



Milestone
PHARMACEUTICALS



Commercial Opportunity Deep Dive for Milestone Pharmaceuticals

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Chief Executive Officer

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December 6, 2022

Forward Looking Statement



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Etripamil is an investigational new drug, which is not approved for commercial distribution in the United States.

Commercial Deep-Dive Agenda



- **Introduction and Overview** of Milestone Pharmaceuticals
- **PSVT Disease Burden** – The Problem
- **Etripamil** – Value Proposition
- **Where Do We Play** – Market Size
- **How Do We Engage** – Commercial Strategy

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Management Team



Joseph Oliveto
Chief Executive Officer



Amit Hasija
Chief Financial Officer



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Chief Medical Officer



Francis Plat, MD
Chief Scientific Officer



Lorenz Muller
Chief Commercial Officer



Jeff Nelson
Chief Operating Officer



Investment Highlights



1. Etripamil potentially offers patients with PVST control over their condition through rapid resolution of episodes when and wherever they occur
2. PSVT is a large untapped market with high unmet need for Patients and Health Care Providers
3. Experienced team with deep understanding of the market from 5+ years of stakeholder engagement
4. Phase 3 clinical trials in PSVT deliver clear statistical efficacy and safety appropriate for patient self-use
5. NDA submission expected mid-2023 enables clear path to market
6. Development in AFib with Rapid Ventricular Rate (AFib-RVR) represents potential to drive future growth

Atrial Arrhythmias with a Common Patient Burden



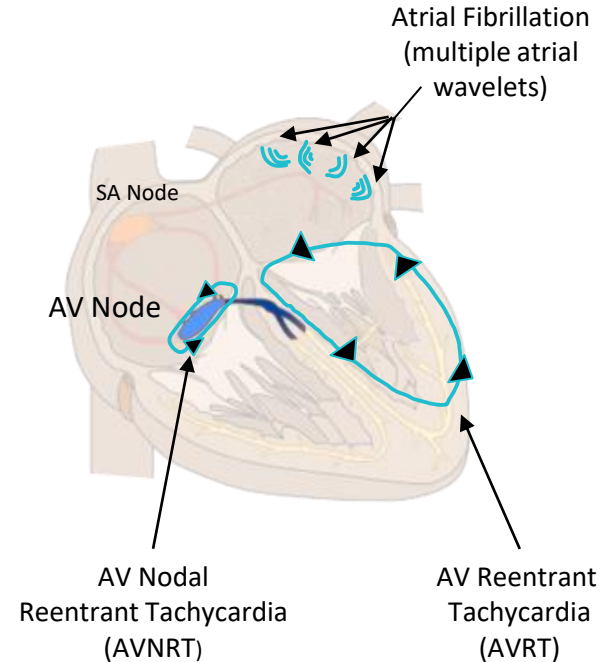
Patients with PSVT and AFib-RVR report feeling a loss of control

PSVT (AVNRT and AVRT)	AFib-RVR (a subset of AFib)
Regular rapid heart rate	Irregular rapid heart rate
Commonly 150 - 250 bpm	Commonly 100 - 175 bpm
Episode frequency and duration is highly variable	

Common Symptoms Include	Heart palpitations	Chest pressure or pain
	Shortness of breath	Fatigue
	Light-headedness	Anxiety

PSVT = Paroxysmal Supraventricular Tachycardia; AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate

Sources: adapted from https://en.ecgpedia.org/index.php?title=Supraventricular_Rhythms, accessed 2/2021



Current Standard of Care for PSVT



Chronic / preventive



- Chronic oral BBs and CCBs
- Uncertain efficacy and unpleasant side effects
- 50-65% of patients with PSVT are actively taking at any time



- Catheter ablation
- Only ~10-15% of patients with PSVT opt for ablation

Acute



- IV adenosine or DC cardioversion
- >150K ED visits/hospital per year
- CCBs/BBs used off-label as “Pill-in-Pocket” despite limitations
- Many patients wait out episodes

PSVT = Paroxysmal Supraventricular Tachycardia; AFib-RVR = Atrial Fibrillation with Rapid Ventricular Rate; IV = Intravenous; CCBs = Calcium Channel Blockers; DC = Direct Current; AAD = Anti Arrhythmic Drugs

Sources: Internal estimates based on market research and longitudinal analysis of Truven/Marketscan and Medicare claims data; Page RL et al, 2015 ACC/AHA/HRS guideline for the management of adult patients with supraventricular tachycardia: executive summary: a report of the ACC/AHA Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. 2016;133:e471–e505; Quantitative market research conducted by Triangle Insights Group (n=250 cardiologists), June-September 2020

Potential Paradigm-Changing Treatment to Empower Patient Control of their Condition



Drawbacks with the current standard of care in the Emergency Department



- Time consuming
- Anxiety provoking
- Costly
- Unpleasant experience with adenosine
- Often results in a hospital admission
- Experienced by patients as a loss of control

Intervention used by the patient when & wherever an episode occurs



Potential to:

- Resolve patient symptoms quickly
- Reduce ED visits / hospital admissions
- Alleviate need for chronic medications
- Be used as an alternative or bridge to ablation procedure

Etripamil: Potential New Treatment for PSVT



- Developed to rapidly terminate episodes of PSVT
- Designed for patient self-administration where and whenever the episodes occur
- Novel, investigational, L-type calcium channel blocker
- Formulated as intranasal spray with:
 - Rapid onset of action ($T_{\max} \leq 7$ min)
 - Short-lasting duration: eliminated from blood within a few hours



PSVT= paroxysmal supraventricular tachycardia. PK = pharmacokinetic. Error bars = standard error (SE).

Sources: Stambler BS, et al., J Am Coll Cardiol. 2018; Wight D, et al. J Am Coll Cardiol. 2022 Mar, 79 (9_Supplement); Ip JE, et al. manuscript in preparation. ; NODE-PK-101, -103, data on file.

