Kyverna Therapeutics Announces Completion of BLA Submission for Miv-cel in Stiff Person Syndrome and Reports Third Quarter 2026 Financial Results

November 12, 2026

BLA submission for miv-cel in SPS completed with request for priority review

Commercial readiness advancing for potential U.S. launch of miv-cel, which would become the first approved therapy for SPS and first approved CAR-T therapy in autoimmune disease

KYSA-6 Phase 3 gMG trial enrollment on-track for completion in mid-2027

Miv-cel's clinical profile continues to set the benchmark for autoimmune CAR T, demonstrating durable clinical benefit and a consistent, well-tolerated safety profile across multiple neurologic autoimmune indications

EMERYVILLE, Calif., Nov. 12, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical immunology company pioneering transformative therapies for people with neurologic autoimmune diseases, today reported portfolio progress and financial results for the third quarter ended September 30, 2026.

"Kyverna is very proud to submit the first BLA for a CAR T-cell therapy in autoimmune disease, paving the way for a potential new standard of care with a single dose, designed to reset the immune system and free patients from lifelong disease and chronic immunotherapies," said Warner Biddle, Chief Executive Officer of Kyverna. "We believe miv-cel's clinical profile, differentiated construct design and established manufacturing process can support a strong launch in SPS, if approved. We continue to advance our commercial readiness activities by hiring key commercial leaders with deep expertise in CAR T, neurology, and rare disease launches, initiating the critical field infrastructure, and working with treatment centers to prepare for potential patient access. Our progress to date is a testament to the dedication of our employees, investigators, patients, and partners. SPS is our lead indication, but we believe it is only the beginning of a much broader opportunity to transform the treatment paradigm for neurologic autoimmune diseases."

Execution of Miv-cel BLA Submission for SPS Seeking Priority Review

- Kyverna has completed the submission of its rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA), seeking priority review of miv-cel (mivocabtagene autoleucel, KYV-101) in stiff person syndrome (SPS) under its Regenerative Medicine Advanced Therapy (RMAT) designation. The BLA submission is based on a comprehensive positive data package from the KYSA-8 registrational trial in patients with SPS.
- In anticipation of a potential FDA approval and commercial launch in 2027, Kyverna is rapidly progressing launch readiness activities through targeted site activation engagements with CAR-T experts, neurologists and payers, and building an integrated patient support and reimbursement network to streamline the treatment journey. With experienced leaders in place, recruiting efforts continue for a focused group of field-based sales and medical specialists.
- One-year SPS data reported at MS Toronto in October 2026 demonstrated miv-cel reversed disability and achieved durable efficacy across all primary and secondary endpoints, with nearly all patients remaining off chronic immunotherapies with a single dose. In addition, miv-cel continues to demonstrate a consistent and well-tolerated safety profile, with no high-grade cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), and no cases of immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS). The primary analysis from KYSA-8 were recently published in the *Journal of American Medical Association (JAMA) Neurology*, and additional one-year biomarker data from KYSA-8 will be presented at ASH 2026.

Progress in Miv-cel Neuroimmunology Franchise

- **Enrollment On Track in KYSA-6 Registrational Trial for Generalized Myasthenia Gravis (gMG):**
  - Phase 2 longer-term follow up data presented in September 2026 and at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting highlight that miv-cel provided a robust and durable effect for up to 1.5 years, with the majority of patients maintaining minimal symptom expression (MSE) and staying free of chronic immunotherapies after a single dose. In addition, miv-cel demonstrated a consistent and well-tolerated safety profile with no high-grade CRS, no ICANS, and no reported cases of IEC-HS.
  - The robust longer-term follow up data continue to de-risk the Phase 3 gMG trial, with enrollment expected to be completed in mid-2027.
- **Progressive Multiple Sclerosis (PMS):**
  - Updated Phase 1 data from an Investigator-initiated trial (IIT) conducted by Stanford University, which were presented at MS Toronto further supported that miv-cel improved disability scores while achieving robust CAR T penetration in the central nervous system (CNS) without the need for chronic immunotherapies. Durable results were achieved beyond two years in the first patient treated, underscoring the durability of treatment effect achieved with a single dose of miv-cel. Miv-cel continues to be well-tolerated with no high-grade CRS and no reported cases of ICANS or IEC-HS.
  - RMAT designation was granted by the FDA for miv-cel in non-active secondary progressive multiple sclerosis (naSPMS). Kyverna expects to share its development strategy in PMS by early 2027.
- **KYV-102 Program Update:**
  - Kyverna has elected to deprioritize its KYV-102 program as the Company continues to focus on accelerating its late-stage neurologic indications with miv-cel. The Company will continue to advance lifecycle management activities for miv-cel to broaden access for

patients and lower costs.

