TG Therapeutics Announces European Launch of BRIUMVI® (ublituximab-xiiy)

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Ex-US partner, Neuraxpharm, launches BRIUMVI in Germany, the first European country

NEW YORK, Feb. 26, 2024 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) (TG Therapeutics) today announced that its ex-US partner, Neuraxpharm Group (Neuraxpharm), a leading European specialty pharmaceutical company focused on the treatment of central nervous system (CNS) disorders, launched BRIUMVI® (ublituximab-xiiy) in Europe, for the treatment of adults patients with relapsing forms of multiple sclerosis (RMS), who have active disease defined by clinical or imaging features. The launch commenced in Germany, with additional launches throughout Europe to follow. In accordance with the ex-US commercialization agreement, TG Therapeutics will receive a milestone payment of $12.5 million for the first launch of BRIUMVI in a European country.

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics, stated, “We want to congratulate our partner, Neuraxpharm, on the official launch of BRIUMVI in Europe. This is an exciting day for patients in Europe with RMS, and we look forward to sharing additional updates as the European launch progresses.”

BRIUMVI is currently approved and commercially available in the US for patients with RMS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. BRIUMVI has also been approved by the European Commission (EC) and the Medicines and Healthcare Products Regulatory Agency (MHRA) to treat adult patients with RMS who have active disease defined by clinical or imaging features in the European Union (EU) and the United Kingdom (UK), respectively. TG Therapeutics entered into an agreement with Neuraxpharm (the commercialization agreement) for the ex-US commercialization of BRIUMVI® in August 2023.

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 European Union (EU) for the treatment of adult patients with RMS with active disease defined by clinical or imaging features.

Highlights from the EU Label for BRIUMVI®
In the EU, BRIUMVI is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

CONTRAINDICATIONS:

- Hypersensitivity to the active substance or to any of the excipients
- Severe active infection
- Patients in a severely immunocompromised state
- Known active malignancies

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Traceability: The name and the batch number of the administered product should be clearly recorded.

Infusion-related reactions (IRRs): Symptoms of IRR may include pyrexia, chills, headache, tachycardia, nausea, abdominal pain, throat irritation, erythema, and anaphylactic reaction.

Patients should premedicate with a corticosteroid and an antihistamine to reduce the frequency and severity of IRRs. The addition of an antipyretic (e.g., paracetamol) may also be considered. Patients treated with ublituximab should be observed during infusions. Patients should be monitored for at least one hour after the completion of the first two infusions. Subsequent infusions do not require monitoring post-infusion unless IRR and/or hypersensitivity has been observed. Physicians should inform patients that IRRs can occur up to 24 hours after the infusion.

Infections: Administration must be delayed in patients with an active infection until the infection is resolved.

It is recommended to verify the patient’s immune status before dosing since severely immunocompromised patients (e.g., significant neutropenia or lymphopenia) should not be treated. Ublituximab has the potential for serious, sometimes life-threatening or fatal, infections. Most of the serious infections that occurred in controlled clinical trials in RMS resolved. There were 3 infection-related deaths that occurred, all in patients treated with ublituximab; the infections leading to death were post-measles encephalitis, pneumonia, and postoperative salpingitis following an ectopic pregnancy.

Progressive Multifocal Leukoencephalopathy (PML): John Cunningham virus (JCV) infection resulting in PML has been observed very rarely in patients treated with anti-CD20 antibodies and mostly associated with risk factors (e.g., patient population, lymphopenia, advanced age, polytherapy with immunosuppressants). Physicians should be vigilant for the early signs and symptoms of PML, which can include any new onset, or worsening of

neurological signs or symptoms, as these can be similar to MS disease.

If PML is suspected, dosing with ublituximab must be withheld. Evaluation including Magnetic Resonance Imaging (MRI) scan preferably with contrast (compared with pre-treatment MRI), confirmatory cerebro-spinal fluid (CSF) testing for JCV Deoxyribonucleic acid (DNA) and repeat neurological assessments, should be considered. If PML is confirmed, treatment must be discontinued permanently.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, has been observed in patients treated with anti-CD20 antibodies.

HBV screening should be performed in all patients before initiation of treatment as per local guidelines. Patients with active HBV (i.e., an active infection confirmed by positive results for HBsAg and anti HB testing) should not be treated with ublituximab. Patients with positive serology (i.e., negative for HBsAg and positive for HB core antibody (HBcAb +) or who are carriers of HBV (positive for surface antigen, HBsAg+) should consult liver disease experts before starting the treatment and should be monitored and managed following local medical standards to prevent hepatitis B reactivation.

Vaccinations: The safety of immunisation with live or live-attenuated vaccines, during or following therapy has not been studied and vaccination with live-attenuated or live vaccines is not recommended during treatment and not until B-cell repletion. All immunisations should be administered according to immunisation guidelines at least 4 weeks prior to treatment initiation for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to treatment initiation for inactivated vaccines.

Vaccination of infants born to mothers treated with ublituximab during pregnancy: In infants of mothers treated with ublituximab during pregnancy, live or live-attenuated vaccines should not be administered before the recovery of B-cell counts has been confirmed. Depletion of B cells in these infants may increase the risks associated with live or live-attenuated vaccines. Measuring CD19-positive B-cell levels, in neonates and infants, prior to vaccination is recommended.

Inactivated vaccines may be administered as indicated prior to recovery from B-cell depletion. However, assessment of vaccine immune responses, including consultation with a qualified specialist, should be considered to determine whether a protective immune response was mounted. The safety and timing of vaccination should be discussed with the infant's physician.

Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

UNDESIRABLE EFFECTS

Summary of the safety profile: The most important and frequently reported adverse reactions are IRRs (45.3%) and infections (55.8%).

The full Summary of Product Characteristics approved in the EU can be consulted in: Briumvi | European Medicines Agency (europa.eu).

Please visit www.briumvi.com for U.S. Important Safety Information for BRIUMVI or please see U.S. Full Prescribing Information.

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 (RMS), 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 the European Union (EU) and the United Kingdom (UK), 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 continuing success of BRIUMVI® (ublituximab-xiiy) for RMS in the US markets, the timing and success of our commercial launch and availability of BRIUMVI for RMS in the EU and other ex-US markets; anticipated healthcare professional and patient acceptance and use of BRIUMVI for either the indication of use approved by the FDA or those approved by the EC; statements regarding the results of the ULTIMATE I & II Phase 3 studies; statements regarding the Company's beliefs about the benefits that BRIUMVI could provide to RMS patients; and statements regarding the Company's expectations regarding future sales of BRIUMVI and the outcome of continuing studies, potential future approvals, and sales of BRIUMVI, and the related impact on the potential sales-based milestone payments under the commercialization agreement, and the Company's and Neuraxpharm's plans and expectations for the

launch and impact of BRIUMVI in the EU.

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, market and sell BRIUMVI in the US or the EU; 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 healthcare provider interest in BRIUMVI will not be sustained; the risk that momentum in US sales for BRIUMVI will not build or remain consistent; the risk that the US BRIUMVI launch does not continue to exceed expectations; the risk that the EU BRIUMVI launch does not meet or 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. and the EU; 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 possible occurrence of any event, change, or other circumstance or condition that could give rise to the termination of the commercialization agreement or other material agreements; the potential for litigation relating to the commercialization of BRIUMVI; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the commercialization agreement or any other proposed transaction; the risk that the Company will not receive some or all of the potential sales-based milestone payments owed; and general political, economic, and business conditions 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.