



TG Therapeutics Announces Phase 1 Data Evaluating Azer-cel in Progressive Multiple Sclerosis in a Late-Breaking Oral Presentation at MSToronto2026

October 23, 2026

First reported clinical evaluation of an allogeneic CD19-directed CAR T-cell therapy in progressive MS demonstrated an encouraging preliminary safety profile with no high-grade CAR-T associated toxicities observed

89% of evaluable participants (16/19) had stable or improved disability scores at Day 90, despite documented progression prior to enrollment on high-efficacy therapies

NEW YORK--(BUSINESS WIRE)--Oct. 23, 2026-- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced initial results from the Company's Phase 1 study evaluating azercabtagene zapreleucel (azer-cel), an investigational, allogeneic CD19-directed chimeric antigen receptor (CAR) T-cell therapy, in patients with progressive multiple sclerosis (MS). The data represent the first reported clinical evaluation of an allogeneic CD19-directed CAR T-cell therapy in progressive MS and were presented in a late-breaking oral session at MSToronto2026, the 10th Joint Meeting of the Americas and European Committees for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS), being held October 21–23, 2026, in Toronto, Canada.

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics, stated, "These initial azer-cel results are particularly encouraging given that all patients entered the study with progressive disability despite prior treatment with high-efficacy therapies, including anti-CD20 treatment. The safety findings to date, together with evidence of B-cell depletion in both the blood and cerebrospinal fluid, demonstrate biological activity at doses that appear tolerable, while stable or improved disability scores in most subjects provide a potential signal of clinical activity. Of particular interest, five of the 18 evaluable patients experienced improvements in disability scores, including three patients with improvements of two or more points on the EDSS scale, an encouraging early finding in a disease where even slowing progression can represent an important therapeutic advance."

Mr. Weiss continued, "While these results remain preliminary, we believe an off-the-shelf CAR T-cell therapy has the potential to offer a meaningful new treatment option for patients with progressive MS, where substantial unmet need remains. We look forward to continuing dose escalation and evaluating longer-term outcomes, and we are grateful to the patients, their families, and the clinical teams who are making this research possible."

TG PRESENTATION:

[Late-Breaking Oral Presentation: First Clinical Evaluation of an Allogeneic CD19-Directed CAR T-Cell Therapy in Progressive Multiple Sclerosis: Initial Results from the Phase 1 TG-Azercel-101 Study](#)

The presentation includes data from 26 participants with progressive MS treated across six azer-cel dose levels, ranging from 30 million to 500 million CAR T-cells, following bendamustine lymphodepletion. All participants had experienced progression independent of relapse activity (PIRA) within the prior 12 months despite high-efficacy disease-modifying therapy, and all had previously received anti-CD20 therapy. The median baseline EDSS score was 6.0, reflecting substantial disability, with patients typically requiring assistance to walk even relatively short distances. As of the September 3, 2026 data cutoff, median follow-up was 4.9 months, with a range of 0.1 to 15.0 months.

Presentation Highlights:

- Azer-cel demonstrated an encouraging initial safety profile in 26 participants, with no dose-limiting toxicities or high-grade CAR T associated toxicities observed across dose levels including no Grade ≥ 3 cytokine release syndrome (CRS), Grade ≥ 2 immune effector cell-associated neurotoxicity syndrome (ICANS), graft-versus-host disease, immune effector cell-associated hemophagocytic syndrome (IEC-HS) and no Grade ≥ 3 infections.
- Despite documented progression prior to enrollment, EDSS scores were stable or improved in 89% of evaluable participants at Day 90 (16/18) and 88% at Day 180 (7/8). Three participants achieved EDSS improvements of at least 2.0 points at Day 90, including one with a 4.0-point improvement.
- At Day 90, most evaluable participants demonstrated stable or improved walking performance (94%; 16/17), upper extremity function (94%; 17/18) and cognitive processing speed (78%; 14/18), with no gadolinium-enhancing T1 lesions or new or enlarging T2 lesions observed in any of the 22 participants evaluable by MRI.
- Peripheral blood B-cell counts were depleted to below 10 cells/ μ L in 96% of participants (25/26), and cerebrospinal fluid (CSF) samples from 21 participants showed a median reduction in CD19-positive B-cell events of 52.3% at Day 10. B-cell reconstitution was observed as early as Day 42 and favored transitional and naïve populations.

These initial findings are from an ongoing, open-label Phase 1 study and are limited by the small number of participants and short follow-up. Dose escalation and longer-term follow-up are ongoing.

The full data presentation is also available on the Publications page of the Company's website at <https://www.tgtherapeutics.com/publications/>.

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 countries outside of the U.S. 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 \(europa.eu\)](http://Briumvi.EuropeanMedicinesAgency.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 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 including several investigational medicines, TG Therapeutics has received approval from the U.S. Food and Drug Administration (FDA) for BRIUMVI® (ublituximab-xiyy) 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 several foreign nations 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](https://twitter.com/TGTherapeutics) and on [LinkedIn](https://www.linkedin.com/company/tgtherapeutics).

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 the potential safety, efficacy, durability of response and therapeutic benefits of azercabtagene zaprelucel (azer-cel) in progressive multiple sclerosis; its potential to provide an off-the-shelf treatment option; the interpretation and potential implications of the preliminary clinical findings described; and the Company's plans for continued dose escalation, longer-term follow-up and further clinical development of azer-cel. Forward-looking statements are based on management's current expectations and beliefs and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied.

These risks and uncertainties include, without limitation: the preliminary nature of the results from this ongoing, open-label Phase 1 study, which involves a small number of participants, multiple dose levels, limited follow-up and no concurrent control group; the possibility that reported results may change as additional participants are treated, follow-up increases and data are collected, reviewed and analyzed; the risk that observed stabilization or improvements in disability and other clinical measures may not be attributable to azer-cel, may not persist or may not be replicated in additional participants or subsequent studies; the risk that changes in B-cell populations or other biomarkers may not translate into clinical benefit; the potential for serious or previously unobserved adverse events associated with azer-cel, lymphodepleting treatment or their combination to emerge with additional treatment or longer follow-up; and the fact that the absence of certain adverse events in a limited population does not establish safety.

Additional risks include delays or difficulties in enrollment, dose escalation, manufacturing, supply, study conduct or data analysis; reliance on third parties for clinical development and manufacturing; the possibility that regulators may require additional studies, longer follow-up or changes to the development program; the Company's ability to obtain adequate funding and maintain the rights and resources necessary to advance development; and the risk that azer-cel may not obtain regulatory approval or become commercially available. Azer-cel is investigational, and its safety and efficacy have not been established.

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.

Investor Relations

Email: ir@tgtxinc.com

Telephone: 1.877.575.TGTX (8489), Option 4

Media Relations

Email: media@tgtxinc.com

Telephone: 1.877.575.TGTX (8489), Option 6

Source: TG Therapeutics, Inc.