

Company Review of AFib-RVR Program

November 2023

Forward Looking Statement



This presentation contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "believe," "continue," "could," "demonstrate," "designed," "develop," "estimate," "expect," "may," "pending," "plan," "potential," "progress," "will" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These forwardlooking statements are based on Milestone's expectations and assumptions as of the date of this Presentation. 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 Presentation include statements regarding the anticipated growth of incidence of AFib and AFib-RVR by 2030; the ability of etripamil to provide patients with a treatment solution that delivers significant symptom relief and helps reduce potential visits to the emergency department; the ability of etripamil nasal spray to rapidly reduce heart rate and provide symptomatic benefit to patients suffering from AFib-RVR; the continued ability of etripamil provided superior time to conversion to normal heart rhythm compared to placebo; the timing of the anticipated launch of etripamil; the success of the NDA submission for etripamil nasal spray and the timing of the FDA's approval of the NDA; and timing of the Phase 2 proof-of-concept trial of etripamil for the treatment of patients with 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, 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 and 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, including in its annual report on Form 10-K for the year ended December 31, 2022, and its Quarterly Report on Form 10-Q for the guarter ended September 30, 2023 under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings, we may make with the U.S. Securities and Exchange Commission. 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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Etripamil is an investigational new drug, which is not approved for commercial distribution in the United States.

Recent Progress and Key Upcoming Events



- **1** RAPID Study published in The Lancet July 2023
- 2 NDA submission for PSVT October 2023
- **3** Leadership Hired in Med. Affairs, Marketing, Market Access 2022/2023
- 4 Initial data in AFib-RVR (NODE-303 study) presented May 2023
- 5 FDA Guidance (pre-IND meeting) on AFib-RVR Phase 3 Study Mid 2023
- 6 AFib-RVR Ph2 (ReVeRA study) data presented at AHA November 2023
- 7 **Operating runway to mid-2025 via RTW financing** March 2023

KOL View on Currently Available Approaches / Unmet Need in AFib



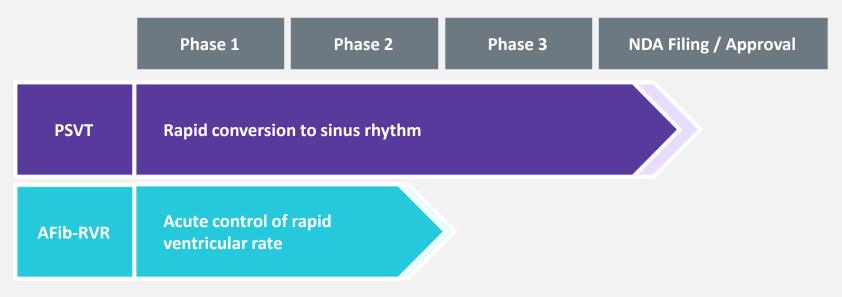
- Regardless of rate- or rhythm-control strategy, break-through episodes of AFib-RVR are frequent, symptomatic, highly burdensome, and disruptive
- Current treatment of acute attacks in the emergency department are burdensome and costly
- Expensive and inefficient use of healthcare system resources
- What would be helpful, and is currently missing, is a simple, fast-acting treatment, that could:
 - be self-administered at-home
 - reduce burden of episodes, and reduce trips to ED and calls to physicians

KOL = Key Opinion Leader; AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate; ED = Emergency Department

Source: Milestone Pharmaceuticals Virtual Key Opinion Leader Event on Etripamil for the Treatment of AFib-RVR, May 22, 2023; https://investors.milestonepharma.com/events-and-presentations



Pharmacology of L-type calcium channel blockers drives broad clinical utility



PSVT = Paroxysmal Supraventricular Tachycardia; AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate; NDA = New Drug Application

Experience and Successful Progress in PSVT Program Applied to AFib-RVR Program



- Track-record of etripamil NS development in PSVT
- Conducted multi-national PSVT development program in at-home setting with tachycardiasymptom prompted, self-administration of etripamil NS
- We demonstrated:
 - ☑ Rapid conversion of PSVT with etripamil NS 70 mg
 - ☑ Optimized efficacy with repeat-dose regimen
 - **☑** Symptomatic improvement
 - Appropriate Safety & Tolerability Profile shown for approach of symptom-prompted, at-home selfadministration
- Resulted in NDA submission

AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate; NS = nasal spray; NDA = New Drug Application; PSVT = Paroxysmal Supraventricular Tachycardia;

ReVeRA - Phase 2 Proof of Concept Trial of Etripamil in AFib-RVR in the Emergency Department Setting





Patient presents to ED with episode of AFib-RVR



Dosing & Assessment



Efficacy Analysis

Inclusion:

- Atrial Fibrillation ≥ 1 hour
- Ventricular Rate (VR) ≥ 110 bpm

Select Exclusions:

- Treated with antiarrhythmic drugs
- Hemodynamically unstable
- Heart failure

- **1**. Baseline ECG for \geq 10 min
- Administer double blind study drug 70 mg etripamil : Placebo (1:1)
- 3. Monitor in-patient for 1 hour
- 4. Six-hour remote cardiac monitor
- 5. Complete safety 24 hours post dose

Primary: Maximum reduction in VR within 60 min

N=50: 90% powered to detect 20 bpm difference in max reduction, α =0.05

- Time to VR reduction
- Duration of VR reductions
 - <100 bpm, ≥ 10% reduction, ≥ 20% reduction
- Patient satisfaction with treatment (TSQM-9)

AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate; TSQM-9, Treatment Satisfaction Questionnaire for Medication; ED = Emergency Department

Assessing Ventricular Rate Reduction with Etripamil – How Much; How Fast; How Long

ReVeRA Study was Designed to Demonstrate:



Sizing of the Study	 Sized to detect 20-bpm reduction¹ vs placebo (in-line with HCP expectations as clinically meaningful, and similar to IV CCBs); assumed 90% power, α=0.05. Target N= 50.
Primary Endpoint	 Reduction in VR; as measured by difference in maximum reduction from baseline per study-arm over 60 min window
Amount of Reduction Secondary Measures	 Achievement of responses of VR <100 bpm, or ≥20% reduction, or ≥10% reduction
Speed of Action Duration of Action	 Time course plots, Time to VR reduction or to achieve responder status Duration of VR <100 bpm, or ≥20% reduction, or ≥10% reduction
Symptomatic Relief	 Measurements of Satisfaction of Effectiveness and Relief of Symptoms utilizing the TSQM-9²
Safety & Tolerability	Adverse event collection and ECG monitoring

¹ Reduction = reduction from VR baseline. ² Treatment Satisfaction Questionnaire for Medication-9, a validated patient reported outcome tool. AFib-RVR = atrial fibrillation with rapid VR, VR = ventricular rate.

ReVeRA Patient Characteristics (Safety Population)¹



Characteristic	Placebo n=29	Etripamil n=27	Total N=56
Age, years			
Mean (SD)	64.59 ± 10.53	64.63 ± 10.61	64.6 (10.47)
Median (range)	66.00 (35.00, 83.00)	64.00 (45.00, 88.00)	65 (35.00, 88.00)
Site Location			
Canada	14 (48.3%)	12 (44.4%)	26 (46%)
The Netherlands	15 (51.7%)	15 (55.6%)	30 (54%)
Sex, female, n (%)	11 (37.9%)	11 (40.7%)	22 (39.3)
Baseline Systolic Blood Pressure (mmHg)			
Mean ± SD (median)	125.59 ± 17.34 (124.00)	130.00 ±19.78 (126.00)	127.71 ± 18.52 (124.50)
Type of AF			
Paroxysmal	22 (75.9%)	20 (74.1%)	42 (75%)
Persistent	5 (17.2%)	5 (18.5%)	10 (17.9%)
Permanent	2 (6.9%)	2 (7.4%)	4 (7.1%)
Baseline Medications, ² n (%)			
Any beta-blocker (BB)	10 (34.5%)	13 (44.8%)	23 (41.1%)
Any NDHP CCB	3 (10.3%)	4 (14.8%)	7 (12.5%)
Any BB or NDHP CCB	13 (44.8%)	15 (55.6%)	28 (50%)
Any Class IC or III antiarrhythmic drug	5 (17.2%)	8 (29.6%)	13 (23.2%)
Anticoagulant, oral	16 (55.1%)	16 (59.3%)	32 (57.1%)