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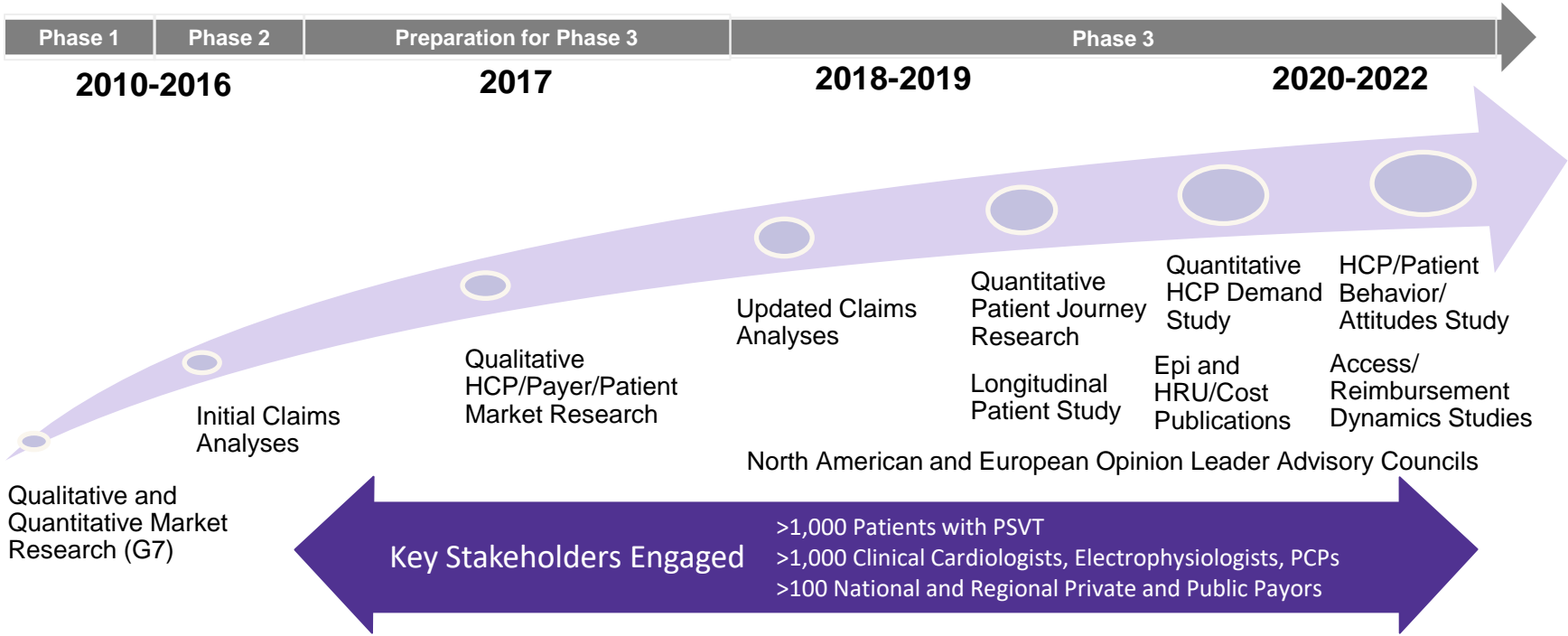


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Milestone Thought Leadership in PSVT



Robust market and customer understanding shown in interviews with 2,000+ stakeholders



Source: Milestone Market Research and Longitudinal Claims Analyses on file

Longitudinal Study Enhances Understanding of Burden of PSVT

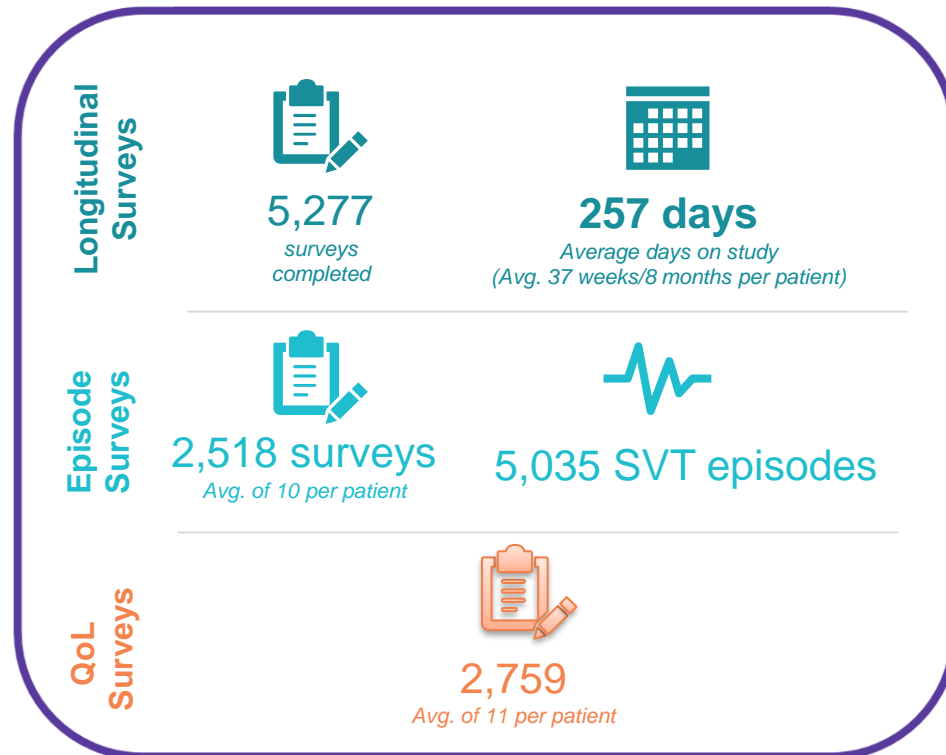


Analysis of Prospective Patient Reported Outcomes (PRO) Longitudinal Data



247 US & UK patients

- **Phase 1: Baseline Survey** (*medical and SVT episode history*)
- **Phase 2: Longitudinal Weekly Surveys** (*episode survey if experienced an episode, QoL survey if not*)



Source(s): PSVT patient market research, 2019 (Blueprint Research Group, n=247, n=198 US & n=49 UK)

Key Characteristics of PSVT for Patients that Define TAM



- ~60%** with multiple 10+ minute moderate/severe* episodes per year
- ~45%** experience an average duration ≥ 30 min / episode
- >20%** experience one or more episodes per year that require medical intervention
- 12-15** median episode frequency per year
 - 35%** last at least 30 minutes
 - 56%** moderate/severe intensity

Target Addressable Market (TAM)

