Milestone Pharmaceuticals Reports Second Quarter 2024 Financial Results and Provides Regulatory and Corporate Update

August 08, 2024

– NDA for CARDAMYST™ in PSVT accepted by FDA in 2Q 2024; PDUFA in March 2025

– Cash of $83.3 million as of June 30, 2024 expected to fund operations into 2026

– Stuart Duty and Andrew Saik Appointed as Independent Board Directors

MONTREAL and CHARLOTTE, N.C., Aug. 08, 2024 (GLOBE NEWSWIRE) -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST) today reported financial results for the second quarter ended June 30, 2024 and provided a regulatory and corporate update.

"The FDA acceptance of our New Drug Application (NDA) for CARDAMYST™ (etripamil) nasal spray (an investigational new drug), has enabled our commercial team to advance preparations for potential approval and launch in 2025," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "Further, we are encouraged by the interest and input from cardiology experts in our Phase 3 AFib-RVR study that we plan to commence in the first half of 2025."

Second Quarter and Recent Program Updates

CARDAMYST for patients with paroxysmal supraventricular tachycardia (PSVT)

- **FDA accepted the NDA of CARDAMYST for PSVT.** On May 26, 2024, the U.S. Food and Drug Administration (FDA) accepted the resubmission of the NDA for CARDAMYST. The FDA Prescription Drug User Fee Act (PDUFA) target date has been set for March 2025.
- **Milestone hosted a KOL webinar entitled "Learnings from the Field: Expert Perspectives on Managing PSVT in the Community Setting."** The event, which is the first of a series of planned webinars learning from community-based health care providers, featured George Mark, MD, FACC and Vivek Sailam, MD from The Heart House and Cooper University Health Care. Both physicians discussed the burden of PSVT on patients and their practice, current treatments and unmet needs, and expectations for how the treatment landscape is likely to evolve in coming years. A replay of the webinar is available on the Milestone corporate website here. The second event of the webcast series is planned for this Fall.

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

- **Planning and Design of Phase 3 pivotal trial is ongoing, following guidance received from FDA in 1Q 2024 meeting.** Milestone is working with experts to finalize the design of a Phase 3 trial for etripamil in AFib-RVR**.** The Company plans to propose to the FDA a Phase 3 clinical study, conducted in the at-home setting, that will enroll patients with a history of symptomatic episodes and use a self-administered, repeat-dose regimen of 70 mg of etripamil nasal spray, similar to what was investigated in the RAPID trial in patients with PSVT. Enrollment is expected to commence in the first half of 2025.
- **Data from previously published studies on etripamil in PSVT and AFib-RVR were featured in presentations at ISPOR 2024 (May 5-8), the 2024 Stanford BioDesign Arrhythmia Technologies Retreat (May 15), and the Annual meeting of the Heart Rhythm Society, Heart Rhythm 2024 (May 16-19).** The publications add to a growing body of literature on the patient- and system-burdens, and costs of PSVT, and to the support for the potential of etripamil to reduce ED visits for patients who are able to self-treat their PSVT episodes. Further information presented included the findings from Milestone's investigation of etripamil in patients with AFib-RVR and the rationale for the Company's Phase 3 program. Copies of the presentations and posters can be found here.

Corporate Updates

- **In July, Stuart Duty and Andrew Saik were appointed as independent directors to the board of directors.** Mr. Duty brings over 30 years of experience in investment banking and operations primarily in the biotechnology and specialty pharmaceuticals sectors. Mr. Saik brings over 25 years of accounting and finance experience, including leading numerous capital structure transformations.

Second Quarter 2024 Financial Results

- As of June 30, 2024, Milestone had cash, cash equivalents, and short-term investments of $83.3 million, compared to $66.0 million as of December 31, 2023.
- Research and development expense, net of tax credits for the second quarter of 2024 was $2.8 million, compared with

$8.6 million for the same period in 2023. For the six months ended June 30, 2024, research and development expense was $6.5 million compared with $18.9 million for the same period in 2023. This decrease in research and development expenses was driven by lower clinical development costs and clinical personnel-related costs driven by completion of phase 3 studies, as well as a decrease in drug manufacturing professional fees and personnel-related costs.

- General and administrative expense for the second quarter of 2024 was $5.0 million, compared with the $4.4 million reported for the same period in 2023. For the six months ended June 30, 2024, general and administrative expense was $9.0 million, compared with the with $8.3 million for the prior year period. The increases between the periods are primarily due to an increase in legal and professional fees, partially offset by a decrease in personnel costs.
- Commercial expense for the second quarter of 2024 was $1.8 million, compared with $3.4 million for the same period in 2023. For the six months ended June 30, 2024, commercial expense was $4.7 million compared with $5.7 million for the prior year period. The decreases are a result of decreases in personnel costs, professional costs and other operational expenses related to commercialization.
- For the second quarter of 2024, net loss was $9.4 million, compared to $16.0 million for the prior year period. For the six months ended June 30, 2024, Milestone's net loss was $19.7 million, compared to $31.0 million in 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 June 30, 2024, filed with the SEC on August 8, 2024.