¹ Safety Population (all randomized patients receiving study drug). ² Baseline = medications started at least 1 day prior to study drug administration. BB = Beta blocker, NDHP = non-dihydropyridine, CCB = calcium channel blocker, Pop = population, SD = standard deviation

ReVeRA Primary Endpoint – Maximum Reduction in VR (60 min)



Primary Endpoint achieved with high degree of statistical significance

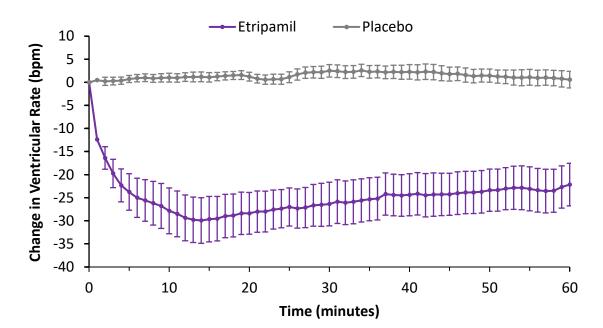
PRIMARY ENDPOINT: Maximum Reduction in VR from Baseline	Placebo NS, ¹ N=25	Etripamil NS, 70 mg, ¹ N=24
Baseline Ventricular Rate (SD)	135.54 (13.93)	130.33 (15.28)
Mean (95% CI), bpm	-5.06 (-7.44, -2.67)	-34.97 (-45.13, -24.87)
Difference in means (95% Cl), bpm		-29.91 (-40.31, -19.52)
p-value ²		<0.0001

¹Efficacy Population (all randomized patients receiving study drug remaining in atrial fibrillation with adequately diagnostic ECG recordings for at least 60 min post drug). Maximum VR reductions determined based on 5-min moving average of VR. ²By ANCOVA. bpm \pm SEM. bpm = beats per minute. CI = confidence interval. SD = standard deviation. VR = ventricular rate.

ReVeRA – Mean VR Change from Baseline (60 min)¹



ReVeRA Data Show Substantial & Rapid Reduction in VR for the Etripamil Group



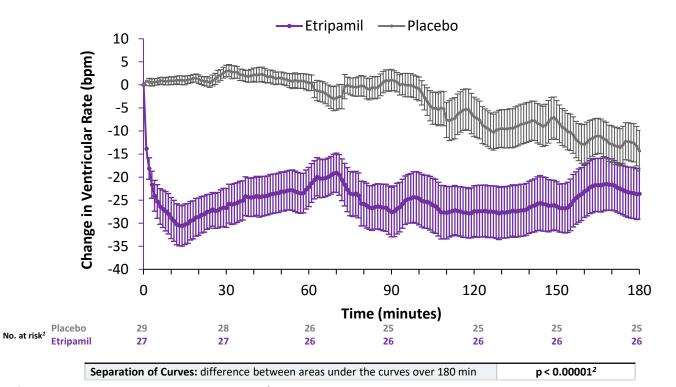
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p-value ²		<0.0001

Note: Data plotted on time course are not those directly used for calculation of Primary Endpoint (by pre-specified plan). X-axis: of plot: time following drug administration; Y-axis: 5min moving average, bpm \pm SEM. ¹Efficacy Population (all randomized patients receiving study drug remaining in atrial fibrillation with adequately diagnostic ECG recordings for at least 60 min post drug). ²By ANCOVA. Bpm = beats per minute. CI = confidence interval. SEM = standard error of the mean, VR = ventricular rate.

