

Kyverna Therapeutics to Highlight Near-Term Strategic Priorities and Key Milestones at the 43rd Annual J.P. Morgan Healthcare Conference

January 13, 2025

Extending Company's leadership position in autoimmune CAR T with prioritized indication strategy; pivoting to late-stage development and commercialization

First-to-market opportunity with KYV-101 in stiff person syndrome; 40% enrolled in pivotal Phase 2 trial with first BLA filing targeted for 2026; fast-follow indications in myasthenia gravis and lupus nephritis

Efficiently expanding into broader autoimmune indications and increasing patient reach with KYV-102 using whole blood rapid manufacturing

Cash runway into 2027 to deliver key milestones

EMERYVILLE, Calif., Jan. 13, 2025 /PRNewswire/ -- Kyverna Therapeutics, Inc. (Kyverna, NASDAQ: KYTX), a clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, announced it will present its 2025 strategic priorities and key milestones during a presentation that will be made by Chief Executive Officer, Warner Biddle, at the 43rd Annual J.P. Morgan Healthcare Conference today, Monday, January 13, 2025.



"2025 will be a transformational year for Kyverna as we accelerate our next wave of growth and pivot to late-stage development and commercialization with our differentiated CD19 CAR T construct, KYV-101," said Warner Biddle, Chief Executive Officer, Kyverna. "Building upon our leadership position, we have sharpened our focus and execution on a prioritized set of opportunities – stiff person syndrome, myasthenia gravis and lupus nephritis – each with a clear and rapid path to market, where we can deliver a profound patient impact. Importantly, these indications serve as a beachhead to other neuroinflammatory and rheumatologic diseases, which we will continue to pursue in a capital-efficient manner alongside next-generation innovations, starting with KYV-102, designed to broaden access to CAR T."

Mr. Biddle added, "We are pleased with our clinical progress to date, having 40% of patients enrolled in KYSA-8, our pivotal KYV-101 Phase 2 trial in stiff person syndrome, which enables us to target a BLA filing in 2026 and puts us on track to deliver the first approved CAR T therapy in an autoimmune disease. Our fast-follow indication, myasthenia gravis, has already enrolled patients in a company-sponsored trial, KYSA-6, and we expect to report interim Phase 2 data in the second half of 2025."

Strategic priorities for the upcoming year include:

- Focused execution on company-sponsored KYSA studies evaluating KYV-101 in priority indications that offer a clear and rapid path to market. This includes advancing ongoing clinical studies in stiff person syndrome (KYSA-8), myasthenia gravis (KYSA-6), and lupus nephritis (KYSA-1 and KYSA-3).
- **Continue regulatory interactions** leveraging the U.S. Food and Drug Administration's Regenerative Medicine Advanced Therapy and Orphan Drug designations for stiff person syndrome and myasthenia gravis.
- Evaluate additional opportunities in a capital-efficient manner, harnessing investigatorinitiated trials (IITs) and other KYSA studies – including multiple sclerosis, systemic sclerosis, and others – to inform the next priority indications for the Company to advance into late-stage development.
- Advance next-generation innovations, including KYV-102, incorporating the Company's whole-blood rapid manufacturing approach, which aims to improve the CAR T patient experience, eliminate apheresis and ultimately broaden CAR T access.

Anticipated Milestones:

Based on these strategic priorities, Kyverna has issued the following guidance on upcoming program milestones:

• Stiff Person Syndrome:

- Complete pivotal Phase 2 enrollment mid-2025
- Report topline pivotal Phase 2 data 1H 2026
- BLA filing in 2026
- Myasthenia Gravis:
 - Confirm registrational path with regulators 1H 2025
 - Report interim Phase 2 data 2H 2025
- Lupus Nephritis:
 - Report Phase 1 data 2H 2025
- Future pipeline:
 - File KYV-102 investigational new drug application 2H 2025

The Company has a cash runway into 2027 to deliver on these key inflection points, with \$321.6 million of cash, cash equivalents, and marketable securities as of September 30, 2024.

Presentation at the J.P. Morgan Healthcare Conference

Warner Biddle will present a company overview at the 43rd Annual J.P. Morgan Healthcare Conference today, January 13, 2025, at 5:15 PM PT. A live webcast of the presentation will be available on the Investors section of Kyverna's website, <u>www.kyvernatx.com</u>. A replay of the webcast will be available on Kyverna's website for approximately 30 days following the conference.

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.

It is currently being evaluated in company sponsored, open-label, Phase 2 trials in stiff person syndrome and 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://kvvernatx.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 or the first approved CAR T therapy in autoimmune; the potential for KYV-102 to shorten the manufacturing process and increase patient reach and CAR T access; anticipated milestones and timing thereof, encluding anticipated timing for the first intended BLA submission for KYV-101 and timing for reporting data as well as expected completion of enrollments; 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-lo

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