Kyverna Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2024 Financial Results

March 27, 2025

Accelerating clinical path to commercialization in stiff person syndrome, myasthenia gravis and lupus nephritis

Aligned with the U.S. Food and Drug Administration (FDA) on a registrational Phase 2 trial design for ongoing KYSA-8 trial in stiff person syndrome; 70% of study enrolled with topline data expected in 1H 2026;
Biologics License Application (BLA) filing targeted for 2026

Clinical data in myasthenia gravis and lupus nephritis expected in 2H 2025

Strong balance sheet extends cash runway into 2027 through key clinical and regulatory catalysts

EMERYVILLE, Calif., March 27, 2025 /PRNewswire/ -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, today reported its business highlights and financial results for the full year 2024.

"Kyverna's first year as a public company was a transformative one, as we demonstrated our leadership position in autoimmune CAR T. We have treated the most CAR T patients in neuroinflammatory and rheumatologic diseases with our differentiated construct, and our clinical experience to date highlights the potential for profound clinical outcomes in autoimmune patients," said Warner Biddle, Chief Executive Officer of Kyverna. "Kyverna has entered 2025 and its next phase of growth with the right strategy and a strong team in place to advance late-stage development of KYV-101 in our three priority indications – stiff person syndrome, myasthenia gravis and lupus nephritis – each with a clear and rapid path to market. We are pleased with our progress in our lead indication, stiff person syndrome, following alignment with the FDA on our registrational trial, KYSA-8, which is an important milestone as we advance KYV-101 toward its first BLA filing in 2026."

Fourth Quarter 2024 Highlights and Recent Business Updates

KYV-101: *Autologous, fully human CD19 CAR T-cell product candidate, incorporating highly potent CD28 co-stimulation. KYV-101 is currently being evaluated in company-sponsored KYSA trials and investigator-initiated trials in numerous B cell mediated autoimmune diseases with a prioritized focus in stiff person syndrome, myasthenia gravis and lupus nephritis.*

Stiff Person Syndrome (SPS)

- Kyverna has aligned with the FDA on a registrational Phase 2 design for its ongoing KYSA-8 trial in SPS, which has enrolled 70% of study participants. Completion of enrollment is expected in mid-2025.

- The Company expects to report topline data from this study in the first half of 2026 and anticipates submitting its first BLA in 2026. The Company received a Regenerative Medicine Advanced Therapy (RMAT) designation and Orphan Drug Designation from the FDA for this program.

- Kyverna continues to progress its chemistry, manufacturing, and controls (CMC) readiness efforts in support of this anticipated BLA filing and has successfully onboarded ElevateBio to manufacture Kyverna's clinical trial product for KYV-101 in SPS.

Myasthenia Gravis (MG)

- Kyverna's Phase 2 trial in MG, KYSA-6, has completed patient enrollment in an initial 6-patient cohort and the Company plans to report interim data from this cohort in the second half of

2025. The Company continues to engage in positive dialogue with the FDA and plans to provide an update on the registrational path for KYV-101 in the first half of this year.

- The Company received an RMAT Designation and Fast Track Designation from the FDA as well as Orphan Drug Designation from both the FDA and European Medicines Agency for this program.

Lupus Nephritis (LN)

- Kyverna is currently advancing two Phase 1/2 trials in LN, KYSA-1 and KYSA-3. Kyverna has completed the dose-escalation cohort of KYSA-1 and is now treating patients at the target dose and expects to report Phase 1 data from both of these trials in the second half of 2025. The Company has received Fast Track Designation from the FDA for this program.

- In November 2024, Kyverna presented clinical data at American College of Rheumatology (ACR) Convergence 2024 demonstrating positive sustained efficacy and durability at >6-month follow-up observed in patients with severe LN treated with KYV-101 at the target dose.

Additional Indications

- Kyverna is efficiently exploring additional opportunities for KYV-101 beyond the Company's priority indications through sponsored clinical trials and investigator-initiated trials (IITs) across numerous other autoimmune diseases, including systemic sclerosis and multiple sclerosis. Data from these efforts will inform selection of the next priority indication(s) to accelerate into late-stage development.

KYV-102: *Next-generation candidate incorporating our patented fully human CD19 CAR T and the Company's proprietary whole-blood rapid manufacturing approach, which aims to improve the CAR T patient experience, eliminate apheresis and broaden CAR T access.*

- Kyverna expects to file an investigational new drug application for KYV-102 in the second half of 2025.

Corporate Updates

- Strengthened management team with addition of Warner Biddle, Chief Executive Officer; Naji Gehchan, MD, MSc, MBA, Chief Medical and Development Officer; Dan Maziasz, Chief Business Officer; Cara Bauer PhD, Chief Human Resources Officer; and Tracy Rossin, Senior Vice President of Corporate Affairs, Communications and Investor Relations.

- Appointed Christi Shaw and Mert Aktar to the Board of Directors, bringing decades of industry leadership in corporate strategy and manufacturing expertise, including gene and cell therapy.

