Kyverna Therapeutics Provides Business Update and Reports Second Quarter 2024 Financial Results

August 12, 2024

- *Actively recruiting clinical trials in neurology and rheumatology with KYV-101*
- *No severe ICANS or CRS reported in first 36 autoimmune disease patients treated with KYV-101*
- *Received FDA RMAT Designation for KYV-101 for treatment of patients with Stiff-Person Syndrome*
- *Received FDA RMAT Designation for KYV-101 for treatment of patients with Myasthenia Gravis*
- *Reported clinical experience with first KYV-101 patient disease-free at 1 year after treatment*

EMERYVILLE, Calif., Aug. 12, 2024 /PRNewswire/ -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, today reported its business highlights and financial results for the second quarter ended June 30, 2024.

"We have shown promising initial safety and efficacy for our lead product candidate, KYV-101, and continue to lead the way in bringing CAR T-cell therapies to patients with autoimmune diseases in the US and Europe," said Peter Maag, Chief Executive Officer of Kyverna. "We believe that KYV-101 brings the power of CD19-directed CAR T therapy to deliver deep tissue-based B cell depletion using a fully human CAR and CD28 costimulatory domain designed by the NIH to improve tolerability. We look forward to sharing more clinical data throughout the rest of 2024 as we strive to fulfill our promise to bring hope to patients living with autoimmune disorders."

Second Quarter 2024 and Recent Business Highlights

- Presented clinical data showing use of the CAR in KYV-101 across 50 patients including 15 different autoimmune conditions at CAR T centers in the US and Europe
- Expanded KYV-101 safety experience with no severe ICANS or CRS Grade ≥3 reported in 36 autoimmune patients treated as of July 31, 2024, using CAR construct designed by the NIH to improve tolerability
- Received two U.S. FDA Regenerative Medicine Advanced Therapy (RMAT) Designations for KYV-101: one for the treatment of patients with Stiff-Person Syndrome, and one for the treatment of patients with myasthenia gravis, building on the emerging body of clinical evidence
- Achieved 100% manufacturing success rate across all 36 cumulative autoimmune patients treated with KYV-101 as of July 31, 2024
- Reported clinical experience of a myasthenia gravis patient who is now free of disease one year after treatment with KYV-101

- Progressed the global KYSA clinical trial program in multiple indications across rheumatology and neurology: Phase 1/2 trials in lupus nephritis (KYSA-1 and KYSA-3), a Phase 1/2 trial in systemic sclerosis (KYSA-5), a Phase 2 trial in myasthenia gravis (KYSA-6), a Phase 2 trial in multiple sclerosis (KYSA-7), and a Phase 2 trial in stiff-person syndrome (KYSA-8)

Upcoming Milestones

- Neurology case reports at ECTRIMS in September 2024
- Rheumatology KYSA Clinical Trial updates at ACR in November 2024
- Guidance on anticipated regulatory phase transitions in 2025, following RMAT meetings with the FDA

Financial Results for the Quarter Ended June 30, 2024
For the quarter ended June 30, 2024, the company reported a net loss of $28.8 million, or a net loss per common share of $0.67, compared to a net loss of $13.1 million, or a net loss per common share of $20.86, for the same period in 2023.

During the six months ended June 30, 2024, net cash used in operating activities was $49.7 million, compared to $22.7 million for the same period in 2023.

Kyverna reported $346.2 million in cash, cash equivalents, and available-for-sale marketable securities as of June 30, 2024.

About Kyverna Therapeutics
Kyverna is a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases.

Our lead CAR T-cell therapy candidate, KYV-101 is advancing through clinical development with sponsored clinical trials across two broad areas of autoimmune disease: rheumatology and neurology, including Phase 2 trials for multiple sclerosis, myasthenia gravis and stiff-person syndrome, a Phase 1/2 trial for systemic sclerosis, and two ongoing multi-center, open-label Phase 1/2 trials in the United States and Germany for patients with lupus nephritis.

