TG Therapeutics Announces Positive Results from Phase 1 Trial Evaluating Subcutaneous BRIUMVI® (ublituximab-xiiy)

June 3, 2026

Pharmacokinetic and pharmacodynamic data support quarterly subcutaneous BRIUMVI dosing regimen currently under evaluation in fully enrolled Phase 3 trial; Top-line Phase 3 data expected year-end 2026 or early 2027

Novel Investigational high concentration subcutaneous formulation of BRIUMVI was well-tolerated with no new safety signals observed

NEW YORK, June 03, 2026 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) (the “Company” or “TG Therapeutics”), today announced positive pharmacokinetic (PK), pharmacodynamic (PD), safety, and tolerability data from its Phase 1 clinical trial evaluating subcutaneous formulation of ublituximab (the active agent in BRIUMVI®) as compared to IV BRIUMVI.

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics, stated, “We are very pleased to report these positive Phase 1 results demonstrating that our proprietary high-concentration, low-volume subcutaneous formulation of BRIUMVI was well tolerated and achieved sustained drug exposure. Importantly, these data strengthen our confidence that the quarterly subcutaneous dosing regimen, currently being evaluated in the ongoing Phase 3 study, can achieve its primary endpoint.”

Mr. Weiss continued, “If approved, subcutaneous BRIUMVI would be the first and only self-administered, at-home, quarterly anti-CD20 therapy for people living with multiple sclerosis, significantly reducing the total number of injections per year as compared to currently available options. Strategically, given the distinct nature of the self-administered portion of the anti-CD20 market, a subcutaneous option could nearly double the addressable market opportunity for the BRIUMVI franchise. We look forward to reporting Phase 3 data later this year or early next year and, if successful, advancing toward a potential approval in 2028.”

KEY FINDINGS FROM THE PHASE 1 SUBCUTANEOUS BRIUMVI TRIAL

Design:

The Phase 1 trial is evaluating the bioavailability, pharmacokinetics (PK), pharmacodynamics (PD), safety, and tolerability of a high-concentration (400 mg/2 mL) subcutaneous formulation of BRIUMVI compared to the currently approved intravenous (“IV”) formulation. To date, over 100 patients have been treated in the trial, including more than 80 patients who received subcutaneous BRIUMVI across multiple dose levels (50 mg – 400 mg) in single and multiple dose cohorts. More than 225 subcutaneous injections of BRIUMVI were administered, of which over 75% were 400 mg (2 mL) injections.

Bioavailability/Pharmacokinetics (Drug Exposure):

- The overall concentration-time profile of subcutaneous BRIUMVI was consistent with expectations for a subcutaneous formulation, with a gradual absorption phase and lower peak concentrations relative to IV, and linear pharmacokinetics were observed over the entire dose range evaluated.
- Subcutaneous BRIUMVI demonstrated mean bioavailability of greater than 60% relative to IV administration, with the lower bound of the 95% confidence interval exceeding 55%.
- PK modeling and simulation informed by the Phase 1 bioavailability data support the conclusion that:
    - the quarterly subcutaneous dosing regimen that is being evaluated in the Phase 3 trial would achieve non-inferior total drug exposure over 24 weeks (AUC 0-Wk24) with an estimated geometric mean ratio (GMR) of 1.21 (with a lower bound of the 90% confidence interval at 1.15), as compared to IV BRIUMVI
    - the every other month subcutaneous dosing regimen that is also being evaluated in the Phase 3 trial, would achieve non-inferior total drug exposure over 24 weeks (AUC 0-Wk24) with an estimated GMR of 1.58 (with a lower bound of the 90% confidence interval at 1.50), as compared to IV BRIUMVI
    - The lower bound of the 90% confidence intervals for both dosing regimens being evaluated in Phase 3 would exceed the threshold required to establish non-inferiority (>0.80), which is the primary endpoint of the ongoing Phase 3 trial.

Pharmacodynamics (Biologic Activity):

- Treatment with subcutaneous BRIUMVI resulted in B-cell depletion consistent with IV BRIUMVI, supporting the biological activity of the subcutaneous formulation.

Safety & Tolerability:

- Subcutaneous administration was generally well tolerated, with treatment-emergent adverse events (TEAEs) consistent with the known safety profile of IV BRIUMVI.

- Local injection-site reactions were infrequent, occurring in less than 5% of patients, and systemic injection-related reactions occurred in approximately 21% of patients. Local and systemic injection reactions were not dose dependent and predominantly occurred at the first injection and resolved in 100% of patients.
- No serious injection-site reactions and no new safety signals were observed.

Conclusion:
The Phase 1 data, including the observed safety profile and modeled PK results, support the quarterly subcutaneous dosing regimen being evaluated in the Phase 3 trial.

The Phase 3 dose of 400 mg in a 2mL injection is consistent with a volume that is suitable for at-home self-administration via an autoinjector device, which will be evaluated in a separate device bridging study to commence later this year.

Final data through 24-weeks from this Phase 1 trial are expected to be presented at a future medical meeting.

ABOUT THE PHASE 3 SUBCUTANEOUS BRIUMVI TRIAL

The Phase 3 trial is a randomized, open-label, parallel-group, multicenter trial designed to evaluate a quarterly and every other month dosing regimen of subcutaneous BRIUMVI compared to the approved IV regimen of BRIUMVI in adults with RMS.

