# Milestone Pharmaceuticals Reports First Quarter 2025 Financial Results and Provides Regulatory and Corporate Update

May 14, 2025

*Resolution of CRL Manufacturing issues in progress - Type A meeting requested*

*No clinical safety or efficacy concerns raised by FDA*

MONTREAL and CHARLOTTE, N.C., May 14, 2025 (GLOBE NEWSWIRE) -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST) today reported financial results for the first quarter ended March 31, 2025. The Company also announced the submission of a meeting request to the U.S. Food and Drug Administration (FDA) as the next step in the resolution of CRL issues.

"Our immediate priority is to engage with the U.S. FDA in order to address the CMC-related issues raised in the CRL received for CARDAMYST as a treatment for PSVT," said Joe Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We are confident we can work with the FDA to fully respond to the CRL and remain committed to the potential of CARDAMYST. If approved, it will be the first and only self-administered therapy for the rapid termination of episodes of PSVT."

**First Quarter and Recent Program Updates**

*Etripamil for Patients with PSVT*

- **CRL for CARDAMYST™ for PSVT received from FDA.** In March 2025, Milestone received a CRL regarding its NDA for CARDAMYST, its lead investigational product for the management of paroxysmal supraventricular tachycardia (PSVT). In the letter, the Agency highlighted two key Chemistry, Manufacturing and Controls (CMC) issues to be addressed: 1) additional information on nitrosamine impurities was requested, based on new draft guidance that was issued during the review of the NDA , and 2) a new inspection of a facility listed in the NDA is required, to ensure it is in compliance with current Good Manufacturing Practices (GMP). The facility, which previously performed a portion of the testing required to release etripamil final product, changed ownership during the review of the NDA. Milestone is prepared to discuss the issues raised in the CRL during the Type A meeting with the FDA.
- **Patent Issued by the U.S. Patent and Trademark Office (USPTO) on a new Method of Use patent for etripamil nasal spray.** The new patent (U.S. Patent No. 12,257,224) covers the repeat dose regimen that was used in the RAPID Phase 3 study that evaluated etripamil in PSVT and is included in the proposed package insert for CARDAMYST. The issued patent potentially extends the intellectual property protection for CARDAMYST in the United States until July 2042, which would be an additional six years of protection for the company's intellectual property portfolio.
- **CARDAMYST highlighted in independent Survey of Managed Care professionals.** Results from an independent survey conducted by *Managed Healthcare Executive* and *The American Journal of Managed Care* were published on May 6, 2025. CARDAMYST was selected by 40% of respondents (which included payers, providers and academics) when asked which new drug is expected to make the biggest difference in patient health. A copy of the article can be accessed here.
- **Commercial Launch Plan investor event held in February.** The event, held on February 25, 2025 in New York City, provided an in-depth overview of the Company's commercial strategy for CARDAMYST nasal spray, if approved. A replay of the event, as well as a copy of the slides, can be found on the corporate website here.
- **Poster on etripamil presented at American College of Cardiology Annual Meeting (ACC.25).** The poster titled, "*Consistency and Predictiveness of Conversion Among Multiple Episodes of Paroxysmal Supraventricular Tachycardia (PSVT) treated with Etripamil: Outcomes from the NODE-303 trial*," was presented at the meeting on March 30, 2025 by James Ip, M.D., Professor, Division of Cardiology, Weill Cornell Medicine, New York Presbyterian Hospital. A copy of the poster can be accessed here.

*Etripamil for patients with atrial fibrillation with rapid ventricular rate (AFib-RVR)*

- **Phase 3 protocol in AFib-RVR finalized** Milestone has finalized the Phase 3 study protocol following FDA's review and obtained concurrence with the Agency to proceed. The Company is pausing initiation of enrollment of the study due to prioritizing resources to resolve the CRL received on the NDA for etripamil in PSVT.

**First Quarter 2025 Financial Results**

- As of March 31, 2025, Milestone had cash, cash equivalents, and short-term investments of $56.0 million, compared to $69.7 million as of December 31, 2024.

- There was no revenue for the first quarter ended March 31, 2025 or for the first quarter of 2024.
- Research and development expense for the first quarter of 2025 was $5.0 million, compared with $3.6 million for the prior year period. The increase was primarily due to higher consulting costs in drug manufacturing and regulatory costs.
- General and administrative expense for the first quarter of 2025 was $5.2 million, compared with $4.0 million for the prior year period. This increase was driven primarily by an increase in outside service costs, partially offset by a decrease in personnel costs.
- Commercial expense for the first quarter of 2025 was $10.4 million, compared with $2.9 million for the prior year period. This increase is a result of additional personnel costs, professional costs and other operational expenses related to preparation for the launch of CARDAMYST. As a result of the CRL, Milestone has temporarily paused the ramping of operational expenditures related to launch, but will maintain the capability to launch quickly, pending approval of CARDAMYST by the FDA.
- For the first quarter of 2025, net loss was $20.8 million, compared to $10.4 million for the prior year period.

For further details on the Company's financials, refer to the Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC.

**About Etripamil**
Etripamil is Milestone's lead investigational product. It is a novel calcium channel blocker nasal spray under clinical development for frequent and often highly symptomatic episodes of PSVT and AFib-RVR. It is designed as a self-administered rapid response therapy for patients thereby bypassing the need for immediate medical oversight. If approved, etripamil is intended to provide health care providers with a new treatment option to enable on-demand care and patient self-management. This portable, self-administered treatment may provide patients with active management and a greater sense of control over their condition. CARDAMYST™, the conditionally approved brand name for etripamil nasal spray, is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT and Phase 2 trial for the treatment of patients with AFib-RVR.