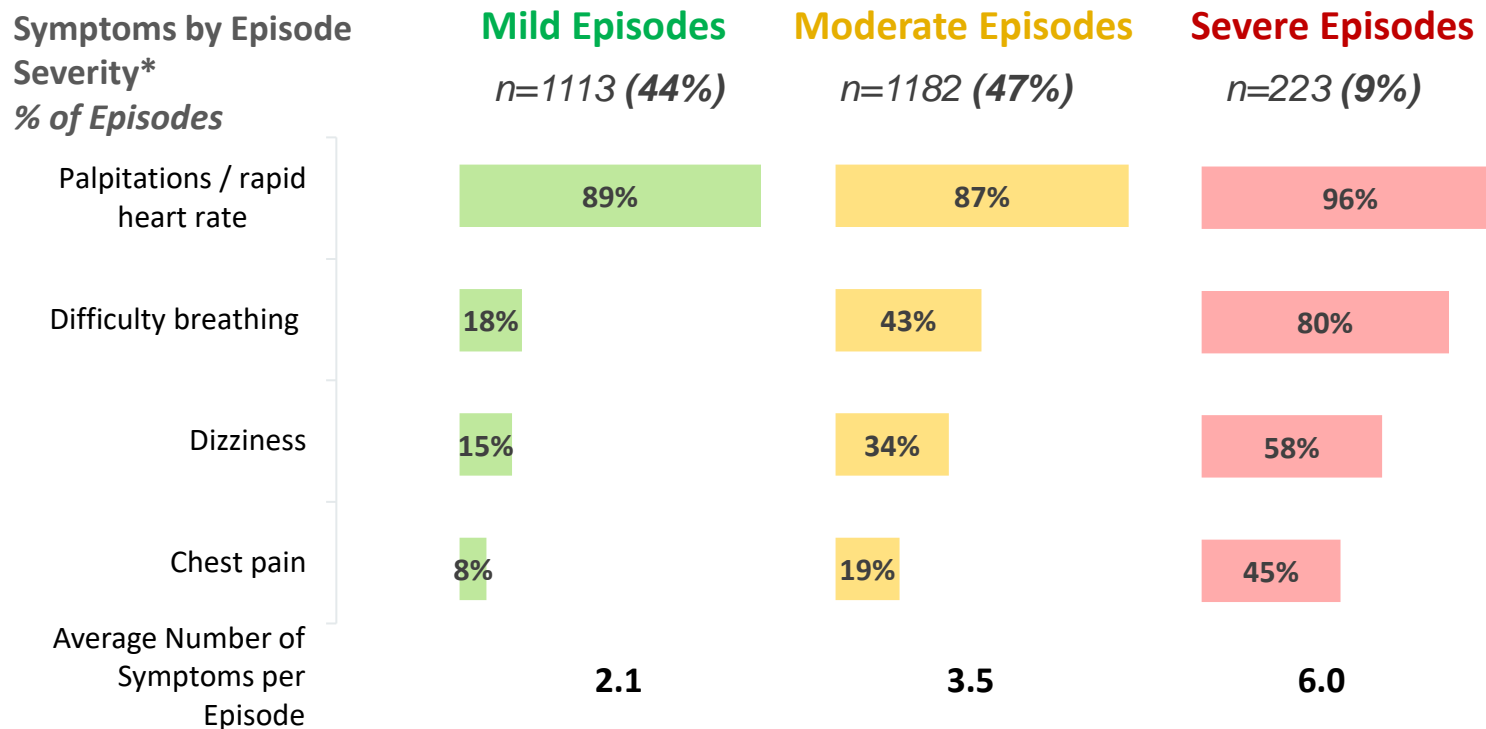
40-60% of patients diagnosed with PSVT

4 - 6 burdensome episodes / year

*Patient stated severity of SVT episode (mild, moderate, or severe)

.Source: 2019 market research with patients conducted by BluePrint Research Group (n=247)

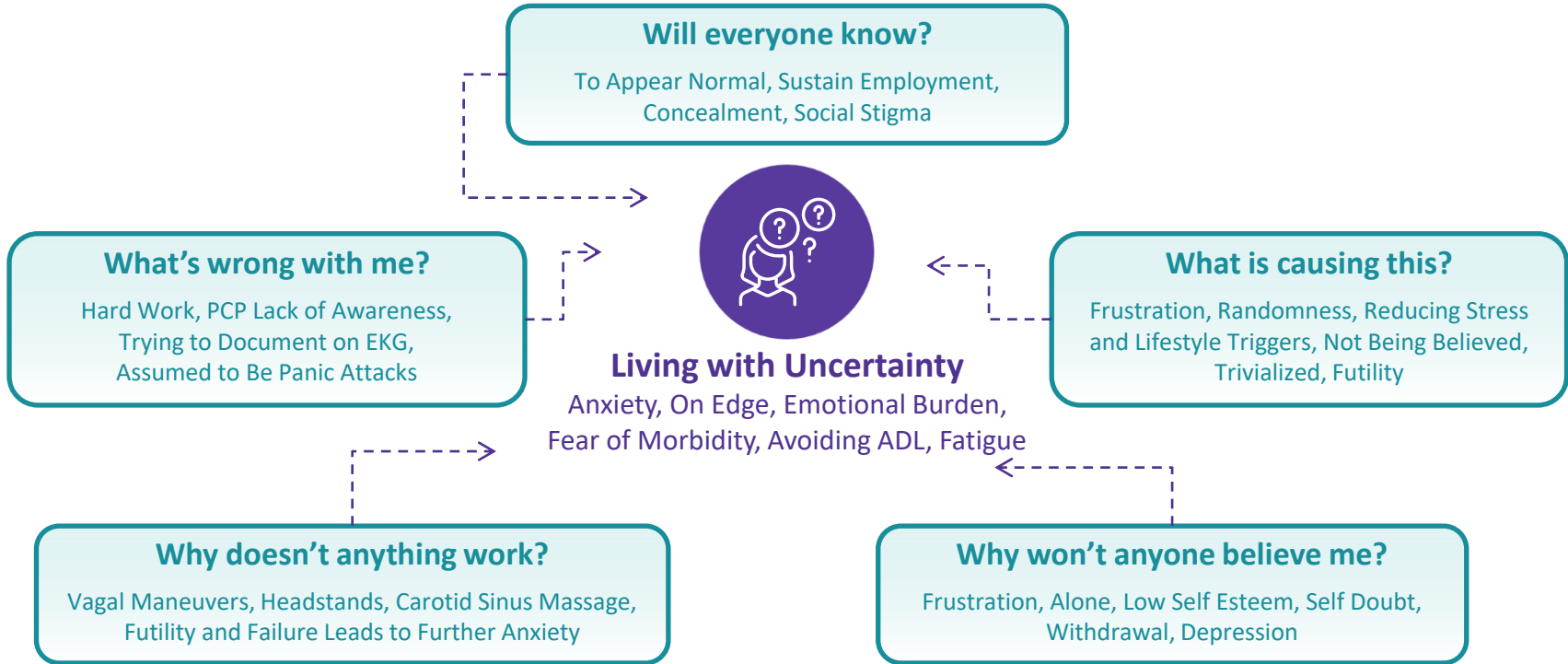
PRO Study Episode Burden – # Symptoms Correlate with Episode Severity



*Severity as self-reported by patient (mild, moderate, severe)

Source: PSVT patient market research, 2019 (Blueprint Research Group, n=247, n=198 US & n=49 UK)

The Emotional Burdens of PSVT, During *and* Between Episodes



Source: K Wood, Supraventricular Tachycardia and the Struggle to be Believed, Eur J Cardiovasc Nurs., 2007 December