Kyverna's pipeline includes next-generation chimeric antigen receptor (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 www.kyvernatx.com.

Forward-looking Statements
This press release contains forward looking statements that are based on management's beliefs and assumptions and on information currently available to management of Kyverna Therapeutics, Inc. ("Kyverna", "we", "our," or the "Company"). All statements other than statements of historical facts contained in this press release are forward looking statements. Forward looking statements include, but are not limited to, statements concerning: the Company's future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, results of preclinical studies and named patient activities, ongoing clinical trials, research and development costs, plans for manufacturing, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations. These forward-looking statements are subject to risks and uncertainties, including the factors described under the Risk Factors section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 26, 2024 and any subsequent Quarterly Reports on Form 10-Q filed by the Company. Actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. When evaluating Kyverna's business and prospects, careful consideration should be given to these risks and uncertainties. These statements speak only as of the date of this press release, and Kyverna undertakes no obligation to update or revise these statements.

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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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 27,321	$ 10,405	$ 49,797	$ 19,116
General and administrative	6,114	2,897	12,996	5,631
Total operating expenses	33,435	13,302	62,793	24,747
Loss from operations	(33,435)	(13,302)	(62,793)	(24,747)
Interest income	4,694	264	7,429	613
Interest expense	(39)	(46)	(83)	(90)

Other expense, net	(23)	(7)	(49)	(10)
Total other income, net	4,632	211	7,297	513
Net loss	(28,803)	(13,091)	(55,496)	(24,234)
Other comprehensive (loss) gain				
Unrealized (loss) gain on available-for-sale marketable securities, net	(36)	8	(41)	26
Total other comprehensive (loss) gain	(36)	8	(41)	26
Net loss and other comprehensive loss	$ (28,839)	$ (13,083)	$ (55,537)	$ (24,208)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.67)	$ (20.86)	$ (1.66)	$ (40.40)
Weighted-average shares of common stock outstanding, basic and diluted	43,125,709	627,589	33,439,886	599,917

Kyverna Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 131,618	$ 34,647
Available-for-sale marketable securities	214,619	22,896
Prepaid expenses and other current assets	2,586	3,121
Total current assets	348,823	60,664
Restricted cash	574	565
Property and equipment, net	3,366	2,326
Operating lease right-of-use assets	7,825	6,494
Finance lease right-of-use assets	1,315	1,790
Other non-current assets	1,213	3,356
Total assets	$ 363,116	$ 75,195
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 4,861	$ 4,358
Accrued compensation	2,722	2,812
Accrued license expense – related party	6,250	6,250
Other accrued expenses and current liabilities	5,775	3,519
Operating lease liabilities, short-term portion	2,867	1,964
Finance lease liabilities, short-term portion	1,003	956
Total current liabilities	23,478	19,859
Operating lease liabilities, net of short-term portion	5,722	5,238
Finance lease liabilities, net of short-term portion	407	921
Total liabilities	29,607	26,018
Commitments and contingencies		
Redeemable convertible preferred stock, no par value; no shares authorized, issued and outstanding as of June 30, 2024; $0.00001 par value, 114,556,997 shares authorized as of December 31, 2023; 114,556,997 shares issued and outstanding as of December 31, 2023; liquidation preference of $181,273 as of December 31, 2023	—	180,574
Stockholders' equity (deficit)		
Preferred stock, 10,000,000 shares authorized, $0.00001 par value, no shares issued and outstanding as of June 30, 2024; no shares authorized, issued, and outstanding as of December 31, 2023	—	—
Common stock, $0.00001 par value; 490,000,000 and 140,492,016 shares authorized as of June 30, 2024 and December 31, 2023, respectively; 43,146,852 and 1,250,103 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	525,085	4,642
Accumulated other comprehensive (loss) income	(37)	4
Accumulated deficit	(191,539)	(136,043)
Total stockholders' equity (deficit)	333,509	(131,397)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 363,116	$ 75,195

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