Milestone Pharmaceuticals Announces First Patient Randomized in the Phase 3 NODE-301 Clinical Trial Evaluating Etripamil for Termination of Paroxysmal Supraventricular Tachycardia (PSVT) Episodes

MONTREAL, Aug. 8, 2018 /PRNewswire/ -- Milestone Pharmaceuticals, a clinical-stage cardiovascular company, today announced that the first patient has been randomized in its Phase 3 clinical study of etripamil. Etripamil is a new investigational, rapid-onset, short-acting calcium channel blocker administered intranasally by the patient designed to terminate paroxysmal supraventricular tachycardia (PSVT) episodes wherever they occur. PSVT is a recurring and sporadic heart arrhythmia caused by abnormalities in the cardiac conduction system. The current standard of care to terminate these episodes is intravenous medication delivered in the emergency department.

The Phase 3, multicenter, randomized, double-blind, placebo-controlled, event-driven study is planned to be conducted in more than 50 cardiology centers in the United States and Canada and will enroll up to 500 patients. Following an in-office test dose of etripamil, patients will take home either 70 mg of etripamil or placebo for when a PSVT episode occurs. Upon onset of an episode, patients will apply a wireless cardiac monitor to their chest to record their heart rhythm, perform a vagal maneuver, and if symptoms persist, administer study drug.

"The design of the NODE-301 study of etripamil will allow us to obtain more clinical evidence of the benefits of this potential treatment for PSVT in an outpatient, real-world setting," said Bruce Stambler, MD, FHRS, Piedmont Heart Institute, Atlanta, GA. "PSVT is an unpredictable disorder and the potential for a fast-acting therapy to resolve the symptoms of PSVT wherever the episodes occur could significantly reduce the burden this condition puts on patients and the healthcare system."

The primary endpoint of the NODE-301 study is time to conversion of PSVT to sinus rhythm after the administration of study drug as confirmed by a central independent adjudication committee. Secondary study endpoints include relief of symptoms commonly associated with an episode of PSVT such as heart palpitations, chest pain, anxiety, shortness of breath, dizziness, and fainting.

"The initiation of the NODE-301 study is an example of our ongoing commitment to improve the lives of patients with PSVT," said Francis Plat, MD, Milestone's Chief Medical Officer. "Etripamil, if approved by regulatory authorities, could empower patients to take control of this anxiety-producing arrhythmia without being reliant on chronic medications or trips to an acute-care facility for treatment."

The study will enroll patients at least 18 years of age with a documented history of PSVT. Patients receiving study treatment in NODE-301 will be eligible to participate in an open-label extension study (NODE-302) where etripamil will be provided for subsequent PSVT episodes. Information regarding the NODE-301 clinical trial can be found here (clinicaltrials.gov study identifier NCT03464019).

"There are well over a million people in the US living with PSVT, resulting in hundreds of thousands of emergency department and doctor's office visits each year," said Eileen Handberg, PhD, ANP-BC, FAHA, FACC, FPCNA, Research Professor of Medicine at the University of Florida. "In addition, countless other patients exist who don't seek care and suffer through their episodes in silence as the current approved treatment options are unpleasant, inconvenient, and/or costly. Providing a way to self-manage PSVT episodes could offer immediate relief for those living with this arrhythmia."

About Etripamil

Etripamil is a new, potent, short-acting, investigational calcium channel blocker being developed as a rapid-onset nasal spray that can be administered by the patient to terminate paroxysmal supraventricular tachycardia (PSVT) episodes wherever and whenever they occur. A Phase 2 clinical trial (NODE-1) was completed in the United States and Canada and published in the Journal of the American College of Cardiology[1]. Milestone is actively recruiting patients and clinical sites globally for the Phase 3 program of etripamil in the at-home setting enrolling patients with confirmed diagnosis of atrioventricular nodal reentrant tachycardia (AVNRT) and atrioventricular re-entry tachycardia (AVRT). Etripamil is not currently approved for the treatment of PSVT or for any other indication anywhere in the world.

About Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia is a condition that afflicts more than 1.7 million people and results in at least 600,000 healthcare claims per year in the U.S. alone[2]. During a PSVT episode, patients may feel palpitations while heart rate increases dramatically, sometimes exceeding 250 beats per minute[3]. Although the condition is not life threatening, it causes great distress to the patient and can result in an emergency department visit where a patient is usually administered intravenous medication.

About Milestone Pharmaceuticals

Milestone, headquartered in Montreal, Canada with a US subsidiary in Charlotte, NC, is a clinical-stage drug development company focused on developing an investigational new drug intended to provide rapid-onset and short-acting treatment of PSVT episodes and other episodic conditions. For more information, please visit www.milestonepharma.com.

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[1] Stambler, B.S. et al.; Etripamil Nasal Spray for Rapid Conversion of Supraventricular Tachycardia to Sinus Rhythm; *J Am Coll Cardiol*. 2018;72(5):489–97
[2] Sacks, N.C. et al; Prevalence of Paroxysmal Supraventricular Tachycardia (PSVT) in the US in Patients Under 65 Years of Age; Abstract and Oral Presentation at the International Academy of Cardiology Annual Scientific Sessions 2018, 23rd World Congress on Heart Disease; Precision Xtract, Boston, MA, USA
[3] Colucci, R.A.; Common types of supraventricular tachycardia: diagnosis and management.; *Am Fam Physician.* 2010;82(8), 942-952.

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