ReVeRA – Mean VR Change from Baseline (180 min)¹

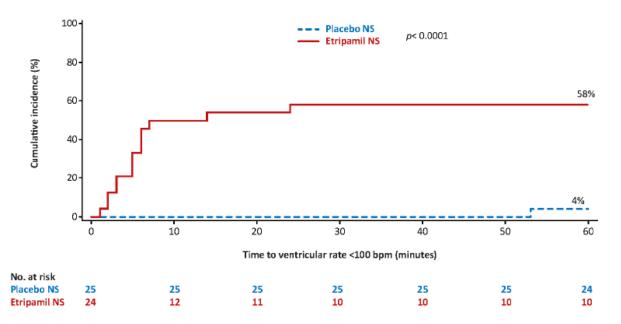


ReVeRA Data Show Lasting Duration of Effect of Etripamil, up to 150 min



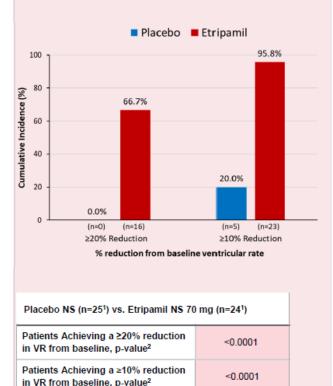
¹mITT Population (all randomized patients receiving study drug). ² From t-test of difference between the areas under the curves (AUC) of plots of absolute mean heart rate. X-axis: of plot: time following drug administration; Y-axis of plot: 5-min moving average, bpm ±SEM. Bpm = beats per minute; CI = confidence interval. SEM = standard error of the mean.

ACHIEVEMENT OF VR <100 BPM OR A REDUCTION OF ≥10% OR ≥20% FROM BASELINE BY 60 MINUTES



Patients Achieving a VR <100 bpm	Placebo NS, n=251	Etripamil NS, 70 mg, n=241	
n (%)	1 (4.0)	14 (58.3)	
p-value ²		<0.0001	
Median time to achieve VR < 100 bpm	not applicable	7 min	

¹ Efficacy Population is comprised of all randomized patients receiving study drug who remained in atrial fibrillation with adequately diagnostic ECG recordings for at least 60 min post drug. ² By chi-square test. Bpm = beats per minute; NS = nasal spray; VR = ventricular rate





ReVeRA Study: TSQM-9 PRO¹ Assessment & Results



ReVeRA Data Show Significant Improvement in Patient-Reported Relief of Symptoms

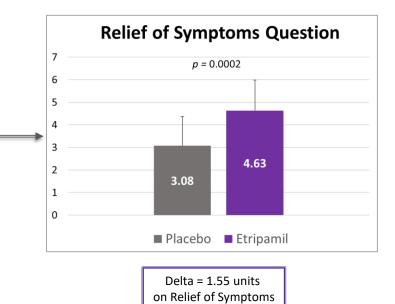
- TSQM-9 PRO¹ includes an Effectiveness Domain
- Domain includes three questions, each answered on 7-point anchored scale

1	2	3	4	5	6	7	
Extremely Dissatisfied	Very Dissatisfied	Dissatisfied	Somewhat Satisfied	Satisfied	Very Satisfied	Extremely Satisfied	

- The domain score is calculated from its three question scores
 - Domain score is on a 0 to 100-point scale
 - Domain score of 50/100 corresponds to a 4/7 = "Somewhat Satisfied"

	Placebo ² N=25	Etripamil ² N=24	p value ³	
Effectiveness Domain Scores, mean (SD)	36.67 (21.64)	62.69 (21.59)	p<0.0001	-

¹ Treatment Satisfaction Questionnaire for Medication-9, a validated Patient-Reported Outcome tool. ² Efficacy Population (all randomized patients receiving study drug remaining in atrial fibrillation with adequately diagnostic ECG recordings for at least 60 min post drug). ³ From t-test



ReVeRA Study - Most Common Adverse Events (≥5% Frequency)



Patients with ≥ 1 of most common adverse events ($\geq 5\%$) ¹	Placebo (N= 29) ²	Etripamil (N=27) ²
Nasal Discomfort	11 (37.9%)	16 (59.3%)
Rhinorrhea	1 (3.4%)	9 (33.3%)
Increased Lacrimation	5 (17.2%)	8 (29.6%)
Throat Irritation		5 (18.5%)
Dizziness	3 (10.3%)	3 (11.1%)
Bradyarrhythmia		2 (7.4%) ³
Epistaxis		2 (7.4%)
Nasal Congestion	1 (3.4%)	2 (7.4%)
Nasopharyngitis		2 (7.4%)
Nasal Congestion	1 (3.4%)	2 (7.4%)
Oropharyngeal Pain		2 (7.4%)
Paresthesia	2 (6.9%)	1 (3.7%)
Intracardiac Thrombus	2 (6.9%)	

¹ Treatment-emergent adverse events, MeDRA terms. ² Safety Population (all randomized patients receiving study drug). ³ Two patients each with 1 event of bradyarrhythmia.