Commercial Deep-Dive Agenda

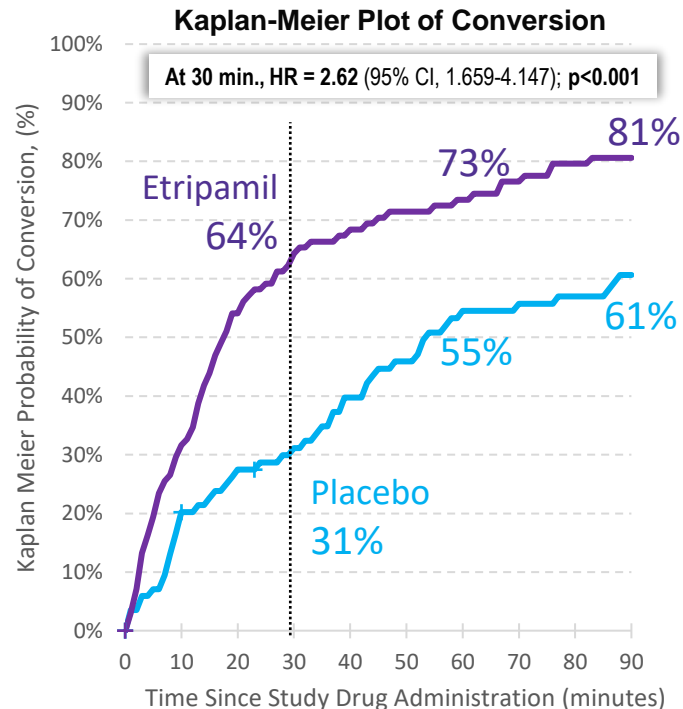


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RAPID-Enabled Target Product Profile for Etripamil



	Etripamil	Placebo
Conversion to Sinus Rhythm at 30 Minutes	64%	31%
Conversion to Sinus Rhythm at 60 Minutes	73%	55%
Median Time to Conversion	17 minutes	54 minutes
Healthcare Resource Utilization	<ul style="list-style-type: none"> Use of Etripamil resulted in a cumulative ~40% difference in ED visits 	
Relief of specific symptoms potentially associated with an SVT episode	<ul style="list-style-type: none"> Etripamil demonstrated significant improvement in symptoms 	
Generally safe and well tolerated	<ul style="list-style-type: none"> Vast majority of adverse events were mild in which 30% of patients experienced transient nasal discomfort / irritation Less than 1% of patients experienced presyncope or 2nd degree AV block 	



Source: James Ip et al (2022, Nov 7): *Self-Administered Etripamil for Termination of Spontaneous Paroxysmal Supraventricular Tachycardia: Primary Analysis from the RAPID Study*. AHA 2022 Late-Breaking Science, Chicago, IL, USA

Etripamil Has Distinct Value Propositions for All Stakeholder Groups



Patients



Rapid & Reliable Relief

Provide meaningful relief from episode symptoms and duration



Patient Empowerment

Empower in disease management & avoid unneeded healthcare visits



Quiet Mind

Reduce worry between episodes with versatile **on-demand** treatment



Active Living

Allow a return to normal functional activity between episodes



Physicians



Familiar & Trusted

Ca+ channel MoA is well known and trusted



Rapid, Safe, & Reliable Relief

Provide meaningful & safe relief from episode symptoms and duration



Versatile 'On-Demand' Treatment

Meet the need for reliable acute outpatient treatment options



Reduction in Healthcare Utilization

Reduce unneeded healthcare use (e.g., unneeded ED visits)



Payers



Addresses Unmet Need

Fill a gap in current treatment with the first indicated, **reliable, on-demand** option



Reduction in Healthcare Utilization

Demonstrate measurable reduction in healthcare utilization and cost-offsets

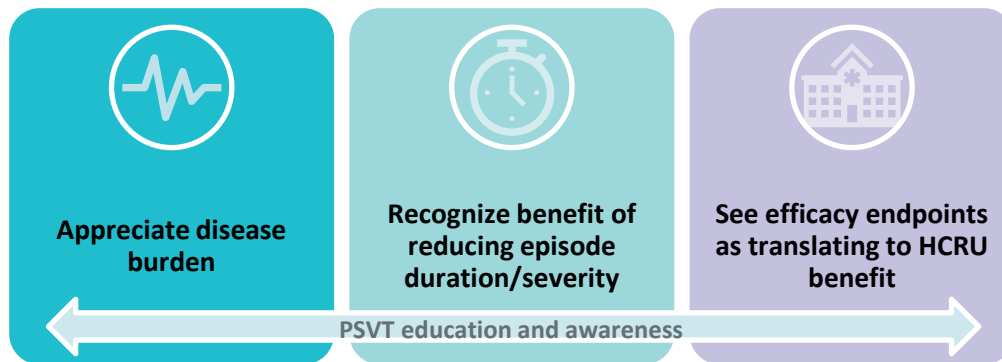


Novel Formulation

New molecule using Ca+ channel MoA

Source: Patient Advisory Boards and Focus Groups with Patient Ambassadors; HRW HCP and Patient Behavioral and Attitudinal Research 2022 ;Triangle Insights Group (Node 301 and Rapid Qual and Quant HCP Demand Research 2020); Trinity Life Sciences analysis of IBM Market Scan and IQVIA PharMetrics Data 2021-2022), CRA Research (US Strategic Pricing Research with Payers 2021, Etripamil Pricing Corridor Research with HCPs and Patients 2022), Payer Ad Board 2022

Market Access Strategy Considerations



- Most US payers are expected to understand the burden of PSVT and the value prop for etripamil
- Not expected to be “budget-impacting” enough to warrant active management
- Minimal market competition less likely to drive large rebate pressure
- Tier placement and utilization management employed are expected to determine physician willingness to prescribe and patient willingness to pay

