TG Therapeutics Provides Business Update and Reports First Quarter 2023 Financial Results

May 1, 2023

First quarter 2023 BRIUMVI net sales of $7.8 million

Over 400 BRIUMVI prescriptions in the first partial quarter from 165+ healthcare providers at 125+ centers

Payor coverage in place for over 50% of covered lives for BRIUMVI

Conference call to be held today, Monday, May 1, 2023, at 8:30 AM ET

NEW YORK, May 01, 2023 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the first quarter ended March 31, 2023, along with recent company developments, and a business outlook for 2023.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, “2023 is off to an exciting start for us at TG. With the U.S. approval and commercial launch of BRIUMVI, we are excited to be able to offer patients the first and only anti-CD20 monoclonal antibody approved for relapsing forms of multiple sclerosis that can be administered in a one-hour infusion, twice a year, following the starting dose, which are some of the attributes that support our belief in BRIUMVI’s best-in-class potential in multiple sclerosis. It’s gratifying to see that the pre-launch enthusiasm for BRIUMVI is translating into the commercial setting and the feedback we have heard from both healthcare providers and patients has been highly encouraging.” Mr. Weiss continued, “Overall, I believe our team is doing a fantastic job and I am pleased to share that in our first partial quarter, essentially two months of commercial availability, we generated approximately $8 million in net sales. The early launch of BRIUMVI has exceeded our internal expectations, and we believe the momentum will continue to build throughout the year.”

Recent Highlights & Developments for BRIUMVI®(ublituximab-xiiy)

- Received U.S. Food and Drug Administration (FDA) approval of BRIUMVI, for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, on December 28, 2022.
- Commercially launched BRIUMVI in the U.S. on January 26, 2023, making it available for patients and physicians.
- Achieved $7.8M in BRIUMVI net sales for the first partial launch quarter, and have payor coverage policies in place for over 50% of covered lives across the U.S.
- Over 400 BRIUMVI prescriptions in the first partial quarter from more than 165 healthcare providers at more than 125 centers.
- Received notification that the U.S. Centers for Medicare & Medicaid Services (CMS) has issued a permanent J-Code (J2329) for BRIUMVI, which will become effective July 1, 2023.
- Received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending the approval of BRIUMVI for the treatment of adult RMS patients with active disease defined by clinical or imaging features.
- Presented additional data, including new analyses, from the ULTIMATE I and II Phase 3 trials at the 2023 Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) annual forum and the American Academy of Neurology (AAN) 75th Annual Meeting.

Key Objectives for 2023

- Continue to build upon the commercial launch of BRIUMVI in RMS
- Obtain broad payor coverage for BRIUMVI
- Continue to present additional data from the ULTIMATE I & II Phase 3 trials of BRIUMVI in RMS

Financial Results for the Three Months Ended March 31, 2023

- **Product Revenue, Net:** Product revenue, net was approximately $7.8 million for the three months ended March 31, 2023, compared to $2.0 million for the three months ended March 31, 2022. Product revenue, net for the three months ended March 31, 2023, consisted of net product sales of BRIUMVI in the United States, which was commercially launched in late January 2023. Product revenue, net for the three months ended March 31, 2022, consisted of net product sales of UKONIQ™ (umbralisib), which was withdrawn from the U.S. market in May of 2022.

- **R&D Expenses:** Total research and development (R&D) expense was $15.9 million for the three months ended March 31, 2023, compared to $48.0 million for the three months ended March 31, 2022. The decrease in R&D expense was primarily attributable to reduced manufacturing expense, clinical trial related expenses, and decreased headcount during the three

months ended March 31, 2023. 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 $28.1 million for the three months ended March 31, 2023, compared to $20.6 million for the three months ended March 31, 2022. The increase was due primarily to approximately $5.2 million in non-cash compensation SG&A expenses incurred during the first quarter of 2023, and other costs, including personnel, associated with the approval of BRIUMVI during the three months ended March 31, 2023.

- **Net Loss:** Net loss was $39.2 million for the three months ended March 31, 2023, compared to $69.0 million for the three months ended March 31, 2022. Excluding non-cash compensation, the net loss for the three months ended March 31, 2023, was approximately $32.4 million, compared to a net loss of $66.9 million for the three months ended March 31, 2022.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $139.7 million as of March 31, 2023. We anticipate that our cash, cash equivalents and investment securities as of March 31, 2023, combined with $20.0 million of available capacity under our existing term loan facility and projected revenues, will be sufficient to fund our planned operations into mid-2024.

CONFERENCE CALL INFORMATION
The Company will host a conference call today, May 1, 2023, at 8:30 AM ET, to discuss the Company's financial results from the first quarter, ended March 31, 2023, and provide a business outlook for the remainder of 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 for the treatment of adults with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

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

IMPORTANT SAFETY INFORMATION
Contraindications: BRIUMVI is contraindicated in patients with:

- Active HBV 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, JCV 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.

ABOUT BRIUMVI PATIENT SUPPORT
BRIUMVI Patient Support is a flexible program designed by TG Therapeutics to support 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 has received approval from the U.S. FDA for BRIUMVI® (ublituximab-xiiy), for the treatment of adult patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and on LinkedIn.

Cautionary Statement
This press release contains forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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 our commercial launch and availability of BRIUMVI® (ublituximab-xiiy) for relapsing forms of multiple sclerosis (RMS); anticipated healthcare professional and patient acceptance and use of BRIUMVI for the FDA-approved indications, and statements regarding the results of the ULTIMATE I & II Phase 3 studies and BRIUMVI as a potential treatment for RMS.

Additional factors that could cause our actual results to differ materially include the following: the Company’s ability to establish and 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 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; and general political, economic and business conditions, including the risk that the ongoing COVID-19 pandemic could have on the safety profile of BRIUMVI and any of our other drug candidates as well as any government control measures associated with COVID-19 that could have an adverse impact on our research and development plans or commercialization efforts. 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, 2022 and in our other filings with the U.S. Securities and Exchange Commission.

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,	
	2023	**2022**
Revenue		
Product revenue, net	$ 7,765	$ 1,978
License revenue	38	38
Total revenue	7,803	2,016
Costs and expenses:		
Cost of product revenue	857	237
Research and development:		
Noncash compensation	1,584	1,895
Other research and development	14,286	46,147
Total research and development	15,870	48,042
Selling, general and administrative:		
Noncash compensation	5,240	226
Other selling, general and administrative	22,828	20,383
Total selling, general and administrative	28,068	20,609
Total operating expenses	44,795	68,888
Operating loss	(36,992)	(66,872)
Other expense (income):		
Interest expense	2,844	2,664
Other income	(604)	(523)

Total other expense (income), net	2,240	2,141
Consolidated net loss	$ (39,232)	$ (69,013)
Net loss per common share:		
Basic and diluted	$ (0.28)	$ (0.51)
Weighted average shares used in computing basic and diluted net loss per common share	140,312,269	134,400,500

Condensed Balance Sheet Information (in thousands):

	March 31, 2023 (Unaudited)	December 31, 2022*
Cash, cash equivalents and investment securities	139,710	174,082
Total assets	197,358	193,572
Accumulated deficit	(1,566,265)	(1,527,033)
Total equity	27,433	58,587

* Condensed from audited financial statements