ReVeRA Study - Summary of Serious Adverse Events



- One etripamil patient experienced 2 SAEs classified as related to study drug
 - Transient severe bradycardia and syncope, assessed as due to hyper-vagotonia
 - Occurred in a patient with a history of vagal events
 - Fully resolved with placing the patient supine and without sequelae
- Two placebo patients experienced 4 SAEs
 - Patient-1: Intracardiac thrombus, peripheral artery occlusion
 - Patient-2: Myocardial ischemia, atrial fibrillation

ReVeRA Study Demonstrated:



Primary Endpoint: Treatment Effect Size	 Goal: 20 bpm VR reduction¹ vs placebo ReVeRA: -30 bpm vs placebo; -35 bpm absolute in etripamil arm
Primary Endpoint: Statistical Significance	 Goal: p ≤ 0.05 ReVeRA: p < 0.0001
Speed of Action	 Goal: quick on-set ReVeRA: quick on-set. Median time to maximum reduction: 13 min in etripamil arm. Rapid achievement of responder status (eg, VR <100 bpm)
Duration of Action	 Goal: at least 30 min (for the 1 dose in this study) ReVeRA: ~150 min
Symptomatic Relief	 Goal: positive trends, show feasibility of TSQM-9² in AFib-RVR patients ReVeRA: Improvement in satisfaction of effectiveness (p<0.0001) & symptom-relief (p=0.0002), and scores apparently exceeding minimally-important-difference benchmarks.
Safety & Tolerability	 Goal: findings aligned with PSVT program experience ReVeRA: goals met (with monitored drug administration)

¹ Reduction from baseline. ² Treatment Satisfaction Questionnaire for Medication-9. AFib-RVR = atrial fibrillation with rapid VR, VR = ventricular rate

FDA Pre-IND Guidance for Path to Approval in AFib-RVR¹



- Single study with self-administered etripamil in at-home setting, to gain a labelled indication via supplemental NDA (sNDA)
- Can utilize the safety database from PSVT
- Primary Endpoint Reduction in Ventricular Rate (VR); etripamil vs. placebo
- Key secondary endpoint must be based on benefit on symptoms, via patient reported outcome (PRO)
 - p < 0.05 to gain approval, assessed in ITT population (all patients self-administering study drug)
 - Key recommendation: use of anchored 7-point scale; FDA gave latitude on specific PRO
 - FDA expectation of 1-unit improvement in Target population (verified AFib-RVR)

1. We have held Pre-IND Meeting with Cardio-Renal Division of FDA. We expect additional discussion with FDA regarding the proposed design of our Phase 3 pivotal trial, including whether the proposed trial will support registration of etripamil for the treatment of AFib-RVR. AFib-RVR = atrial fibrillation with rapid VR. VR = ventricular rate

Proposed Phase 3 Registrational Study in AFib-RVR



- Key Inclusion Criterion: history of symptomatic episodes of AFib-RVR
- Patients self-administer drug at-home for perceived episodes of AFib-RVR
- Dose: etripamil NS 70 mg (same as proposed indication in PSVT); repeat-dose regimen
- Primary endpoint = maximum reduction in VR, same as ReVeRA; etripamil vs placebo
- Key Secondary endpoint = symptom relief, via PRO
- Objectives:
 - Show p < 0.05 for Primary and Key Secondary endpoints in ITT population; no alpha-spend
 - Show meaningful PRO-based change in Target population (eg, 1-point change on 7-point scale)
- Estimated study size: N \approx 150-200 total events, based on¹: 90% power, p < 0.05
- Timing
 - FDA Confirmation of Ph3 Protocol: 1Q 2024
 - Study Start: Mid 2024
 - Top-Line Data: Mid 2026

¹ Sizing assumptions also include **PRO delta of 1.2 points**, standard deviation = 1.6, Target/ITT population ratio of 0.70. AFib-RVR = atrial fibrillation with rapid ventricular rate; ITT = intention to treat; PSVT = paroxysmal supraventricular tachycardia; TSQM = Treatment Satisfaction Questionnaire for Medication PRO; PRO = patient reported outcome



