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

August 1, 2023

Second quarter 2023 BRIUMVI® net sales of $16 million in the United States, representing 100% quarter over quarter growth; total net revenue of approximately $24 million since launch

Over 1,200 BRIUMVI prescriptions since launch from 340+ healthcare providers at 225+ centers across the U.S.

Payor coverage in place for approximately 80% of covered lives for BRIUMVI

Agreement with Neuraxpharm for the ex-U.S. commercialization of BRIUMVI in RMS strengthens balance sheet with pro-forma cash balance, inclusive of the upfront payment, of approximately $285 million

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

NEW YORK, Aug. 01, 2023 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the second quarter ended June 30, 2023, along with recent company developments, and a business outlook for 2023.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, “We are pleased to report our second quarter 2023 results, representing our first full quarter of BRIUMVI sales, which exceeded our expectations. It’s been gratifying to see BRIUMVI adopted by such a broad range of MS centers and providers so early into our launch and we are humbled when we hear positive feedback on patients’ experience with BRIUMVI. With its glycoengineering for efficient B-cell depletion, lowest reported annualized relapse rates of any CD20 agent in RMS Phase 3 trials and rapid and reliable 1-hour infusion, a number of providers have already made BRIUMVI their CD20 of choice in RMS. I believe our quarterly performance showcases the unwavering dedication of our team, and the potential of BRIUMVI, to improve the lives of patients with MS.” Mr. Weiss continued, “With an ex-U.S. partner in place, we can continue to focus our now enhanced resources on our U.S. commercial launch. I believe our team has executed well on our early launch plan and we are looking forward to building on this momentum as we move forward with the next phase of our launch strategy.”

Recent Highlights & Developments

United States (U.S.) Commercialization of 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, and commercially launched BRIUMVI in the U.S. on January 26, 2023, making it available for patients and physicians.
- Achieved $16 million in BRIUMVI net sales for the second quarter 2023, total net product revenue of $23.8 million since launch.
- Secured payor coverage policies for approximately 80% of covered lives across the U.S.
- Over 800 BRIUMVI prescriptions in the second quarter of 2023, marking over 1200 prescriptions since launch, from more than 340 healthcare providers at more than 225 centers.
- Received a permanent J-Code (J2329) for BRIUMVI from the U.S. Centers for Medicare & Medicaid Services (CMS), which became effective July 1, 2023.

European Commercialization of BRIUMVI

- Received European Commission (EC) approval of BRIUMVI, for the treatment of adult patients with RMS who have active disease defined by clinical or imaging features, on June 1, 2023.
- Announced an agreement with Neuraxpharm for the ex-U.S. commercialization of BRIUMVI in RMS today, August 1, 2023. Agreement terms include a total deal size of $645 million with over $150 million in upfront and near-term milestones, tiered double-digit royalties up to 30% and an option to buy-back all rights under the commercialization agreement for a period of two years in the event of an acquisition of TG.

General Business

- Strengthened our cash position with current pro-forma cash of approximately $285 million.
- Presented additional data, including new analyses, from the ULTIMATE I and II Phase 3 trials at the 2023 Consortium of Multiple Sclerosis Centers (CMSC) annual meeting.

Key Objectives for 2023

- Continue to build upon the U.S. commercial launch of BRIUMVI in RMS
- Continue to increase access to BRIUMVI
- Continue to generate and present additional clinical trial data for BRIUMVI in RMS

Financial Results for the Three and Six Months Ended June 30, 2023

- **Product Revenue, Net:** Product revenue, net was approximately $16.0 million and $23.8 million for the three and six months ended June 30, 2023, compared to $0.6 million and $2.5 million for the three and six months ended June 30, 2022. Product revenue, net for the three and six months ended June 30, 2023, consisted of net product sales of BRIUMVI in the U.S., which was commercially launched in late January 2023. Product revenue, net for the three and six months ended June 30, 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 $28.1 million and $44.0 million for the three and six months ended June 30, 2023, compared to $26.9 million and $74.9 million for the three and six months ended June 30, 2022. The decrease in R&D expense during the six months ended June 30, 2023 was primarily attributable to reduced manufacturing expense and clinical trial related expenses, offset by an increase in license milestone expense of approximately $6.0 million during the six months ended June 30, 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 $30.7 million and $58.8 million for the three and six months ended June 30, 2023, compared to $12.6 million and $33.2 million for the three and six months ended June 30, 2022. The increase was primarily due to non-cash compensation SG&A expenses incurred, and other costs, including personnel, associated with the commercialization of BRIUMVI during the three and six months ended June 30, 2023.
- **Net Loss:** Net loss was $47.6 million and $86.8 million for the three and six months ended June 30, 2023, compared to $40.5 million and $109.5 million for the three and six months ended June 30, 2022. Excluding non-cash compensation, the net loss for the three and six months ended June 30, 2023, was approximately $35.1 million and $67.5 million, compared to a net loss of $41.5 million and $108.4 million for the three and six months ended June 30, 2022.
- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $144.9 million as of June 30, 2023. We anticipate that our cash, cash equivalents and investment securities as of June 30, 2023, combined with the upfront payment of $140.0 million received as part of our ex-U.S. commercialization agreement and projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will be sufficient to fund our planned operations for the foreseeable future.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, August 1, 2023, at 8:30 AM ET, to discuss the Company's financial results from the second quarter, ended June 30, 2023, the Neuraxpharm ex-U.S. commercialization agreement, 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 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, 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.

The full SmPC approved in the 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 has received U.S. Food and Drug Administration (FDA) approval for BRIUMVI® (ublituximab-xiiy), for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, as well as European Commission (EC) approval 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 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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenue				
Product revenue, net	16,036	$556	23,801	2,534

License revenue	38	38	76	76
Total revenue	16,074	594	23,877	2,610
Costs and expenses:				
Cost of product revenue	1,911	23	2,768	260
Research and development:				
Noncash compensation	5,664	2,328	7,247	4,223
Other research and development	22,458	24,546	36,744	70,693
Total research and development	28,122	26,874	43,991	74,916
Selling, general and administrative:				
Noncash compensation	6,877	(3,304)	12,117	(3,077)
Other selling, general and administrative	23,838	15,942	46,666	36,324
Total selling, general and administrative	30,715	12,638	58,783	33,247
Total operating expenses	60,748	39,535	105,542	108,423
Operating loss	(44,674)	(38,941)	(81,665)	(105,813)
Other expense (income):				
Interest expense	3,627	3,017	6,471	5,681
Other income	(691)	(1,448)	(1,295)	(1,971)
Total other expense (income), net	2,936	1,569	5,176	3,710
Consolidated net loss	$(47,610)	$(40,510)	$(86,841)	$(109,523)
Net loss per common share:				
Basic and diluted	$(0.34)	$(0.30)	$(0.62)	$(0.81)
Weighted average shares used in computing basic and diluted net loss per common share	141,503,738	137,779,904	140,911,295	134,591,250

Condensed Balance Sheet Information (in thousands):

	June 30, 2023 (Unaudited)	**December 31, 2022***
Cash, cash equivalents and investment securities	144,905	174,082
Total assets	220,854	193,572
Accumulated deficit	(1,613,875)	(1,527,033)
Total equity	40,453	58,587

* Condensed from audited financial statements