The primary endpoint of the Phase 3 trial is to demonstrate non-inferior drug exposure (levels in the blood) after administration of subcutaneous BRIUMVI compared to IV BRIUMVI over 24 weeks. Overall drug exposure for each arm is measured by area under the serum concentration-time curve from baseline through Week 24 (AUC 0-Wk24). AUC values within each treatment arm are summarized using geometric means and then compared between treatment arms using a ratio of those geometric means (GMR). Non-inferiority is achieved if the lower bound of the 90% confidence interval for the GMR of subcutaneous BRIUMVI relative to IV BRIUMVI is >0.80.

Secondary endpoints include additional pharmacokinetic parameters, pharmacodynamics, safety, and radiological effects.

Participants in the Phase 3 trial were randomized into one of three treatment arms:

Arm A — IV BRIUMVI (approved regimen):
150 mg on Day 1 and 450mg on Day 15, Week 24 and every 24 weeks thereafter
Total dose administered through Week 24: **600 mg**

Arm B — Subcutaneous BRIUMVI (every-other-month dosing):
400 mg administered on Day 1, Day 15, Week 8, and every 8 weeks thereafter
Total dose administered through Week 24: **1,600 mg**

Arm C — Subcutaneous BRIUMVI (quarterly dosing):
400 mg administered on Day 1 and 15, and Week 12, and every 12 weeks thereafter
Total dose administered through Week 24: **1,200 mg**

The Phase 3 trial has completed enrollment, and topline results are expected in late 2026 or early 2027.

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 several non-U.S. jurisdictions 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 HB surface antigen (HBsAg) and anti-HB tests. For patients who are negative for 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): PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. JCV infection resulting in PML has been observed in patients treated with anti-CD20 antibodies, including BRIUMVI, 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. 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.

Liver Injury: Clinically significant liver injury, without findings of viral hepatitis, has been reported in the postmarketing setting in patients treated with anti-CD20 B-cell depleting therapies approved for the treatment of MS, including BRIUMVI. Signs of liver injury, including markedly elevated serum hepatic enzymes with elevated total bilirubin, have occurred from weeks to months after administration.

Patients treated with BRIUMVI found to have an alanine aminotransaminase (ALT) or aspartate aminotransferase (AST) greater than 3x the upper limit of normal (ULN) with serum total bilirubin greater than 2x ULN are potentially at risk for severe drug-induced liver injury. Obtain liver function tests prior to initiating treatment with BRIUMVI, and monitor for signs and symptoms of any hepatic injury during treatment. Measure serum aminotransferases, alkaline phosphatase, and bilirubin levels promptly in patients who report symptoms that may indicate liver injury, including new or worsening fatigue, anorexia, nausea, vomiting, right upper abdominal discomfort, dark urine, or jaundice. If liver injury is present and an alternative etiology is not identified, discontinue BRIUMVI.

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, biotechnology company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline, TG Therapeutics has received approval from the U.S. Food and Drug Administration (FDA) for BRIUMVI® (ublituximab-xiiy) to treat adult patients with relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, as well as approval from several regulatory agencies outside of the U.S. 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 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. All statements contained in this press release other than statements of historical facts, including statements regarding our future results of operations and financial position, our strategic and financial initiatives, our business strategy, and objectives for future operations may constitute forward-looking statements. 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 our plans, business strategies and operations related to the commercialization of BRIUMVI® (ublituximab-xiiy) for RMS in the United States, or any jurisdictions outside of the United States; anticipated healthcare professional (HCP) and patient acceptance and use of BRIUMVI for the approved indications; expectations of future revenue for BRIUMVI, or TG expenses or profit estimates or targets; expectations and timing for our subcutaneous BRIUMVI program, including feasibility, approvability and commercial acceptance, expectations and timing for our ENHANCE Phase 3b trial combining day 1 and day 15 doses, including, feasibility, approvability and commercial acceptance and impact on BRIUMVI sales, and expectations and timing for any of our pipeline products or programs, including Azer-cel or BRIUMVI in MG.

Additional factors that could cause our actual results to differ materially include the following: the Company's ability to continue to commercialize 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 be sustained during the course of the year; the risk that the commercialization of BRIUMVI 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 variations 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; 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 2026 development pipeline anticipated milestones or goals in the timeframe projected or at all, including (i) completing a pivotal program for subcutaneous ublituximab, (ii) enrolling patients into a trial evaluating BRIUMVI in MG, or (iii) enrolling patients into a trial evaluating azer-cel; the risk that clinical trial data readouts may be delayed due to a number of factors including enrollment, data collection, data maturity or other factors; the risk that despite positive Phase 1 data projecting a positive outcome, that the Phase 3 subcutaneous BRIUMVI program will not meet the primary endpoint, or if it successfully meets the primary endpoint, still will not lead to the approval of subcutaneous BRIUMVI by the FDA or other regulatory authorities or, if approved, will not achieve commercial acceptance; the risk that, if subcutaneous BRIUMVI is approved and achieves commercial acceptance, the anticipated expansion of the addressable market will not be realized; the risk that the Phase 3b ENHANCE trial despite being successful will not lead to an approval by the FDA or achieve commercial acceptance for a consolidated initiation regimen; the risk that we will not move forward with the development of BRIUMVI in MG and Azer-Cel following these preliminary studies; the uncertainties generally inherent in research and development, including the risk that the data from Phase 1 studies, including safety and efficacy, may not be replicated in Phase 3 studies conducted in larger populations with longer follow-up; regulatory developments, legislative actions, executive orders, including the imposition of tariffs and policy changes in the U.S. and other jurisdictions; 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, 2025 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.