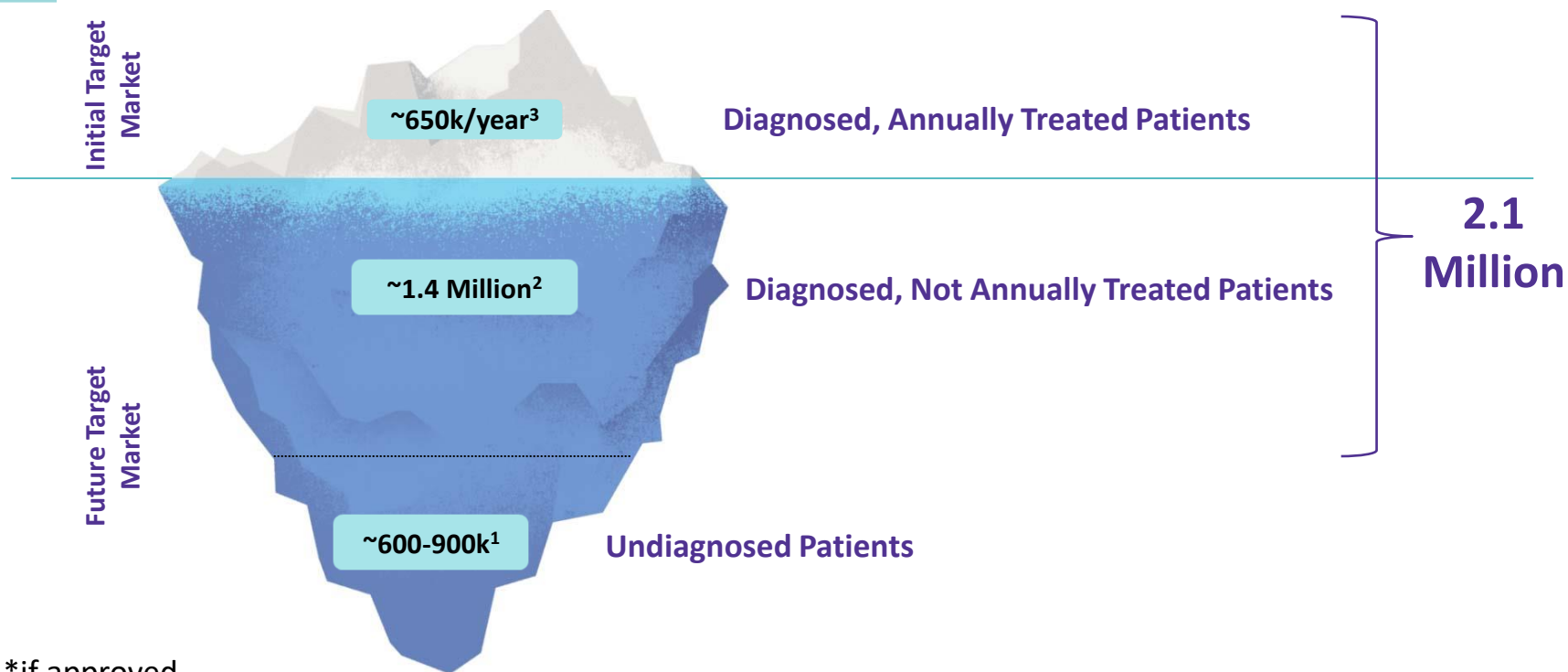
Sources: CRA Research (US Strategic Pricing Research with Payers 2021, Etripamil Pricing Corridor Research with HCPs and Patients 2022), Payer Ad Board 2022

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Core PSVT Market is Addressable *Now**, with Large Potential for Expansion



*if approved

Sources: 1) assumes annual incidence rate for PSVT of ~300k from longitudinal claims analysis and the average time to diagnosis (currently 2-3 years) can be reduced to <6 months 2) Calculated as the difference between PSVT prevalence of 2.1M and annual treatment rate of ~650k from Truven MarketScan data, 2008-2016 analyzed by Precision Xtract, 2019 3) Estimated number of unique patients with annual claims for PSVT from Truven MarketScan data, 2008-2016 analyzed by Precision Xtract, 2019.

Understanding Epidemiology of PSVT Using Longitudinal Claims Data



	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Unique Patients	648,518	417,249	379,346	344,891	311,771	2,101,775

Diagram illustrating the relationship between Unique Patients, Annually Treated Patients, 5-year Incidence Patients, and 5-year Prevalence Patients. Arrows indicate that Annually Treated Patients (Year 1) and 5-year Incidence Patients (Years 1-5) contribute to the total Unique Patients, while 5-year Prevalence Patients (Years 1-5) also contribute to the total Unique Patients.

Analyzed commercial and Medicare claims data over a 9-year period, where patients were required to have five years of continuous enrollment

- ✓ **1+ PSVT code** required in the **Emergency Department or inpatient setting** (unique patients managed acutely) or,
- ✓ **2+ PSVT codes** required in the **outpatient setting** (additional unique patients managed chronically)

Source: Data on file from IBM MarketScan® Commercial Research Database (<65y) and the Medicare Limited Dataset (≥65y), with demographic, enrollment and claims data for commercially insured (Truven) and Medicare covered patients using PSVT code 427.0 or I47.1 for up to a 9-year interval between 2008 and 2016 inclusive.

New Publication Addresses Under-reporting of Prevalence of PSVT



Received: 10 December 2020 | Revised: 4 May 2021 | Accepted: 10 May 2021
DOI: 10.1111/joa.13109

ORIGINAL ARTICLES

WILEY

Prevalence and incidence of patients with paroxysmal supraventricular tachycardia in the United States

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Disclaimer: Michael Rehorn receives research support from Pfizer and Boston Scientific; Naomi Sacks, Mala Emdin, Bridget Healey, Madison Preib, and Philip Cyr are employees of Precision Health Economics, which received research support from Medtronic Pharmaceuticals. Such funding reports research support from Bristol-Myers Squibb, Pfizer, Janssen Pharmaceuticals, Food and Drug Administration, Glaxo, and Boston Scientific consulting/advisory board support from Medtronic, Boston Scientific, Pfizer, Janssen Pharmaceuticals, Bristol-Myers Squibb, Pfizer, and Portia. DSMH support from Medtronic.

Abstract

Background: Paroxysmal supraventricular tachycardia (PSVT) encompasses a range of heart rhythm disorders leading to rapid heart rates. By virtue of its episodic nature, diagnosing PSVT is difficult and estimating incidence and prevalence on a population level is challenging. The objective of this study was to estimate the incidence and prevalence of PSVT in the United States (US) in contemporary practice.

Methods and Results: An observational retrospective longitudinal study using claims, enrollment, and demographic data from the IBM MarketScan[®] Commercial Research database (age <65) and the Medicare Limited Data Set (age ≥65) from 2008 to 2016. Patients with a PSVT diagnosis code (ICD-9: 427.0; ICD-10: I47.1) on ≥2 outpatient, ≥1 emergency room, or ≥1 inpatient visit were considered as having PSVT. Patients with atrial fibrillation/atrial flutter (AF/AFL) were excluded from the initial analysis given the potential for misclassification. Incidence was estimated by assessing diagnoses made during year 5 of continuous enrollment. Finally, a sensitivity analysis was performed by including patients with both PSVT and AF/AFL diagnoses. Period prevalence and incidence rate were estimated to be 32329 (2032–3429) and 57.8 (52.8–63.3) per 100 000 individuals, respectively, when excluding patients with AF/AFL. Projected to the 2018 US Census, prevalence and incidence are 1.26 million (1.21–1.30 million) and 188,981 (172,891–206,943), respectively. Including patients with AF/AFL, the prevalence may increase to 47977 (4679–4918) with an incidence of 93.4 (86.9–100.5) per 100 000 individuals or a prevalence of 2.06 million (2.01–2.12 million).
Conclusions: Approximately 1 in 300 people in the US had PSVT with the highest rates in older and female patients.