Financial Results for the Third Quarter Ended September 30, 2026

- Kyverna reported $170.6 million in cash, cash equivalents, and marketable securities as of September 30, 2026, which, in addition to amounts available for draw from the Oxford Finance amended loan facility, is expected to provide operating runway into 2028.
- Research and Development (R&D) expenses were $27.0 million for the third quarter ended September 30, 2026.
- General and Administrative (G&A) expenses were $15.9 million for the third quarter ended September 30, 2026.
- For the third quarter ended September 30, 2026, the Company reported a net loss of $41.9 million, or a net loss per common share of $0.68.

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 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 submitted Biologics License Application (BLA) for miv-cel 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: the potential for miv-cel to be the first FDA-approved treatment for SPS and potential first approved autoimmune CAR-T therapy; the potential for miv-cel to be a new standard of care with a single dose that may reset the immune system to free patients from lifelong disease and chronic immunotherapies; Kyverna's belief that miv-cel's clinical profile, differentiated construct design and established manufacturing process can support a strong launch in SPS; the potential that miv-cel may be approved and potential timing for commercial launch; Kyverna's opportunity to transform the treatment paradigm for neurologic autoimmune diseases; the KYSA-6 Phase 3 trial for gMG and expected timing for completion of enrollment in such trial; Kyverna's readiness for commercial launch of miv-cel in SPS; Kyverna's plans to advance lifecycle management activities for miv-cel to broaden patient access and lower costs; Kyverna's operating runway; Kyverna's potential first-in-class neuroimmunology CAR T franchise; the potential for miv-cel to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases; miv-cel's potential to deliver durable, drug-free, disease-free remission in autoimmune diseases with a single dose; any potential benefits of RMAT designation for miv-cel; and Kyverna's expected upcoming pipeline milestones, including for SPS, gMG, PMS and additional pipeline opportunities. 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; the ability to enroll patients in clinical trials on anticipated timelines; the possibility that results from prior clinical trials, named-patient access activities and preclinical studies may not necessarily be predictive of future results; the possibility that the FDA may not accept the BLA for filing or grant priority review, may require additional data, trials or studies, or may not approve miv-cel on the anticipated timeline or at all; Kyverna's ability to successfully commercialize miv-cel, if approved; intellectual property rights; and other factors discussed in the "Risk Factors" section of Kyverna's previously filed Annual Report on Form 10-K for the year ended December 31, 2025 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2026 to be filed with the U.S. Securities and Exchange Commission on or about the date hereof. 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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Kyverna Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 27,023	$ 30,457	$ 81,884	$ 103,706
General and administrative	15,876	8,270	41,938	26,839
Total operating expenses	42,899	38,727	123,822	130,545
Loss from operations	(42,899)	(38,727)	(123,822)	(130,545)
Interest income	1,680	2,000	5,936	7,189
Interest expense	(728)	(7)	(2,069)	(45)
Other income (expense), net	6	(53)	(33)	(102)

Total other income, net	958	1,940	3,834	7,042
Net loss	(41,941)	(36,787)	(119,988)	(123,503)
Other comprehensive (loss) income				
Unrealized (loss) gain on available-for-sale marketable securities, net	(9)	49	(248)	(76)
Total other comprehensive (loss) income	(9)	49	(248)	(76)
Net loss and other comprehensive loss	$ (41,950)	$ (36,738)	$ (120,236)	$ (123,579)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.68)	$ (0.85)	$ (1.96)	$ (2.85)
Weighted-average shares of common stock outstanding, basic and diluted	61,960,238	43,415,367	61,102,693	43,284,111

Kyverna Therapeutics, Inc.
Condensed Balance Sheets
(in thousands)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	$ 170,572	$ 279,253
Prepaid expenses and other current assets	5,686	3,700
Total current assets	176,258	282,953
Restricted cash	551	551
Operating lease right-of-use assets	7,492	3,568
Other non-current assets	5,136	6,754
Total assets	$ 189,437	$ 293,826
Liabilities and stockholders' equity		
Current liabilities	$ 25,136	$ 36,487
Loan payable, net	24,958	24,743
Other non-current liabilities	6,189	320
Stockholders' equity	133,154	232,276
Total liabilities and stockholders' equity	$ 189,437	$ 293,826