TG Therapeutics Reports First Quarter 2025 Financial Results and Raises BRIUMVI Full Year Revenue Guidance

May 5, 2025

First quarter 2025 BRIUMVI U.S. net revenue of $119.7 million

Raises full year 2025 global net revenue target to approximately $575 million and raises full year BRIUMVI U.S. net revenue target to approximately $560 million

Conference call to be held today, Monday, May 5, 2025, at 8:30 AM ET

NEW YORK, May 05, 2025 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) (the Company or TG Therapeutics) today announced its financial results for the first quarter of 2025, along with recent company developments and provided an update on 2025 revenue guidance.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, "2025 is off to a strong start, and I'm incredibly proud of the progress made thus far. Our performance in the first quarter, including BRIUMVI's $119.7 million in U.S. net sales, demonstrates the growing confidence in our treatment and the increasing adoption by healthcare providers. This momentum, combined with the positive feedback we're hearing from both patients and clinicians, reinforces our belief that we can achieve our long-term goal of BRIUMVI becoming the number one prescribed anti-CD20 treatment based on dynamic market share." Mr. Weiss continued, "In addition to our ongoing BRIUMVI commercialization efforts, we are continuing to invest in innovation, including simplifying the BRIUMVI treatment regimen, advancing subcutaneous BRIUMVI, and developing azer-cel for progressive MS. All with a focus on developing treatment options designed to improve the lives of individuals living with MS."

Recent Highlights & Developments

BRIUMVI® (ublituximab-xiiy) Commercialization

- BRIUMVI U.S. net product revenue of $119.7 million for the first quarter of 2025, representing approximately 137% growth over the same period last year
- Expansion of commercialization outside of the U.S. with our partner, Neuraxpharm, with BRIUMVI now commercially available in additional countries in the European Union, United Kingdom and Switzerland

BRIUMVI Data

- Presented five-year data from the open-label extension study of the ULTIMATE I & II Phase 3 clinical trials evaluating BRIUMVI in adult patients with relapsing forms of multiple sclerosis (RMS) which demonstrated that 92% of patients were free from disability progression after five years of treatment, an annualized relapse rate of 0.02 during year 5 of treatment (equivalent to one relapse occurring every fifty years of patient treatment), and an overall safety profile that remained consistent, with no new safety signals emerging over 5 years of continuous treatment and no observed cases of progressive multifocal leukoencephalopathy (PML) to date.
- Presented data from the ENHANCE Phase 3b clinical trial evaluating alternative dosing strategies for BRIUMVI in patients with RMS which demonstrated that:
    - A single 600 mg BRIUMVI infusion on Day 1 was well tolerated in individuals with RMS regardless of prior treatment or B-cell depletion status
    - Rapid 30-minute BRIUMVI infusions were well tolerated in patients with RMS
- Published two articles in medical journals:
    - "Switching to Ublituximab from Prior anti-CD20 Monoclonal Antibody Therapy: A Case Report Series", published in *Frontiers in Immunology,* demonstrating a retrospective case series of seven individuals with multiple sclerosis (MS) treated in private practice or at an MS clinic who switched to ublituximab from a different anti-CD20 monoclonal antibody therapy due to efficacy or tolerability concerns, published in *Frontiers in Immunology*
    - "The Evolution of Anti-CD20 Treatment in Multiple Sclerosis", published in *CNS DRUGS,* demonstrating the differentiating characteristics within the anti-CD20 monoclonal antibody class used to treat MS, published in *CNS DRUGS*.

Pipeline Status

- Phase 1 clinical trial evaluating subcutaneous BRIUMVI in patients with RMS remains ongoing
- Phase 1 clinical trial evaluating BRIUMVI in patients with Myasthenia Gravis (MG) remains ongoing
- Phase 1 clinical trial evaluating azercabtagene zapreleucel (azer-cel) in patients with primary progressive multiple sclerosis is now open for enrollment

2025 Financial Guidance

- Raises BRIUMVI U.S. net product revenue target to $560 million for the full year 2025 (prior guidance of $525 million for full year 2025)
- Raises total global revenue target to $575 million for the full year 2025 (prior guidance of $540 million for full year 2025)
- Second quarter 2025 BRIUMVI U.S. net product revenue target of $135 million Full year 2025 target operating expense of approximately $300 million (excluding non-cash compensation and cost of goods sold)