KEYWORDS

atrial fibrillation, atrial flutter, incidence, paroxysmal supraventricular tachycardia, prevalence

150
MESA Study
ELECTROPHYSIOLOGY
Paroxysmal Supraventricular Tachycardia in the General Population
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Marshfield, Wisconsin

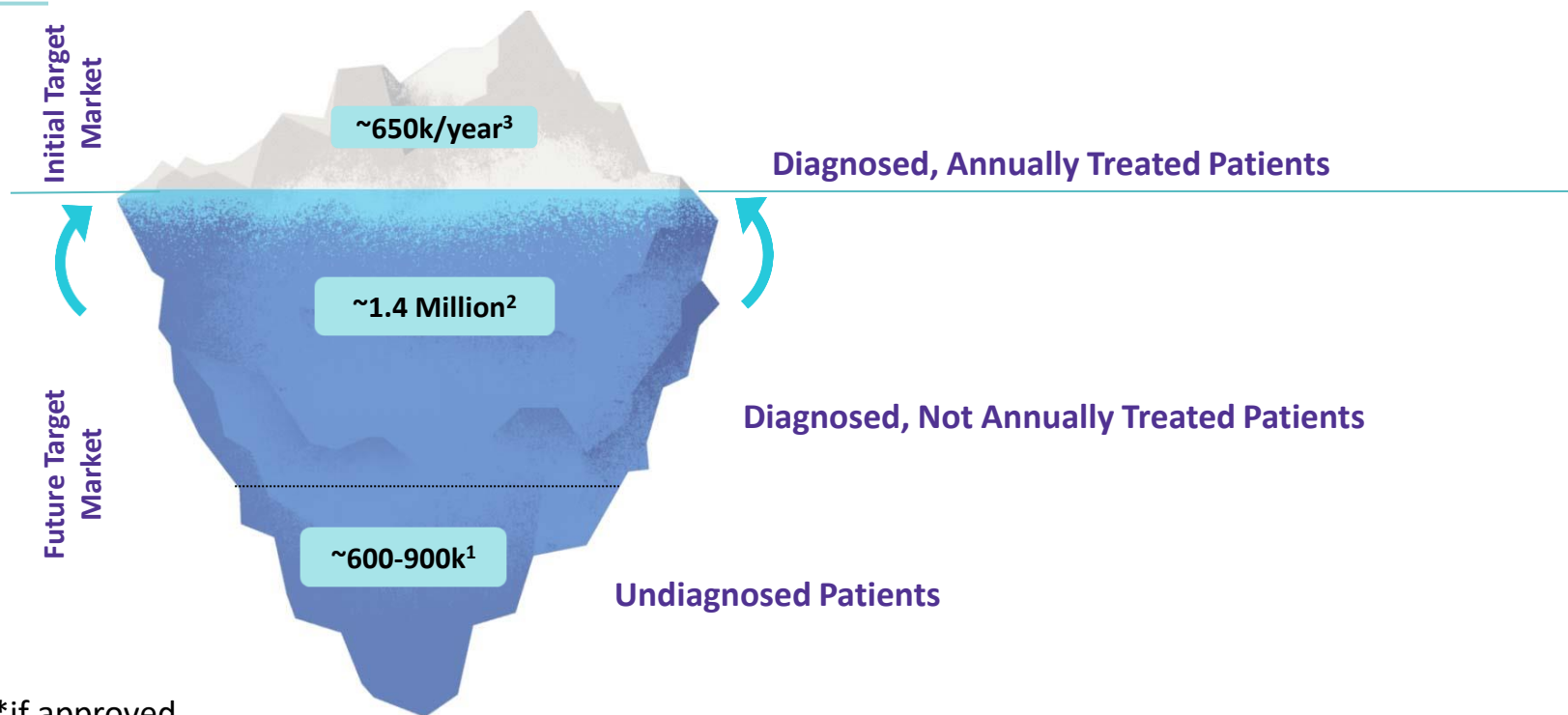
ORIGINAL RESEARCH
PREEMPT Study
American Heart Association
Contemporary Burden and Correlates of Symptomatic Paroxysmal Supraventricular Tachycardia
Alan S. Go, MD, Mark A. Hlatky, MD, Taylor I. Liu, MD, PhD, Dongjie Fan, MSPH, Elisha A. Garcia, BS, Sue Hee Sung, MPH, Matthew D. Solomon, MD, PhD

- 1.3-2.1M diagnosed patients with PSVT
- MESA/PREEMPT identify only patients presenting to healthcare settings acutely, with the episode confirmed on ECG during the encounter
- Less than 25% of patients in RAPID on placebo sought medical intervention
- Less than 40% of incident cases in MESA would have been detected by PSVT ICD-9 Code 427.0
- Potential 2.5X under-reporting of diagnosed patients with PSVT

J Cardiac Electrophysiol. 2021;1-8. | wileyonlinelibrary.com/journal/jce | © 2021 Wiley Periodicals, LLC

Source: Orejarena LA, Vidaillet H Jr, DeStefano F, Nordstrom DL, Vierkant RA, Smith, PN, Hayes JJ. Paroxysmal supraventricular tachycardia in the general population. *J Am Coll Cardiol.* 1998;31:150–157. Alan S. Go, MD; Mark A. Hlatky, MD; Taylor I. Liu, MD, PhD; Dongjie Fan, MSPH; Elisha A. Garcia, BS; Sue Hee Sung, MPH; Matthew D. Solomon, MD, PhD. Contemporary Burden and Correlates of Symptomatic Paroxysmal Supraventricular Tachycardia. *J Am Heart Assoc.* 2018;7:e008759. DOI: 10.1161/JAHA.118.008759.