Anticipated Milestones
Kyverna has issued the following guidance on upcoming program milestones:

- **SPS:**
  - Complete Pivotal Phase 2 Enrollment mid-2025
  - Report Topline Pivotal Phase 2 Data 1H 2026
  - BLA filing in 2026
- **MG:**
  - Confirm Registrational Path with Regulators 1H 2025
  - Report Interim Phase 2 Data 2H 2025
- **LN:**

    - Report Phase 1 Data 2H 2025
- **Future Pipeline:**
    - File KYV-102 IND application 2H 2025

Financial Results for the Year Ended December 31, 2024
Kyverna reported $286.0 million in cash, cash equivalents, and available-for-sale marketable securities as of December 31, 2024. The Company expects this to provide a cash runway into 2027, which is sufficient to achieve key inflection points across its priority indications.

For the year ended December 31, 2024, the Company reported a net loss of $127.5 million, or a net loss per common share of $3.33, compared to a net loss of $60.4 million, or a net loss per common share of $89.61, for the same period in 2023.

During the year ended December 31, 2024, net cash used in operating activities was $114.3 million, compared to $52.4 million for the same period in 2023.

About KYV-101
Uniquely designed, KYV-101 is an autologous, fully human CD19 CAR T-cell product candidate with highly potent CD28 co-stimulation and designed for tolerability, which is under investigation for B-cell-driven autoimmune diseases. With KYV-101, Kyverna is pioneering a durable disease-clearing approach aiming for deep B cell depletion, an immune system reset, and long-term remission in autoimmune diseases.

KYV-101 is currently being evaluated in a company-sponsored, open-label, pivotal Phase 2 trial in stiff person syndrome, a Phase 2 trial in myasthenia gravis and Phase 1/2 trials for lupus nephritis, as well as in investigator-initiated trials and company-sponsored trials for multiple indications. The clinical experience to date with KYV-101 highlights the potential for transformative clinical outcomes in autoimmune patients.

About KYV-102
KYV-102 leverages the same fully human, clinically validated CD19 CAR-T construct as KYV-101. It incorporates the Ingenui-T platform, a proprietary, next-generation process that utilizes whole blood with a rapid manufacturing approach.

Kyverna intends to broaden CAR T patient access with KYV-102 by eliminating the need for apheresis starting material and reducing the manufacturing turnaround time from conventionally manufactured CAR T products.

About Kyverna Therapeutics
Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a clinical-stage biopharmaceutical company focused on liberating patients through the curative potential of cell therapy. Kyverna's lead CAR T-cell therapy candidate, KYV-101, is advancing through clinical development with Phase 2 trials for stiff person syndrome and myasthenia gravis, and two ongoing multi-center Phase 1/2 trials for patients with lupus nephritis. The Company is also harnessing investigator-initiated trials and other KYSA studies, including in multiple sclerosis and systemic sclerosis, to inform the next priority indications for the Company to advance into late-stage development. Its pipeline includes next-generation CAR T-cell therapies in both autologous and allogeneic formats with properties intended to be well suited for use in B cell-driven autoimmune diseases. 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: Kyverna's strategic priorities and focus; the status of its Phase 2 trial in stiff person syndrome as a pivotal trial; the potential for KYV-101 to be the first-to-market in stiff person syndrome; the potential for KYV-102 to improve the patient experience and broaden CAR T access; anticipated milestones and timing thereof, including anticipated timing for the first intended BLA submission for KYV-101 and timing for reporting data as well as expected completion of enrollments; the speed at which any approvals may be obtained; Kyverna's engagement with regulators; Kyverna's anticipated cash runway; and Kyverna's clinical trials, investigator initiated trials and named-patient activities. 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 possibility that the FDA or other regulatory agencies may conclude that Kyverna's Phase 2 trial in stiff person syndrome is not sufficient to be registration-enabling and may require additional trials or studies to support its intended BLA submission; 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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Kyverna Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Year Ended December 31,	
	2024	2023
Operating expenses		
Research and development	$ 112,473	$ 49,923
General and administrative	30,131	12,483
Total operating expenses	142,604	62,406
Loss from operations	(142,604)	(62,406)
Interest income	15,359	2,282
Interest expense	(142)	(187)

Other expense, net	(90)	(55)
Total other income, net	15,127	2,040
Net loss	(127,477)	(60,366)
Other comprehensive income		
Unrealized gain on available-for-sale marketable securities, net	101	30
Total other comprehensive income	101	30
Net loss and other comprehensive loss	$ (127,376)	$ (60,336)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.33)	$ (89.61)
Weighted-average shares of common stock outstanding, basic and diluted	38,334,571	673,622

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

	December 31,	
	2024	**2023**
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	$ 285,979	$ 57,543
Prepaid expenses and other current assets	4,622	3,121
Restricted cash	552	565
Property and equipment, net	3,347	2,326
Operating lease right-of-use assets	6,468	6,494
Finance lease right-of-use assets	841	1,790
Other non-current assets	2,836	3,356
Total assets	$ 304,645	$ 75,195
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities	$ 33,756	$ 19,859
Non-current liabilities	4,302	6,159
Redeemable convertible preferred stock	—	180,574
Stockholders' equity (deficit)	266,587	(131,397)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 304,645	$ 75,195

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