



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

November 4, 2024

Third quarter 2024 U.S. BRIUMVI net revenue of \$83.3 million

Raises full year 2024 U.S. BRIUMVI net revenue target to \$300 - \$305 million

Conference call to be held today, November 4, 2024, at 8:30 AM ET

NEW YORK, Nov. 04, 2024 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) (the Company or TG Therapeutics) today announced its financial results for the third 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, "The positive feedback and uptake of BRIUMVI in the marketplace continues to outpace our expectations and we are excited to share with you the results of another quarter of growth and execution of our BRIUMVI launch and pipeline development. With \$83.3 million of U.S. BRIUMVI net sales for the third quarter and continued strong commercial launch effort, we believe we are on a path for continued growth into the end of the year and into 2025 and further toward our long-term goal of becoming the number one prescribed anti-CD20 in terms of dynamic market share." Mr. Weiss continued, "Everyone at TG is focused on individuals living with relapsing forms of multiple sclerosis, and to that end, we continue to make strides with our clinical programs designed to improve their treatment experience, including shortening infusion times, minimizing infusion visits, offering a subcutaneous BRIUMVI option, and developing novel treatments such as our allogeneic CD19 CAR-T. We look forward to a strong close to 2024 and are excited for further progress in 2025 both commercially and clinically."

Recent Highlights & Developments

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

- BRIUMVI U.S. net product revenue of \$83.3 million for the third quarter of 2024, reflecting approximately 15% quarter-over-quarter growth and over 230% growth from the same quarter last year

BRIUMVI Clinical Data Presentations

- Presented updated data at the 2024 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting including:
 - New five year data from the ULTIMATE I & II Phase 3 trials evaluating BRIUMVI in 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 which remained consistent over 5 years of continuous treatment, with no new safety signals emerging with prolonged treatment.
 - New data from the ENHANCE Phase 3b trial evaluating BRIUMVI in patients with RMS which demonstrated that:
 - Rapid 30-minute BRIUMVI infusions are well tolerated with all infusion related reactions being mild (Grade 1) and resolving completed, and
 - RMS patients who are already B-cell depleted can safely switch from a prior anti-CD20 therapy directly to 450 mg of BRIUMVI administered in 1 hour as an initial infusion, without a 150 mg initial dose, with 97% of infusions being completed without interruption or slowing.

Pipeline

- Initiated a phase 1 clinical trial evaluating subcutaneous ublituximab in RMS
- 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)

Manufacturing

- Secured FUJIFILM Diosynth Biotechnologies as a secondary US-based manufacturer of BRIUMVI out of its Holly Spring, North Carolina, United States, based facility.

2024 Updated Target U.S. BRIUMVI Guidance

- Raising BRIUMVI U.S. net product revenue target to \$300 to \$305 million for the full year 2024 (prior guidance of \$290 to \$300 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

Financial Results for Third Quarter 2024

- **Product Revenue, net:** Product revenue, net was approximately \$83.3 million and \$206.4 million for the three and nine months ended September 30, 2024, respectively, compared to \$25.1 million and \$48.9 million for the three and nine months ended September 30, 2023, respectively. Product revenue, net for both the three and nine months ended September 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 \$0.6 million and \$14.4 million for the three and nine months ended September 30, 2024, respectively, compared to \$140.7 million and \$140.8 million for the three and nine months ended September 30, 2023, respectively. License, milestone, royalty and other revenue for the nine months ended September 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. License, milestone, royalty and other revenue for the nine months ended September 30, 2023 is predominantly comprised of recognition of the one-time \$140.0 million non-refundable upfront payment under the Commercialization Agreement with Neuraxpharm.
- **R&D Expenses:** Total research and development (R&D) expense was approximately \$20.1 million and \$70.4 million for the three and nine months ended September 30, 2024, respectively, compared to \$14.8 million and \$58.7 million for the three and nine months ended September 30, 2023, respectively. The increase in R&D expense during the three and nine months ended September 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 \$42.0 million and \$115.3 million for the three and nine months ended September 30, 2024, respectively, compared to \$32.8 million and \$91.6 million for the three and nine months ended September 30, 2023, respectively. The increase in both periods was primarily due to other selling, general and administrative costs, including personnel and consultants, associated with the commercialization of BRIUMVI during the period ended September 30, 2024.
- **Net Income:** Net income was \$3.9 million and \$0.1 million for the three and nine months ended September 30, 2024, respectively, compared to net income of \$113.9 million and \$27.1 million for the three and nine months ended September 30, 2023, respectively.
- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were \$341.0 million as of September 30, 2024. We anticipate that our cash, cash equivalents and investment securities as of September 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, November 4, 2024 at 8:30 AM ET to discuss the Company's financial results from the third quarter ended September 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 \(europa.eu\)](http://Briumvi|EuropeanMedicinesAgency(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-xiyy) 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](https://twitter.com/TGTherapeutics) and on [LinkedIn](https://www.linkedin.com/company/tgtherapeutics).

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-xiyy) 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; ; 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; 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.

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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.

Statements of Operations Information (in thousands, except share and per share amounts; unaudited):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Revenue				
Product revenue, net	83,297	25,068	206,381	48,868
License, milestone, royalty and other revenue	582	140,747	14,438	140,823
Total revenue	83,879	165,815	220,819	189,691
Costs and expenses:				
Cost of revenue	9,341	3,509	23,087	6,277
Research and development:				
Noncash compensation	3,028	2,915	8,000	10,162
Other research and development	17,110	11,838	62,417	48,581
Total research and development	20,138	14,753	70,417	58,743
Selling, general and administrative:				
Noncash compensation	8,745	6,269	22,593	18,386
Other selling, general and administrative	33,221	26,500	92,742	73,167
Total selling, general and administrative	41,966	32,769	115,335	91,553
Total costs and expenses	71,445	51,031	208,839	156,573
Operating income	12,434	114,784	11,980	33,118
Other expense (income):				
Interest expense	10,832	3,713	16,967	10,184
Other income	(2,666)	(2,859)	(5,128)	(4,154)
Total other expense , net	8,166	854	11,839	6,030
Net income before taxes	\$4,268	\$113,930	\$141	\$27,088
Income tax expense	388	-	89	-
Net Income	\$3,880	\$113,930	\$52	\$27,088
Net income per common share:				
Basic	\$0.03	\$0.80	\$0.00	\$0.19
Diluted	\$0.02	\$0.73	\$0.00	\$0.19
Weighted average shares of common stock outstanding				
Basic	145,102,479	142,871,227	145,342,337	141,571,785
Diluted	160,714,388	155,871,749	160,366,927	145,952,913

Condensed Balance Sheet Information (in thousands):

	September 30, 2024	December 31, 2023*
	(Unaudited)	
Cash, cash equivalents and investment securities	341,041	217,508
Total assets	586,014	329,587
Total equity	192,157	160,502

* Condensed from audited financial statements