TG Therapeutics Provides Business Update and Reports Fourth Quarter and Year-End 2023 Financial Results

February 28, 2024

Fourth quarter and full year 2023 BRIUMVI U.S. net revenue of approximately $40 million and $89 million, respectively

Conference call to be held today, February 28, 2024, at 8:30 AM ET

NEW YORK, Feb. 28, 2024 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) (the Company or TG Therapeutics) today announced its financial results for the fourth quarter and year ended December 31, 2023, along with recent company developments.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, “2023 was an exciting year of execution for TG, which we believe has set the stage for a successful 2024. The BRIUMVI launch exceeded our expectations, and we ended the year with approximately $89 million in U.S. net revenue and provided a BRIUMVI U.S. net revenue target of $220 - $260 million for 2024. Further executing on our corporate objectives in 2023, we presented the first data from our ENHANCE Phase 3 b trial evaluating patients who switch from prior CD20 therapy to BRIUMVI, and recently broadened our BRIUMVI clinical efforts to include subcutaneous development and potential expansion beyond MS. We look forward to sharing additional developments from these efforts throughout the year, as well as advancing our recent pipeline addition, azer-cel, an allogeneic CAR T into clinical development in autoimmune disease.” Mr. Weiss continued, “We were also pleased to see our ex-US partner, Neuraxpharm, commence the launch of BRIUMVI in Europe this week. As the year progresses, we look forward to providing continued updates on our launch of BRIUMVI in the U.S. and sharing data updates throughout the year at major medical meetings.”

2023 Highlights & Recent Developments

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

- BRIUMVI U.S. net product revenue of $39.9 million and $88.8 million for the fourth quarter and full year of 2023, respectively
- Approximately 3200 BRIUMVI prescriptions received by the TG Therapeutics hub since launch, from approximately 640 healthcare providers at approximately 400 centers

European Commercialization of BRIUMVI

- Received European Commission (EC) approval of BRIUMVI, for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) who have active disease defined by clinical or imaging features
- Announced an agreement with Neuraxpharm Group (Neuraxpharm) for the ex-U.S. commercialization of BRIUMVI in RMS
- Received approval by the Medicines and Healthcare Products Regulatory Agency (MHRA) for BRIUMVI to treat adult patients with RMS with active disease defined by clinical or imaging features in the United Kingdom (UK)
- Launched BRIUMVI in the first European country, Germany, with our partner, Neuraxpharm

General Business

- Year-end 2023 cash position of $217.5 million
- Entered into a global license agreement with Precision BioSciences, Inc. (Precision) for the development and commercialization of Precision’s allogeneic CD19 CAR T therapy program, azercabtagene zapreleucel (azer-cel), for the treatment of autoimmune disorders and all other non-oncology indications
- Presented the first data from the ENHANCE Phase 3b trial evaluating patients who switch from another CD20 antibody to BRIUMVI
- Obtained three additional patents from the United States Patent and Trademark Office (USPTO) for BRIUMVI, extending patent protection through 2042

2024 Target BRIUMVI Guidance

- BRIUMVI U.S. net product revenue target of approximately $220 million to $260 million for the full year 2024
- Full year 2024 target operating expense of approximately $250 million

2024 Development Pipeline Anticipated Milestones

- Commence clinical development of subcutaneous BRIUMVI
- Commence a trial evaluating BRIUMVI in an additional autoimmune disease outside of multiple sclerosis (MS)

- Commence a trial evaluating azer-cel in autoimmune disease
- Present data from the ENHANCE Phase 3b CD20 switch trial at multiple conferences throughout the year

Financial Results for Fourth Quarter and Full Year 2023

- **Product Revenue, net:** Product revenue, net includes net product sales of BRIUMVI in the U.S. of $39.9 million and $88.8 million for the three and twelve months ended December 31, 2023, respectively. Also included in product revenue, net for the three and twelve months ended December 31, 2023 is $3.2 million of BRIUMVI product revenue for product sold to Neuraxpharm in support of that commercial launch. Product revenue, net for the three and twelve months ended December 31, 2022, consisted of net product sales of UKONIQ™ (umbralisib), which was withdrawn from the U.S. market in May of 2022.

