Milestone Pharmaceuticals Reports Second Quarter 2020 Financial Results and Provides Clinical and Corporate Update

August 12, 2020

MONTREAL and CHARLOTTE, N.C., Aug. 12, 2020 /PRNewswire/ -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today reported financial results for the second quarter ended June 30, 2020 and provided a clinical and corporate update.

"With the benefit of having completed our first Phase 3 clinical trial and a clear and efficient registration path defined for etripamil in **paroxysmal supraventricular tachycardia (PSVT)**, we remain fully committed to bringing this therapy to PSVT patients highly in need of better treatment options," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We are on track to reopen the RAPID study later this year and believe the updated study design will allow us to best maximize the potential clinical utility of etripamil, including in patients with more persistent **supraventricular tachycardia** (SVT) events. With our recent $25 million private placement, we believe we are well positioned to execute on the remainder of the PSVT program and look forward to providing updates on our progress in the coming months."

Recent Updates

- **Announced Regulatory Guidance and Updated Clinical Development Plan for Etripamil in PSVT.** In July 2020, Milestone announced a clinical and regulatory update for its pivotal program with etripamil in PSVT following interactions with the U.S. Food and Drug Administration (FDA).

  The FDA indicated that two studies, the second part of NODE-301, which the Company has renamed the RAPID study, and the completed NODE-301 study could potentially fulfill the efficacy requirement for Milestone's New Drug Application for etripamil in patients with PSVT. In addition, the FDA agreed to the following program changes:

  - An updated statistical analysis plan (SAP) for both the RAPID and NODE-301 studies under which the primary efficacy endpoint will be defined as time to conversion over the first 30 minutes, with a target p-value of less than 0.05 for each study. When employing this updated SAP, results from the NODE-301 study show that 54% of etripamil patients vs. 35% of placebo patients converted within 30 minutes (HR 1.87, p=0.02).
  - In an effort to maximize the potential treatment effect of etripamil, the RAPID study will allow for an optional repeat administration of study drug (either 70 mg of etripamil or placebo) in patients who have not experienced symptom relief within 10 minutes of the first study drug administration.

  Milestone expects to reopen enrollment in the RAPID study later this year, with data anticipated in late 2021 or early 2022.

- **Raised $25 Million Through Private Placement.** In July 2020, Milestone entered into a securities purchase agreement with affiliates of an existing shareholder, RTW Investments, LP, whereby Milestone sold pre-funded warrants to acquire an aggregate 6,655,131 common shares at a purchase price of $3.7465 per pre-funded warrant. Each pre-funded warrant is exercisable for one common share at an exercise price of $0.01 per share, has no expiration date, and is immediately exercisable, subject to certain beneficial ownership limitations. Aggregate proceeds received by the Company were $25 million.

Second Quarter 2020 Financial Results

- As of June 30, 2020, Milestone had cash, cash equivalents, and short-term investments of $85.4 million and 24.7 million shares outstanding.
- Research and development expenses for the second quarter of 2020 were $8.6 million compared with $10.5 million for the prior year period. For the six months ended June 30, 2020, research and development expenses were $20.5 million compared with $18.3 million for the prior year period. The increase in the first half of 2020 reflects the increased clinical development costs and manufacturing and formulation activities supporting Milestone's Phase 3 clinical trial and the efforts in developing a clinical pathway for etripamil.
- General and administrative expenses for the second quarter of 2020 were $3.0 million compared with $1.6 million for the prior year period. For the six months ended June 30, 2020, general and administrative expenses were $5.7 million compared with $2.6 million for the prior year period. The increase reflects additional increasing insurance costs, professional fees and administrative headcount in the first half of 2020 compared to the same period in 2019 primarily to support the compliance requirements of being a public company.

- Commercial expenses for the second quarter of 2020 were $1.5 million compared with $2.2 million for the prior year period. For the six months ended June 30, 2020, commercial expense was $3.7 million compared with $4.4 million for the prior year period. The decrease in the three and six months ended June 30, 2020 reflects the efforts in reducing operating expenses affecting primarily pre-commercialization activities as Milestone focuses its efforts on an optimized clinical development pathway for etripamil.
- For the second quarter of 2020, operating loss was $13.1 million compared to $14.3 million in 2019. For the six months ended June 30, 2020, Milestone's operating loss was $29.9 million compared to $25.3 million in the prior year period.

About Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia (PSVT) is a rapid heart rate condition characterized by intermittent episodes of supraventricular tachycardia (SVT) that start and stop suddenly and without warning. Episodes of SVT are often associated with symptoms including palpitations, sweating, chest pressure or pain, shortness of breath, sudden onset of fatigue, lightheadedness or dizziness, fainting, and anxiety. Certain calcium channel blockers have long been approved for the treatment of PSVT as well as other cardiac conditions; however, when calcium channel blockers are used for the termination of SVT episodes, they must be administered intravenously under medical supervision, usually in an emergency department or other acute care setting.

About Etripamil

Etripamil, the Company's lead investigational product, is designed to be a rapid response therapy for episodic cardiovascular conditions. The novel calcium channel blocker is self-administered via a nasal spray which may shift the current treatment paradigm for many patients with PSVT from the emergency department to the at-home setting. Milestone is conducting a comprehensive development program for etripamil, with Phase 3 trials underway in PSVT, and plans to commence a Phase 2 proof-of-concept trial in patients with atrial fibrillation with a rapid ventricular rate, with subsequent studies expected in other conditions where calcium channel blockers are used.

About Milestone Pharmaceuticals

Milestone Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines. Milestone Pharmaceuticals operates in Canada and the United States. For more information, visit www.milestonepharma.com and follow the Company on Twitter at @MilestonePharma.

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 "may," "will," "expect," "plan," "anticipate," "estimate," "potential," "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 potential of etripamil as a promising therapy for PSVT patients, the design, progress, timing, scope and results of RAPID and other clinical trials, Milestone's ability to execute on the remainder of the PSVT program, Milestone's plans to study etripamil for atrial fibrillation patients and other conditions where calcium channel blockers are used. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, 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 and evaluation of clinical trials, and whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications, among others, as well as risks related to pandemics and public health emergencies, including those related to COVID-19, and risks related the sufficiency of Milestone's capital resources and its ability to raise additional capital. These and other risks are set forth in Milestone's filings with the U.S. Securities and Exchange Commission, including in its quarterly report on Form 10-Q for the quarter ended June 30, 2020, under the caption "Risk Factors." 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.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF LOSS AND COMPRENHENSIVE LOSS

(Unaudited)

[In US dollars]	**'000** Three months ended June 30, **2020** $	2019 $		**'000** Six months ended June 30, **2020** $	2019 $
Operating expenses					
Research and development, net of tax credits	**8,622**	10,527		**20,493**	18,292
General and administrative	**2,956**	1,641		**5,659**	2,620
Commercial	**1,527**	2,166		**3,710**	4,352
Loss from operations	**(13,105)**	(14,334)	#	**(29,862)**	(25,264)
Interest income, net of bank charges	**126**	672		**540**	1,172
Loss and comprehensive loss before income taxes	**(12,979)**	(13,662)		**(29,322)**	(24,092)
Income tax expense	**-**	(4)		**-**	18
Net loss and comprehensive loss for the period	**(12,979)**	(13,658)		**(29,322)**	(24,110)
Weighted average number of shares outstanding, basic and diluted	**24,628,049**	13,190,638		**24,588,413**	6,931,611

Net loss per share, basic and diluted	**$ (0.53)**	$ (1.04)	**$ (1.20)**	$ (3.48)

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

[In US dollars]	'000	
	June 30, 2020	December 31, 2019
	$	$
ASSETS		
Current Assets		
Cash, cash equivalents and short-term investments	**85,426**	119,818
Prepaid expenses and other current assets	**6,980**	2,681
Total current assets	**92,406**	122,499
Operating lease right of use asset	**377**	524
Property and equipment	**356**	405
Total assets	**93,139**	123,428
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	**4,834**	7,997
Operating lease liabilities	**157**	330
Total current liabilities	**4,991**	8,327
Operating lease liabilities	**132**	184
Total liabilities	**5,123**	8,511
Shareholders' Equity		
Share capital		
Common shares, no par value, unlimited shares authorized, 24,692,953 shares issued at June 30, 2020 and 24,505,748 shares issued at December 31, 2019	**226,676**	226,245
Additional paid in Capital	**5,795**	3,805
Cumulative translation adjustment	**(1,634)**	(1,634)
Accumulated Deficit	**(142,821)**	(113,499)
Total shareholders' equity	**88,016**	114,917
Total liabilities and shareholders' deficit	**93,139**	123,428

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