Milestone Partner Ji Xing Pharmaceuticals Ltd Announces Positive Topline Results from the Phase 3 Study of Etripamil in PSVT in China

September 06, 2024

MONTREAL and CHARLOTTE, N.C., Sept. 06, 2024 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced its licensing partner, Ji Xing Pharmaceuticals Ltd, released positive topline results from a multi-center, randomized, double-blind, placebo-controlled trial in China evaluating the efficacy and safety of etripamil nasal spray in paroxysmal supraventricular tachycardia (PSVT). The trial design closely matched the RAPID Phase 3 Study of etripamil in PSVT conducted by Milestone in North America and Europe.

The 500-patient Phase 3 trial (JX02002) met its primary endpoint, with a Kaplan Meier analysis shows a statistically significantly greater proportion of patients who self-administered etripamil converted from PSVT to sinus rhythm within 30 minutes compared to placebo (40.5% vs. 15.9%, respectively; hazard ratio [HR] = 3.00; 95% CI 1.58-5.71; p<0.001). Statistically significant (p<0.05) results were also shown for the secondary efficacy endpoints for percent of patients' PSVT converted to sinus rhythm by 10, 15, 45, and 60 minutes after self-administration of study drug.

Ji Xing further reported that, overall, treatment emergent adverse events were comparable between treatment groups, and there were no reported serious adverse events related to etripamil. The safety and tolerability data from the JX02002 trial were consistent with previous clinical studies. This important study further expands the etripamil global development program to more than 2,000 unique patients treated with etripamil.

"Congratulations to Ji Xing and all the clinical investigators on the successful completion of this large Phase 3 study of etripamil in PSVT," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We are proud to partner with our colleagues at Ji Xing as they advance etripamil toward regulatory approval in China, with the potential to help millions of patients struggling with PSVT."

Under the terms of the license agreement announced on May 21, 2021, Milestone granted Ji Xing an exclusive license to develop and, if regulatory approval is obtained, commercialize etripamil in patients with PSVT in Greater China. Milestone received an upfront cash payment consisting of $15 million along with a $5 million equity investment by RTW Investments, LP. In addition, Milestone remains eligible to receive up to $107.5 million in milestone payments and royalties on future sales of etripamil in Greater China (including Mainland China, Hong Kong, Macau & Taiwan). Milestone supplies etripamil and delivery devices to Ji Xing. Ji Xing is responsible for development and commercialization costs in Greater China.

About PSVT

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 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 atrial fibrillation with rapid ventricular rate (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 and forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995 and applicable Canadian securities laws ("forward looking statements"). 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 potential for etripamil for PSVT to receive regulatory approval in China and the ability of Milestone to receive up to $107.5 million in milestone payments and royalties on future sales of etripamil in Greater China. 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) and the Canadian securities regulatory authorities, including in its annual report on Form 10-K for the year ended December 31, 2023, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings Milestone may make with the SEC and the Canadian securities regulatory authorities, which is available under Milestone's profile on EDGAR at www.sec.gov and on SEDAR at www.sedarplus.ca. Except as required by applicable 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 or based on future events or otherwise.

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

Investor Relations
Chris Calabrese,
ccalabrese@lifesciadvisors.com

Kevin Gardner,
kgardner@lifesciadvisors.com

Source: Milestone Pharmaceuticals Inc.