



Kyverna Therapeutics Highlights Promising Updated Clinical Data with Miv-cel in Progressive Multiple Sclerosis at MS Toronto 2026

October 23, 2026

Single-dose miv-cel continues to demonstrate promising clinical benefit in progressive multiple sclerosis, achieving robust CAR T-cell penetration in the central nervous system (CNS) and improving disability scores while removing the need for chronic immunotherapies

Durable results extending beyond two years in the first patient treated

Consistent, well-tolerated safety profile with no high-grade CRS and no cases of ICANS or IEC-HS

RMAT designation granted in treatment of non-active secondary progressive multiple sclerosis (naSPMS); update on development strategy expected by early 2027

EMERYVILLE, Calif., Oct. 23, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical immunology company pioneering transformative therapies for people with neurologic autoimmune diseases, today announced updated data from a Phase 1 investigator-initiated trial (IIT) of miv-cel (mivocabtagene autoleucel, KYV-101) in patients with progressive multiple sclerosis (PMS). The data will be shared today in an oral presentation at MS Toronto 2026, the joint ACTRIMS-ECTRIMS meeting.

"There remains a substantial unmet need for therapies that can meaningfully alter the course of progressive multiple sclerosis," said Jeffrey Dunn, MD, Lily Sarafan Director of Neuroimmunology, Clinical Professor and Chief of Neuroimmunology at Stanford University. "In this early-phase study, miv-cel demonstrated encouraging tolerability, with evidence of CAR T-cell penetration into the central nervous system and biologic findings consistent with an immune reset. Importantly, we also observed sustained improvements in measures of neurologic disability and patient-reported function among evaluable participants. While these preliminary findings require confirmation in larger controlled trials, they provide an important proof of concept that miv-cel may offer a potential novel approach to treating progressive multiple sclerosis."

Stanford Oral Presentation

Title: Safety and Preliminary Efficacy of CD-19 Directed CAR T-Cell Therapy in Progressive Multiple Sclerosis: A Phase 1 Study

Presenter: Jeff Dunn, M.D., Lily Sarafan Director of Neuroimmunology, Clinical Professor and Chief of Neuroimmunology, Stanford University

Date & Time: Friday, October 23, 2026, 11:05 – 11:15 AM ET

Stanford University is conducting an open-label, Phase 1, single-center study of miv-cel in patients with non-relapsing progressive multiple sclerosis, either secondary progressive MS (SPMS) or primary progressive MS (PPMS). Six patients were treated with either 33M (n=3) or 100M (n=3) CAR T-cell dose levels using a bendamustine lymphodepleting (LD) regimen.

The oral presentation features updated data from six patients with available efficacy data from five patients, with follow-up of more than two years in the longest-treated patient. Key highlights include:

Efficacy:

- All five patients with available data demonstrated stable to improved expanded disability status scale scores (EDSS) as of last follow-up, with the majority (4/5) showing sustained clinical benefit through one year.
- Four patients with more than one-year of follow-up sustained improvement without further need for chronic immunotherapies. The first patient treated with miv-cel achieved sustained clinical benefit beyond two years.

Biological activity:

- Robust CAR T-cell expansion detected in peripheral blood and penetration in cerebrospinal fluid (CSF), with peak levels at approximately day 14.
- Complete depletion of CD19-positive peripheral B cells was achieved in all participants, followed by repopulation beginning at month 3, consistent with the emergence of naïve B cells, supporting evidence of immune reset.
- Additional biomarker data, including CSF oligoclonal bands and kappa free light chain, continue to support favorable immunological impact at one year.

Safety:

- Consistent, well-tolerated safety profile with no high-grade CRS and no reported cases of ICANS or IEC-HS.

"We are encouraged by the long-term durability and safety results with miv-cel in progressive multiple sclerosis, which add to the strong body of evidence supporting miv-cel's transformative potential across neurologic autoimmune diseases," said Naji Gehchan, Chief Medical and Development Officer of Kyverna Therapeutics. "The consistent, durable clinical benefit and well-tolerated safety profile observed across our indications are underpinned by miv-cel's unique construct, specifically developed by Kyverna in autoimmune disease to enable immune reset by deeply and broadly depleting B-cells with a single dose. With our RMAT designation, we look forward to working with the FDA on our development plan in progressive multiple sclerosis and providing an update by early 2027."

About miv-cel (mivocabtagene autoleucel, KYV-101)

Miv-cel is a fully human, autologous, CD19-targeting CAR T-cell therapy with CD28 co-stimulation. It is uniquely designed for potency and tolerability

with the potential to achieve deep B-cell depletion, reset the immune system, and deliver durable drug-free, disease-free remission in autoimmune diseases with a single dose. Miv-cel is under investigation for B-cell driven autoimmune diseases and is produced using a well-established, validated manufacturing process. To date, more than 100 patients have been treated with miv-cel across a range of autoimmune diseases, and the clinical data demonstrates a consistent and well-tolerated safety profile.

About Multiple Sclerosis

Multiple sclerosis is a chronic autoimmune disease causing neurodegeneration, in which patients can experience a range of symptoms including blurred vision, slurred speech, tremors, numbness, extreme fatigue, problems with memory and concentration, and, in severe cases, the inability to walk or stand. B cells play a significant role in MS by producing autoantibodies that attack the protective sheath around the nerves, activating T cells, and increasing inflammation. Current disease-modifying treatments for MS aim to reduce the frequency of disease relapse and delay a progression of disability, but the disease remains a chronic condition that will progressively worsen for most patients.

About Kyverna Therapeutics

Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a late-stage clinical immunology company pioneering differentiated therapies with curative potential for neurologic autoimmune diseases. Kyverna's lead autologous CD19-targeting CAR T-cell therapy candidate, miv-cel (mivocabtagene autoleucel, KYV-101), has demonstrated the potential to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases. Kyverna is advancing its potentially first-in-class neuroimmunology franchise with its recently completed registrational trial in stiff person syndrome (SPS) and an ongoing registrational trial for generalized myasthenia gravis (gMG).

Miv-cel has received three FDA Regenerative Medicine Advanced Therapy (RMAT) designations, in SPS, gMG, and non-active secondary progressive multiple sclerosis (naSPMS) based on compelling clinical data and significant unmet need, further reinforcing the therapy's potential across neuroimmunology. Additionally, the Company continues to advance new innovations that broaden access and choice for patients, expanding its leadership position in the field. For more information, please visit <https://kyvernatx.com>.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements." The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Forward-looking statements in this press release include, without limitation, those related to: miv-cel's potential to meaningfully alter the course of, or offer a novel approach to treating, progressive multiple sclerosis; miv-cel's transformative potential across neurologic autoimmune diseases; Kyverna's development plans in progressive multiple sclerosis and expected timing for providing an update on its development strategy for multiple sclerosis; the potential for miv-cel to achieve deep B-cell depletion, reset the immune system, and deliver durable drug-free, disease-free remission in autoimmune diseases with a single dose or to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases; Kyverna's pipeline opportunities; and Kyverna's potentially first-in-class neuroimmunology franchise. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to market conditions; risks related to the timing and outcome of regulatory submissions and interactions with the FDA; the ability to enroll patients in clinical trials on anticipated timelines; the possibility that topline results may change following further analysis or differ from final results; the possibility that results from prior clinical trials, named-patient access activities and preclinical studies may not necessarily be predictive of future results; and other factors discussed in the "Risk Factors" section of Kyverna's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q that Kyverna has filed or may subsequently file with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this press release are based on the current expectations of Kyverna's management team and speak only as of the date hereof, and Kyverna specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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