or other healthcare professionals with questions about BRIUMVI should visit www.briumvi.com.

The full Summary of Product Characteristics approved in the European Union (EU) for BRIUMVI can be found here Briumvi | European Medicines Agency (europa.eu).

ABOUT BRIUMVI PATIENT SUPPORT in the U.S.
BRIUMVI Patient Support is a flexible program designed by TG Therapeutics to support U.S. patients through their treatment journey in a way that works best for them. More information about the BRIUMVI Patient Support program can be accessed at www.briumvipatientsupport.com.

ABOUT MULTIPLE SCLEROSIS
Relapsing multiple sclerosis (RMS) is a chronic demyelinating disease of the central nervous system (CNS) and includes people with relapsing-remitting multiple sclerosis (RRMS) and people with secondary progressive multiple sclerosis (SPMS) who continue to experience relapses. RRMS is the most common form of multiple sclerosis (MS) and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. It is estimated that nearly 1 million people are living with MS in the United States and approximately 85% are initially diagnosed with RRMS.[1,2] The majority of people who are diagnosed with RRMS will eventually transition to SPMS, in which they experience steadily worsening disability over time. Worldwide, more than 2.3 million people have a diagnosis of MS.[1]

ABOUT TG THERAPEUTICS
TG Therapeutics is a fully integrated, commercial stage, 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 Therapeutics has received approval from the U.S. Food and Drug Administration (FDA) for BRIUMVI® (ublituximab-xiiy) for the treatment of adult patients with relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, as well as approval by the European Commission (EC) and the Medicines and Healthcare Products Regulatory Agency (MHRA) for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features in Europe and the United Kingdom, respectively. For more information, visit www.tgtherapeutics.com, and follow us on X (formerly Twitter) @TGTherapeutics and on LinkedIn.

BRIUMVI® is a registered trademark of TG Therapeutics, Inc.

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.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. In addition to the risk factors identified from time to time in our reports filed with the U.S. Securities and Exchange Commission (SEC), factors that could cause our actual results to differ materially include the below.

Such forward looking statements include but are not limited to statements regarding expectations for the timing and success of the ongoing commercialization and availability of BRIUMVI® (ublituximab-xiiy) for RMS in the United States and Europe; anticipated healthcare professional (HCP) and patient acceptance and use of BRIUMVI for the approved indications; expectations of future revenue for BRIUMVI, expenses, or profits; expectations for our pipeline products; our ability to initiate and execute the proposed share repurchase program; and the results of the ENHANCE or ULTIMATE I & II Phase 3 studies.

Additional factors that could cause our actual results to differ materially include the following: the Company's ability to maintain and continue to maintain a commercial infrastructure for BRIUMVI, and to successfully, or in the timeframe projected, market and sell BRIUMVI; the risk that trends in prescriptions are not maintained or that prescriptions are not filled; the failure to obtain and maintain payor coverage; the risk that HCP interest in BRIUMVI will not be sustained; the risk that momentum in sales for BRIUMVI will not build during the course of the year; the risk that the commercialization of BRIUMVI does not continue to exceed expectations; the risk that our current or future BRIUMVI revenue targets will not be achieved; the failure to obtain and maintain requisite regulatory approvals, including the risk that the Company fails to satisfy post-approval regulatory requirements, the potential for variation from the Company's projections and estimates about the potential market for BRIUMVI due to a number of factors, including, further limitations that regulators may impose on the required labeling for BRIUMVI (such as modifications, resulting from safety signals that arise in the post-marketing setting or in the long-term extension study from the ULTIMATE I and II clinical trials); the Company's ability to meet post-approval compliance obligations (on topics, including but not limited to product quality, product distribution and supply chain, pharmacovigilance, and sales and marketing); the Company's reliance on third parties for manufacturing, distribution and supply, and other support functions for our clinical and commercial products, including BRIUMVI, and the ability of the Company and its manufacturers and suppliers to produce and deliver BRIUMVI to meet the market demand for BRIUMVI; potential regulatory challenges to the Company's plans to seek marketing approval for the product in jurisdictions outside of the U.S.; the uncertainties inherent in research and development; the risk that any individual patient's clinical experience in the post-marketing setting, or the aggregate patient experience in the post-marketing setting, may differ from that demonstrated in controlled clinical trials such as ULTIMATE I and II; the risk that the Company does not achieve its 2024 development pipeline anticipated milestones in the timeframe projected or at all, including the development of subcutaneous BRIUMVI, commencing a trial evaluating BRIUMVI in an autoimmune disease outside of MS, or commencing a trial evaluating azer-cel; our ability to initiate and execute the proposed share repurchase program; and general political, economic, and business conditions. 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, 2023 and in our other filings with the SEC.

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.

CONTACT:

Investor Relations
Email: ir@tgtxinc.com
Telephone: 1.877.575.TGTX (8489), Option 4

Media Relations:
Email: media@tgtxinc.com
Telephone: 1.877.575.TGTX (8489), Option 6

1. MS Prevalence. National Multiple Sclerosis Society website. https://www.nationalmssociety.org/About-the-Society/MS-Prevalence. Accessed October 26, 2020. **2.** Multiple Sclerosis International Federation, 2013 via Datamonitor p. 236.

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,	
	2024	**2023**	**2024**	**2023**
Revenue				
Product revenue, net	72,596	16,036	123,084	23,801
License, milestone, royalty and other revenue	870	38	13,855	76
Total revenue	73,466	16,074	136,939	23,877
Costs and expenses:				
Cost of revenue	8,304	1,911	13,745	2,768
Research and development:				
Noncash compensation	2,520	5,664	4,972	7,247
Other research and development	15,036	22,458	45,306	36,744
Total research and development	17,556	28,122	50,278	43,991
Selling, general and administrative:				
Noncash compensation	6,962	6,877	13,848	12,117
Other selling, general and administrative	31,828	23,838	59,522	46,666
Total selling, general and administrative	38,790	30,715	73,370	58,783
Total costs and expenses	64,650	60,748	137,393	105,542
Operating income (loss)	8,816	(44,674)	(454)	(81,665)
Other expense (income):				
Interest expense	3,977	3,627	6,265	6,471
Other income	(1,712)	(691)	(2,592)	(1,295)
Total other expense , net	2,265	2,936	3,673	5,176
Net income (loss) before taxes	$ 6,551	$ (47,610)	$ (4,127)	$ (86,841)
Income tax benefit	328	-	299	-
Net Income (loss)	$ 6,879	$ (47,610)	$ (3,828)	$ (86,841)
Net income (loss) per common share:				
Basic	$ 0.05	$ (0.34)	$ (0.03)	$ (0.62)
Diluted	$ 0.04	$ (0.34)	$ (0.03)	$ (0.62)
Weighted average shares of common stock outstanding				
Basic	144,727,482	141,503,738	145,464,255	140,911,295
Diluted	159,423,571	141,503,738	145,464,255	140,911,295

Condensed Balance Sheet Information (in thousands):

	June 30, 2024 (Unaudited)	**December 31, 2023***
Cash, cash equivalents and investment securities	217,252	217,508
Total assets	401,207	329,587
Total equity	177,568	160,502

* Condensed from audited financial statements