2025 Development Pipeline Anticipated Milestones

- Commence pivotal program of subcutaneous BRIUMVI
- Commence a pivotal program based on the improved dosing regimens evaluated in the ENHANCE trial, with the goal of enhancing the patient experience on intravenous BRIUMVI
- Continue enrollment of participants into the ongoing clinical trial evaluating BRIUMVI in autoimmune diseases outside of MS
- Continue enrollment of participants into the Phase 1 clinical trial evaluating azer-cel for the treatment of autoimmune diseases, beginning with progressive forms of MS
- Present updated data at major medical conferences throughout the year

Financial Results for First Quarter 2025

- **Product Revenue, Net:** Product revenue, net was approximately $119.7 million for the three months ended March 31, 2025, compared to $50.5 million for the three months ended March 31, 2024. Product revenue, net for both the three months ended March 31, 2025 and March 31, 2024, 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 $1.2 million for the three months ended March 31, 2025, compared to $13.0 million for the three months ended March 31, 2024. License, milestone, royalty and other revenue for the three months ended March 31, 2024 is predominantly comprised of a $12.5 milestone payment under the commercialization agreement with Neuraxpharm for the first key market commercial launch of BRIUMVI in the European Union.

- **R&D Expenses:** Total research and development (R&D) expense was $46.4 million for the three months ended March 31, 2025, compared to $32.7 million for the three months ended March 31, 2024. The increase in R&D expense for the three months ended March 31, 2025, was primarily attributable to manufacturing expenses incurred in connection with our ublituximab subcutaneous development work during the period.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $50.3 million for the three months ended March 31, 2025, compared to $34.6 million for the three months ended March 31, 2024. The increase was primarily due to other selling, general and administrative costs, including marketing, personnel and consultants, associated with the commercialization of BRIUMVI for the three months ended March 31, 2025.

- **Net Income (Loss):** Net income was $5.1 million for the three months ended March 31, 2025, compared to a net loss of $10.7 million for the three months ended March 31, 2024.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $276.2 million as of March 31, 2025. We anticipate that our cash, cash equivalents and investment securities as of March 31, 2025, 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, May 5, 2025, at 8:30 AM ET, to discuss the Company's financial results from first quarter 2025.

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 HB surface antigen (HBsAg) and anti-HB tests. For patients who are negative for 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) in Europe, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, and Swissmedic in Switzerland, for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features. 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 commercialization and availability of BRIUMVI® (ublituximab-xiiy) for RMS in the United States, the European Union, the United Kingdom, Switzerland or other jurisdictions outside of the United States; 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; and statements regarding 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 be sustained during the course of the year; the risk that the commercialization of BRIUMVI does not continue to exceed expectations; the risk that our 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 variations 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 2025 development pipeline anticipated milestones in the timeframe projected or at all, including commencing a pivotal program for subcutaneous ublituximab, commencing a pivotal program based on data from the ENHANCE trial, enrolling patients into a trial evaluating BRIUMVI in an autoimmune disease outside of MS, or enrolling patients into a trial evaluating azer-cel; regulatory developments, legislative actions, executive orders, including the imposition of tariffs and policy changes in the U.S. and other jurisdictions; 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, 2024 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.

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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 March 31,	
	2025	**2024**
Revenue		
Product revenue, net	$119,655	$50,488
License, milestone, royalty and other revenue	1,201	12,986
Total revenue	120,856	63,474
Costs and expenses:		
Cost of revenue	15,541	5,441
Research and development:		
Noncash compensation	3,331	2,452
Other research and development	43,031	30,270
Total research and development	46,362	32,722
Selling, general and administrative:		
Noncash compensation	11,640	6,887
Other selling, general and administrative	38,691	27,694
Total selling, general and administrative	50,331	34,581
Total operating expenses	112,234	72,744
Operating profit (loss)	8,622	(9,270)
Other expense (income):		
Interest expense	6,757	2,288
Other income	(3,603)	(880)
Total other expense, net	3,154	1,408
Net income (loss) before taxes	5,468	(10,678)
Income Taxes	408	29
Net Income (Loss)	$5,060	$(10,707)
Net income (loss) per common share:		
Basic	$0.03	$(0.07)
Diluted	$0.03	$(0.07)
Weighted average shares of common stock outstanding:		
Basic	146,677,783	146,209,213
Diluted	162,769,202	146,209,213

Condensed Balance Sheet Information (in thousands):

	March 31, 2025 (Unaudited)	**December 31, 2024***
Cash, cash equivalents and investment securities	276,240	311,001
Total assets	656,689	577,690

Total equity	237,288	222,364

* Condensed from audited financial statements