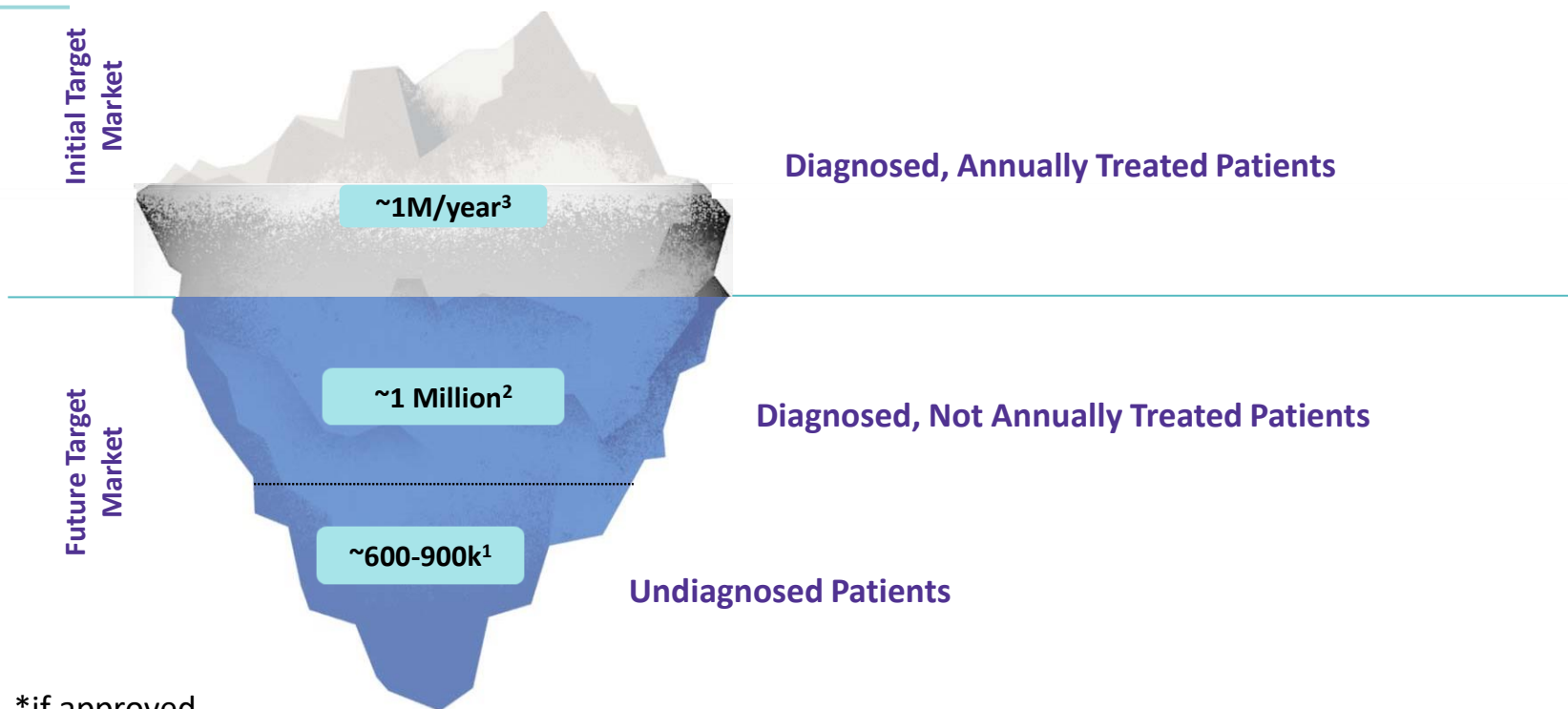
Core PSVT Market is Addressable Now*, with Large Potential for Expansion



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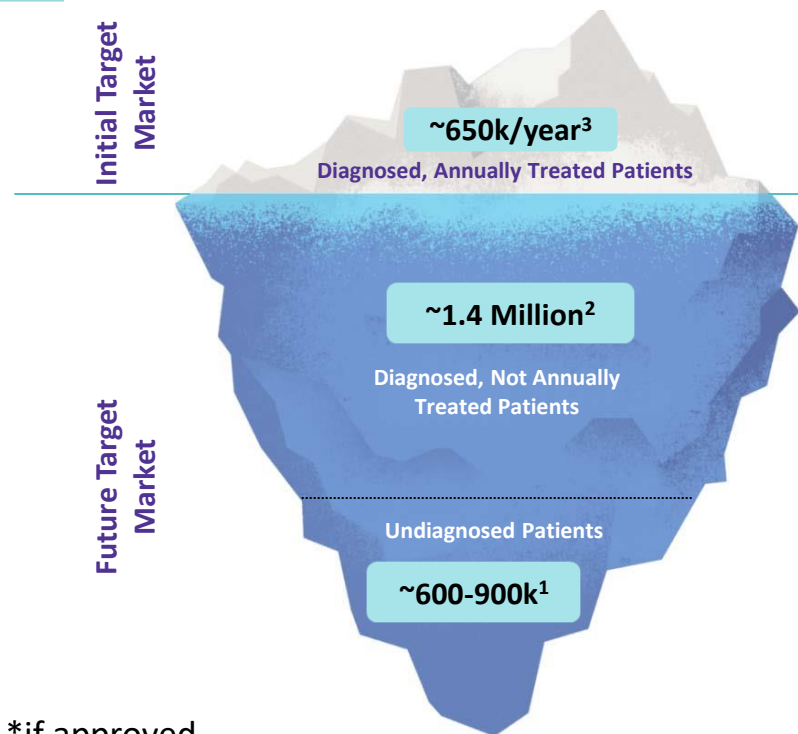
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Strategy to Address

- Hyperfocus on Early Adopters (Cardiologists)
- Quality Reimbursement/Co-Pay Support
- Omnichannel Patient Activation
- Expanded Access
- PCP Market Development/Expansion
- Institutional & Urgent Care Market Expansion
- Market Development Through Digital Diagnostics
- Targeted DTC –TV

*if approved

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Management of Patients with PSVT and Call Point Targeting