About Paroxysmal Supraventricular Tachycardia

An estimated two million people in the United States are currently diagnosed with PSVT which is a type of arrhythmia or abnormal heart rhythm. PSVT is characterized by episodes of sudden onset rapid heartbeats often exceeding 150 to 200 beats per minute. The heart rate spike is unpredictable and may last several hours. The rapid heart rate often causes disabling severe palpitations, shortness of breath, chest discomfort, dizziness or lightheadedness, and distress, forcing patients to limit their daily activities. The uncertainty of when an episode of PSVT will strike or how long it will persist can provoke anxiety in patients and negatively impact their day-to-day life between episodes. The impact and morbidity from an attack can be especially detrimental in patients with underlying cardiovascular or medical conditions, such as heart failure, obstructive coronary disease, or dehydration. Many health care providers are dissatisfied with the lack of effective treatment options with patients often requiring prolonged, burdensome, and costly trips to the emergency department or even invasive cardiac ablation procedures.

About Atrial Fibrillation with Rapid Ventricular Rate

An estimated five million Americans suffer from atrial fibrillation (AFib), a common arrhythmia marked by an irregular, disruptive and often rapid heartbeat. The incidence of AFib is expected to grow to approximately 10 million by 2025 and up to about 12 million by 2030. A subset of patients with AFib experience episodes of abnormally high heart rate most often accompanied by palpitations, shortness of breath, dizziness, and weakness. While these episodes, known as AFib-RVR, may be treated by oral calcium channel blockers and/or beta blockers, patients frequently seek acute care in the emergency department to address symptoms. In 2016, nearly 800,000 patients were admitted to the emergency department due to AFib symptoms where treatment includes medically supervised intravenous administration of calcium channel blockers or beta blockers, or electrical cardioversion. With little available data for AFib-RVR, Milestone's initial market research indicates that 30 to 40% of patients with AFib experience one or more symptomatic episodes of RVR per year that require treatment, suggesting a target addressable market of approximately three to four million patients in 2030 for etripamil in patients with AFib-RVR.

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™ (etripamil) nasal spray, 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: our expected cash runway into 2026; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the FDA, including the timing of the FDA's review of the NDA; the potential of etripamil to help patients living with these serious heart arrythmias and to reduce ED visits for patients who are able to self-treat their PSVT episodes; the timing of the launch of etripamil; and the timing, design and outcomes of our clinical trials, including our Phase 3 study in AFib-RVR. 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; whether the FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful, the risks inherent in biopharmaceutical product development and clinical trials, including the lengthy and uncertain regulatory approval process; 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, 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, 2023 and its quarterly report on Form 10-Q for the quarter ended June 30, 2024, under the caption "Risk Factors," as such discussion 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.

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

	Three months ended June 30,		Six months ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue	$ —	$ —	$ —	$ 1,000
Operating expenses				
Research and development, net of tax credits	2,815	8,622	6,454	18,879
General and administrative	5,046	4,445	8,999	8,334
Commercial	1,801	3,369	4,685	5,725
Loss from operations	(9,662)	(16,436)	(20,138)	(31,938)
Interest income	1,186	1,213	2,180	1,801
Interest expense	(887)	(820)	(1,759)	(856)
Net loss and comprehensive loss	$ (9,363)	$ (16,043)	$ (19,717)	$ (30,993)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	66,165,461	42,937,036	58,160,286	42,895,387
Net loss per share, basic and diluted	$ (0.14)	$ (0.37)	$ (0.34)	$ (0.72)

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

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 13,262	$ 13,760
Short-term investments	69,991	52,243
Research and development tax credits receivable	776	643
Prepaid expenses	1,713	3,178
Other receivables	1,617	3,208
Total current assets	87,359	73,032

Operating lease right-of-use assets	1,651	1,917
Property and equipment	222	277
Total assets	$ 89,232	$ 75,226
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 4,000	$ 6,680
Operating lease liabilities	567	546
Total current liabilities	4,567	7,226
Operating lease liabilities, net of current portion	1,156	1,457
Senior secured convertible notes	51,531	49,772
Total liabilities	57,254	58,455
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 53,269,565 shares issued and outstanding as of June 30, 2024, 33,483,111 shares issued and outstanding as of December 31, 2023	287,932	260,504
Pre-funded warrants - 12,910,590 issued and outstanding as of June 30, 2024 and 9,577,257 as of December 31, 2023	53,076	48,459
Additional paid-in capital	36,713	33,834
Accumulated deficit	(345,743)	(326,026)
Total shareholders' equity	31,978	16,771
Total liabilities and shareholders' equity	$ 89,232	$ 75,226



Source: Milestone Pharmaceuticals Inc.