**About Milestone Pharmaceuticals**
Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is a biopharmaceutical company developing and commercializing innovative cardiovascular solutions to improve the lives of people living with complex and life-altering heart conditions. The Company's focus on understanding unmet patient needs and improving the patient experience has led us to develop new treatment approaches that provide patients with an active role in self-managing their care. Milestone's lead investigational product is etripamil, a novel calcium channel blocker nasal spray that is being studied for patients to self-administer without medical supervision to treat symptomatic episodic attacks associated with PSVT and AFib-RVR.

**Forward-Looking Statements**
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "continue," "could," "demonstrate," "designed," "develop," "estimate," "expect," "may," "pending," "plan," "potential," "progress," "will", "intend" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Milestone's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding: the outcomes of future interactions with the FDA, including the potential Type A meeting; Milestone's ability to address the issues raised in the CRL on a timely basis, if at all; the outcome of the potential NDA resubmission; CARDAMYST's potential as a novel treatment option to help patients with PSVT; potential protections afforded by U.S. patents; CARDAMYST's ability to make the biggest difference in patient health, as compared to other available treatment options; the timing of patient enrollment in the Phase 3 study of etripamil for AFib-RVR; and other statements not related to historical facts. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, whether our future interactions with the FDA will have satisfactory outcomes; whether and when, if at all, our NDA for etripamil will be approved by the FDA; uncertainties related to the timing of initiation, enrollment, completion, evaluation and results of our clinical trials; risks and uncertainty related to the complexity inherent in cleaning, verifying and analyzing trial data; and whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications, among others, general economic, political, and market conditions, including deteriorating market conditions due to investor concerns regarding inflation, international tariffs, Russian hostilities in Ukraine and ongoing disputes in Israel and Gaza and overall fluctuations in the financial markets in the United States and abroad, risks related to pandemics and public health emergencies, and risks related the sufficiency of Milestone's capital resources and its ability to raise additional capital in the current economic climate. These and other risks are set forth in Milestone's filings with the U.S. Securities and Exchange Commission (SEC), including in its 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 March 31, 2025, in each case under the caption "Risk Factors," as such discussions may be updated from time to time by subsequent filings Milestone may make with the SEC. Except as required by law, Milestone assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Contact:
Kim Fox, Vice President, Communications, kfox@milestonepharma.com

Investor Relations
Kevin Gardner, kgardner@lifesciadvisors.com

**Milestone Pharmaceuticals Inc.**
**Condensed Consolidated Balance Sheets (Unaudited)**
***(in thousands of US dollars, except share data)***

| | March 31, 2025 | December 31, 2024 |
|---|---|---|

| | | |
|---|---|---|
| **Assets** | | |
| **Current assets** | | |
| Cash and cash equivalents | $ 45,085 | $ 25,314 |
| Short-term investments | 10,873 | 44,381 |
| Research and development tax credits receivable | 994 | 901 |
| Prepaid expenses | 2,356 | 1,840 |
| Other receivables | 1,167 | 1,490 |
| **Total current assets** | 60,475 | 73,926 |
| Operating lease right-of-use assets | 1,234 | 1,376 |
| Property and equipment | 176 | 197 |
| **Total assets** | $ 61,885 | $ 75,499 |
| **Liabilities, and Shareholders' (Deficit) Equity** | | |
| **Current liabilities** | | |
| Accounts payable and accrued liabilities | $ 12,421 | $ 7,555 |
| Operating lease liabilities | 542 | 571 |
| **Total current liabilities** | 12,963 | 8,126 |
| Operating lease liabilities, net of current portion | 758 | 874 |
| Senior secured convertible notes | 54,287 | 53,352 |
| **Total liabilities** | 68,008 | 62,352 |
| **Shareholders' (Deficit) Equity** | | |
| Common shares, no par value, unlimited shares authorized, 53,464,273 shares issued and outstanding as of March 31, 2025, 53,353,984 shares issued and outstanding as of December 31, 2024 | 288,188 | 288,048 |
| Pre-funded warrants - 12,910,590 issued and outstanding as of March 31, 2025 and 12,910,590 as of December 31, 2024 | 53,076 | 53,076 |
| Additional paid-in capital | 40,919 | 39,568 |
| Accumulated deficit | (388,306) | (367,545) |
| **Total shareholders' (deficit) equity** | (6,123) | 13,147 |
| **Total liabilities and shareholders' equity** | $ 61,885 | $ 75,499 |

**Milestone Pharmaceuticals Inc.**
**Condensed Consolidated Statements of Loss (Unaudited)**
***(in thousands of US dollars, except share and per share data)***

| | Three months ended March 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Revenue** | $ — | $ — |
| **Operating expenses** | | |
| Research and development, net of tax credits | 4,978 | 3,639 |
| General and administrative | 5,167 | 3,953 |
| Commercial | 10,378 | 2,884 |
| **Loss from operations** | (20,523) | (10,476) |
| Interest income | 697 | 994 |
| Interest expense | (935) | (872) |
| **Net loss and comprehensive loss** | $ (20,761) | $ (10,354) |
| **Weighted average number of shares and pre-funded warrants outstanding, basic and diluted** | 66,285,406 | 50,155,111 |

| | | |
|---|---|---|
| **Net loss per share, basic and diluted** | $ (0.31) | $ (0.21) |

Source: Milestone Pharmaceuticals Inc.