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 investigator-initiated 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, www.kyvernatx.com. 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://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 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, including 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-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.

Contact:

Investors: InvestorRelations@kyvernatx.com
Media: media@kyvernatx.com

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