Market Opportunity for Etripamil in AFib-RVR

KOL View on Currently Available Approaches / Unmet Need in AFib



- Regardless of rate- or rhythm-control strategy, break-through episodes of AFib-RVR are frequent, symptomatic, highly burdensome, and disruptive
- Current treatment of acute attacks in the emergency department are burdensome and costly
- Expensive and inefficient use of healthcare system resources
- What would be helpful, and is currently missing, is a simple, fast-acting treatment, that could:
 - be self-administered at-home
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KOL = Key Opinion Leader; AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate; ED = Emergency Department

Source: Milestone Pharmaceuticals Virtual Key Opinion Leader Event on Etripamil for the Treatment of AFib-RVR, May 22, 2023; https://investors.milestonepharma.com/events-and-presentations

PSVT & AFib-RVR Populations in the US

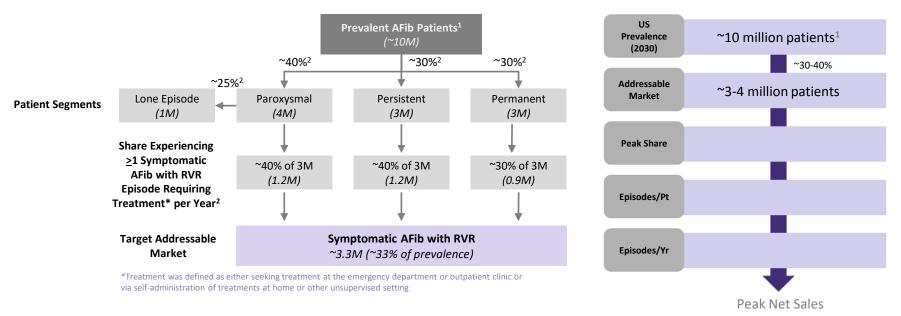


			Atrial Fibrillation
	PSVT		
Total Patients (2030)	2.6 Million ³		10 Million ¹
Discharged ED Visits & Hospital Admissions (2016) ²	145 Thousand		785 Thousand
Target Addressable Market (2030) Patient Population1.0-1.6 Million ⁵			AFib-RVR
			~3-4 Million ⁴

Source(s): **1.** Colilla et al., Am. J. Cardiol. 2013, 112(8), 1142-1147; Miyasaka et al., Circulation, 2006, 114, 119-125. American Heart Association **2.** HCUP ED & Admissions Data (2016), accessed January 2021. **3.** Rehorn et al. Journal of Cardiovascular Electrophysiology. 2021 Aug; 32(8): 2199-2206. doi: 10.1111/jce.15109. Epub 2021 Jun 14. 2018 prevalence of 2M anticipated to grow at a CAGR of ~2% **4.** Quantitative Survey conducted by Triangle Insights, May 2021, N=250 Clinical Cardiologists, Interventional Cardiologists, and Electrophysiologists. **5.** Estimate of TAM (~40%-60% of prevalence) based 2019 market research with patients conducted by BluePrint Research Group, (n=247)

Peak US Market Opportunity for Etripamil in AFib-RVR

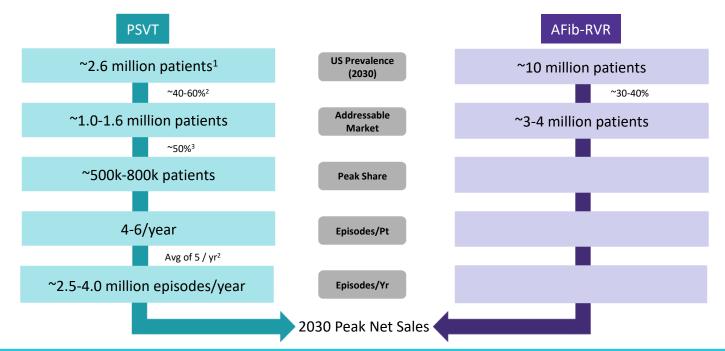
Market research suggests a target addressable market of ~3-4 million patients for AFib-RVR by 2030



AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate

Colilla et al., Am. J. Cardiol. 2013, 112(8), 1142-1147; Miyasaka et al., Circulation, 2006, 114, 119-125; 10M estimate reflects the midpoint of published estimates (~8M to ~12M by 2025 or 2030)
 Quantitative Survey conducted by Triangle Insights, May 2021, N=250 Clinical Cardiologists, Interventional Cardiologists, and Electrophysiologists