- **License, Milestones and Other Revenue:** License, milestone and other revenue was approximately $0.8 million and $141.7 million for the three and twelve months ended December 31, 2023, respectively, compared to less than $0.1 million and $0.2 million for the three and twelve months ended December 31, 2022, respectively. License, milestone, and other revenue for the twelve months ended December 31, 2023, is primarily related to the $140.0 million one-time payment received from Neuraxpharm in July 2023 upon execution of the agreement for the ex-U.S. commercialization of BRIUMVI in RMS.

- **R&D Expenses:** Total research and development (R&D) expense was $17.4 million and $76.2 million for the three and twelve months ended December 31, 2023, respectively, compared to $29.6 million and $125.4 million for the three and twelve months ended December 31, 2022, respectively. The decrease in R&D expense is primarily attributable to reduced clinical trial related expenses, license milestones, manufacturing expense, and lower fees paid to consultants and outside service providers during the twelve months ended December 31, 2023, over the comparable period in 2022. Prior to the approval of BRIUMVI, manufacturing costs pertaining to BRIUMVI were expensed to R&D expense in the period incurred, and following approval are reflected in inventory.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $31.2 million and $122.7 million for the three and twelve months ended December 31, 2023, respectively, and $22.5 million and $70.0 million for the three and twelve months ended December 31, 2022, respectively. The increase was primarily due to non-cash compensation SG&A expenses incurred, and other costs, including personnel and consultants, associated with the commercialization of BRIUMVI during the three and twelve months ended December 31, 2023.

- **Net Loss/Net Income:** Net loss was $14.4 million for the three months ended December 31, 2023 and net income was $12.7 million for the twelve months ended December 31, 2023, compared to net loss of $53.0 million and $198.3 million for the three and twelve months ended December 31, 2022, respectively.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $217.5 million as of December 31, 2023. We anticipate that our cash, cash equivalents and investment securities as of December 31, 2023, combined with projected revenues from BRIUMVI, will be sufficient to fund the Company's planned operations into cash flow positivity based on the current operating plan.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, February 28, 2024, at 8:30 AM ET, to discuss the Company's financial results from the fourth quarter and full year ended December 31, 2023.

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 US 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 commercial launch 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; 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, launch, market and sell BRIUMVI; the risk that early trends in prescriptions are not maintained or that prescriptions are not filled; the failure to obtain and maintain payor coverage; the risk that early 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 BRIUMVI launch 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 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 commencing 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 or December 31, 2022 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 December 31,		Twelve months ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue				
Product revenue, net	$ 43,137	$ 42	$ 92,005	$ 2,633
License, milestone and other revenue	834	38	141,657	152
Total revenue	43,971	80	233,662	2,785
Costs and expenses:				
Cost of revenue	7,855	3	14,131	265
Research and development:				
Noncash compensation	2,848	5,753	13,010	13,224
Other research and development	14,601	23,882	63,182	112,128
Total research and development	17,449	29,635	76,192	125,352
Selling, general and administrative:				
Noncash compensation	6,537	5,298	24,923	5,961
Other selling, general and administrative	24,615	17,206	97,783	64,046
Total selling, general and administrative	31,152	22,504	122,706	70,007
Total costs and expenses	56,456	52,142	213,029	195,624
Operating income (loss)	(12,485)	(52,062)	20,633	(192,839)
Other expense (income):				
Interest expense	2,432	2,862	12,615	10,191
Other income	(891)	(1,930)	(5,044)	(4,695)
Total other expense, net	1,541	932	7,571	5,496
Net income (loss) before taxes	$ (14,026)	$ (52,994)	$ 13,062	$ (198,335)
Income taxes	390	-	390	-
Net income (loss)	$ (14,416)	$ (52,994)	$ 12,672	$ (198,335)
Net income (loss) per common share:				
Basic	$ (0.10)	$ (0.39)	$ 0.09	$ (1.46)
Diluted	$ (0.09)	$ (0.39)	$ 0.09	$ (1.46)
Weighted average common shares outstanding:				
Basic	143,092,594	137,108,759	141,955,112	135,411,258
Diluted	156,091,786	137,108,759	148,508,465	135,411,258

Condensed Balance Sheet Information (in thousands):

	December 31, 2023 (Unaudited)	December 31, 2022*
Cash, cash equivalents and investment securities	217,508	174,082
Total assets	329,587	193,572
Accumulated deficit	(1,514,361)	(1,527,033)
Total equity	160,502	58,587

* Condensed from audited financial statements