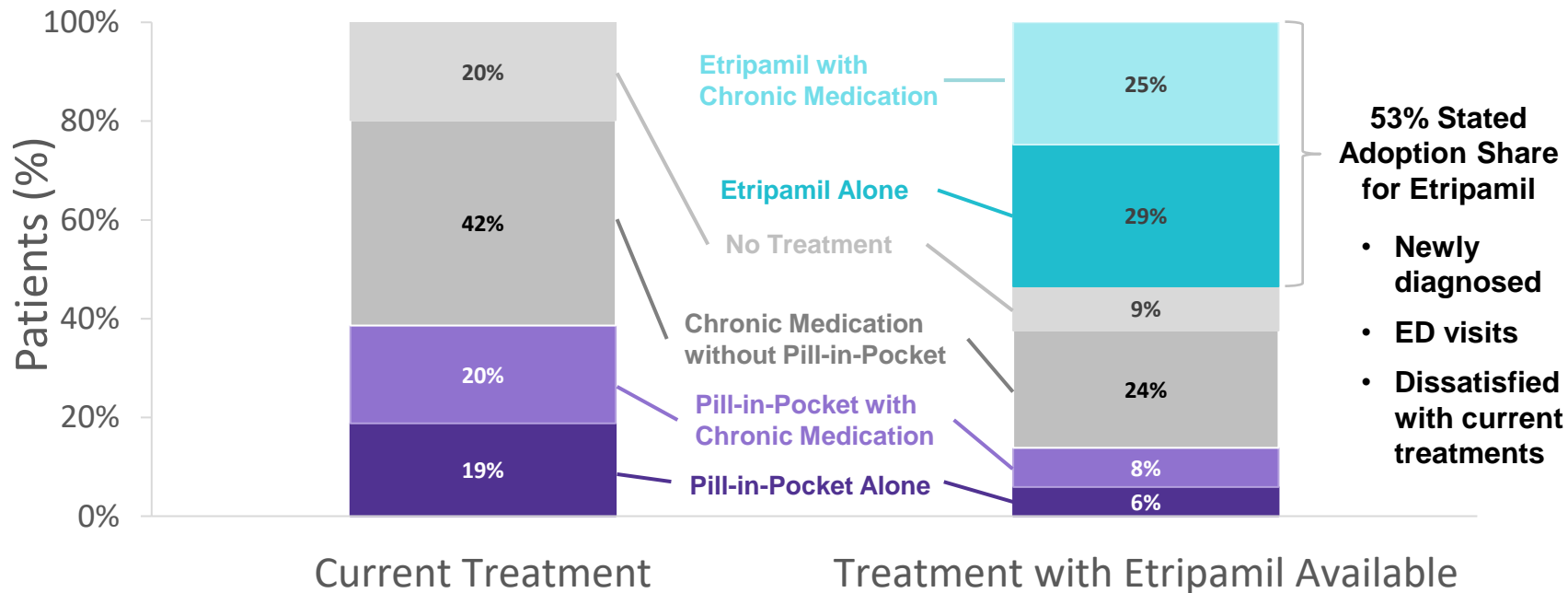
Majority of patients with PSVT managed by CV specialists, leading to commercial efficiencies

		Clinical Cardiologists	Primary Care Physicians	Electro-physiologists
% of patients managed		~60%	~30%	~10%
Long-term Use	<i>Add to or Replace Chronic Medications</i>	Primary Target		
Medium-term Use	<i>Defer Ablation</i>			
Short-term Use	<i>Bridge to Ablation</i>			
				Secondary Target

- Targeted sales force to reach majority of available opportunity
- Significant overlap with most common CV portfolio call points (e.g., heart failure, OACs, lipidemia, diabetes)

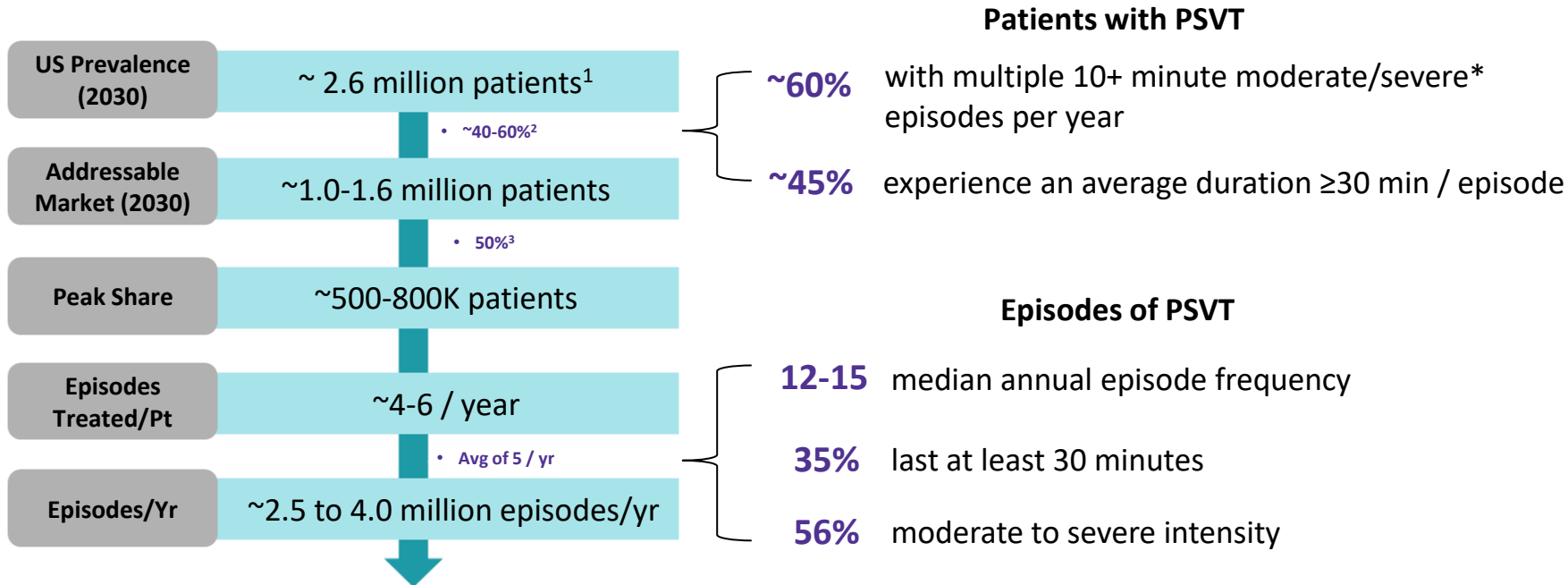
PSVT = Paroxysmal Supraventricular Tachycardia; CV = Cardiovascular; OAC = Oral Anti-Coagulants
 Source: Milestone Market Research on file

Cardiologists Report >50% Stated Adoption of Etripamil when Shown RAPID Study Product Profile



Source: Quantitative market research conducted by Triangle Insights Group (n=250 cardiologists), June-September 2020

Peak US Market Opportunity for Etripamil in PSVT



\$2B+ Peak US Net Revenue Opportunity

*Patient stated severity of SVT episode (mild, moderate, or severe)

Peak US net revenue estimates assume a net price of \$500-\$1,000/Rx at launch and that patients prescribed etripamil use the product on average to treat 4 episodes per year

Sources: Internal estimates based on market and outcomes research, Milestone Pharmaceuticals. 1. Rehorn et al. Journal of Cardiovascular Electrophysiology. 2021 Aug; 32(8): 2199-2206. doi: 10.1111/jce.15109. Epub 2021 Jun 14. 2. 2019 market research with patients conducted by Blueprint Research Group (n=247) . 3. 2020 market research with HCPs conducted by Triangle Insights Group, 2020 (n=250).

Commercial Deep-Dive: Key Takeaways



- PSVT represents a large and actionable population in the US with significant potential for expansion
- Most patients with PSVT experience episodes that could benefit from etripamil
- RAPID study results enable a target product profile that appeals to physicians and patients while not overly burdening payers
- PSVT market dynamics allow for early success and substantial room to expand
- Milestone has the foundational market understanding and commercialization expertise to successfully launch etripamil in the US



Thank you