Peak US Market Opportunity for Etripamil in PSVT and AFib-RVR



Market Research Suggests a TAM of 4+ Million Patients across both PSVT and AFib-RVR Indications

AF - RVR = Atrial Fibrillation with Rapid Ventricular Rate; TAM = Target Addressable Market

Sources: 1. Rehorn et al. Journal of Cardiovascular Electrophysiology. 2021 Aug; 32(8): 2199-2206. doi: 10.1111/jce.15109.; 2. 2019 market research with patients conducted by BluePrint Research Group, (n=247); 3. 2020 market research with healthcare providers conducted by Triangle Insights Group, (n=250)

Milestone - Atrial Fibrillation Program Overview

Finances – as of September 30, 2023





Cash and short-term investments of \$75.7M



Equity - 43.1M in shares and pre-funded warrants outstanding

- 33.5M common shares
- 9.6M pre-funded warrants⁽²⁾



Cash as of September 30, 2023 together with synthetic royalty financing expected to fund operations into mid-2025

Synthetic Royalty Financing of

\$75M available upon approval⁽¹⁾

- (1) In March 2023, Milestone announced a \$125.0M strategic with RTW Investments. The financings consists of \$50.0M in convertible notes issued in March 2023, and a commitment \$75.0M in non-dilutive royalty funding if etripamil is approved by the FDA.
- (2) Common shares as of November 13, 2023. Pre-funded warrants as of September 30, 2023.

Milestone Pharma - Targeting Significant Unmet Need for Patient Management of Common Heart Conditions





Targeting Common Arrhythmias

- PSVT
- AFib-RVR
- High burden on patients and on the healthcare system



Empowering Patients to Treat Themselves

- Etripamil: novel calcium channel blocker
- Fast-acting, well-tolerated, portable, on-demand
- Shift from Emergency Department to patient self-management



Positioned for **Success**

- Positive Phase 3 results in PSVT
- NDA submission Oct 2023
- AFib-RVR program expands market
- Phase 2 data Nov 2023
- Experienced leadership driving commercialization

PSVT = Paroxysmal Supraventricular Tachycardia; AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate; NDA = New Drug Application



Appendix

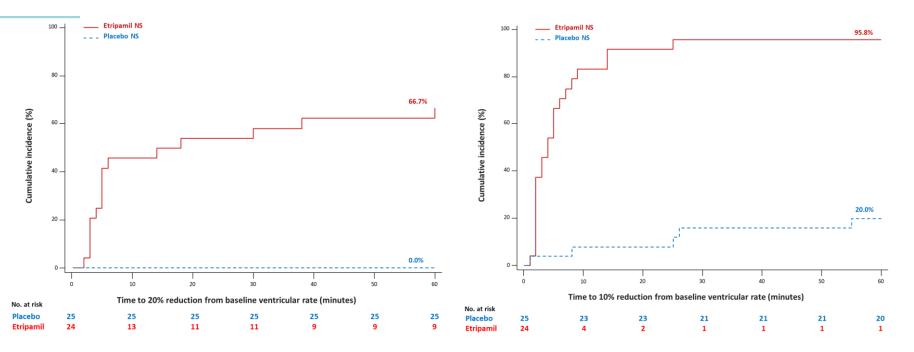
TSQM-9: Effectiveness Domain Questions



Answer scale for	1	2	3	4	5	6	7
each question:	Extremely Dissatisfied	Very Dissatisfied	Dissatisfied	Somewhat Satisfied	Satisfied	Very Satisfied	Extremely Satisfied

- 1. How satisfied or dissatisfied are you with the ability of the medication or treat your condition?
- 2. How satisfied or dissatisfied are you with the way the medication relieves your symptoms?
- 3. How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?

Time from Drug Administration to ≥20% and ≥10% Reductions from Baseline Ventricular Rate



	≥ 20% reduction	≥ 10% reduction
Difference in achievement of % reduction, p-value ^{1, 2}	<0.0001	<0.0001
Median time to achieve % reduction	Placebo: not achieved	Placebo: not achieved
from baseline VR	Etripamil: 14 min	Etripamil: 4 min

¹ Efficacy Population is comprised of all randomized patients receiving study drug who remained in atrial fibrillation with adequately diagnostic ECG recordings for at least 60 min post drug. ² By chi-square test.

Milestone - Atrial Fibrillation Program Overview

100