Self-administered Etripamil for Termination of Spontaneous Paroxysmal Supraventricular Tachycardia: Primary Analysis from the RAPID Study

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James E. Ip, MD:

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• Received honoraria/speaking/consulting fee for Abbott Medical, Boston Scientific, and Medtronic Inc

• Membership on advisory committee and/or steering committee for Abbott Medical and Medtronic Inc

• Membership on data safety monitoring committee for Boston Scientific

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The trial was conducted and coordinated by Medpace and IQVIA.
Etripamil: Potential New Treatment for PSVT

- Novel, investigational, L-type calcium channel blocker
- Formulated for intranasal spray with:
  - Rapid onset of action ($T_{\text{max}} \leq 7$ min)
  - Short-lasting: inactivated by blood esterases
- Developed to satisfy unmet need for self-administered therapy that is convenient & safe outside healthcare setting
- Effective at rapidly terminating AV nodal-dependent PSVT

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

Stambler BS, et al., J Am Coll Cardiol. 2018
Objective: Evaluate the efficacy and safety of etripamil nasal spray in patients experiencing a PSVT episode in an at-home setting.

**Screening visit**

**Key inclusion criteria**
- Patients ≥18 years
- ECG-documented diagnosis of PSVT
- Hx of PSVT lasting ≥20 min

**Key exclusion criteria**
- Evidence of ventricular pre-excitation
- 2nd or 3rd degree AV block
- History of severe symptoms of hypotension or syncope during PSVT

**Test dose visit**

**Test dose given**
- 70 mg etripamil repeat dose regimen
- Administer in clinic while in sinus rhythm for safety evaluation

**RANDOMIZATION (1:1)**

**PLACEBO NS 1**

**ETRIPAMIL NS 70 mg / 70 mg 1**

**At-Home Treated PSVT Event**

- Patient recognizes symptoms
- Applies cardiac monitor (ECG)
- Attempts VM
- Administers double-blind study drug
- If symptoms persist for 10 minutes, dose study drug again

**Outcome measures**

**Independent Adjudication, Primary Efficacy Analysis**
- ECG of event is adjudicated for PSVT; only PSVT events count to primary efficacy
- **Primary Endpoint = PSVT conversion to SR Kaplan Meier analysis over 30 min**
- **Power:** 90%, alpha < 0.05; delta = 19% in conversion rates between arms
- **Study concluded when 180 confirmed PSVT events**

1. Second dose of study drug self-administered if SVT episode does not resolve within 10 minutes after first dose
2. Includes 29 events of single-dose double-blind study drug administration from NODE-301 Part 1 patients who experienced an event after event lock in that study; all blinds maintained.

ECG = electrocardiogram; AV = atrioventricular; PSVT = paroxysmal supraventricular tachycardia; Hx = history; SR = sinus rhythm; VM = vagal maneuver; NS = nasal spray.

Stambler, BS et al. Am Ht. J (2022)
1 Received test dose of etripamil (34 received 1 x 70 mg, 672 received 2 x 70 mg)
2 34 randomized to single-dose regimen in NODE-301 Part 1; 658 randomized to optional repeat-dose regimen (repeat dose if symptoms persisted after 10 minutes) in RAPID.
3 July 20, 2022
4 Took randomized drug during episode of perceived PSVT, 34 received a single-dose drug regimen, 221 received an optional repeat dose regimen (2nd dose if symptoms persisted after 10 min)
5 Took randomized drug during episode of verified PSVT confirmed by independent adjudication, 29 received single-dose regimen, 154 received optional repeat dose regimen (repeat dose if symptoms persisted after 10 min)

Overall safety population
N = 706
- Test dose
  - N = 706
  - 14 not randomized, (9 test dose failures, 5 Other)
- Randomized
  - N = 692
  - 102 discontinued by time of RAPID data cut. 335 no treated PSVT episode at time of RAPID data cut; continuing in RAPID Extension study, blind maintained.

Safety population
N = 255
- Placebo
  - n = 120
- Etripamil
  - n = 135

Efficacy population
N = 184
- PSVT treated with placebo
  - n = 85
- PSVT treated with etripamil
  - n = 99

Blinded Adjudication of Safety Population
- No ECG (9%)
- Non-PSVT (19%)
- Verified PSVT (72%)

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### Demographics & Baseline Characteristics (Safety Population)

<table>
<thead>
<tr>
<th>Age, years</th>
<th>Placebo (N=120)</th>
<th>Etripamil (N=135)</th>
<th>Overall (N=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>56.2 (12.0)</td>
<td>52.4 (14.0)</td>
<td>54.2 (13.2)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>58.0 (21, 78)</td>
<td>52.0 (19, 82)</td>
<td>55.0 (19, 82)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sex, female, n (%)</th>
<th>Placebo (N=120)</th>
<th>Etripamil (N=135)</th>
<th>Overall (N=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>88 (73.3)</td>
<td>93 (68.9)</td>
<td>181 (71.0)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Race, n (%)</th>
<th>Placebo (N=120)</th>
<th>Etripamil (N=135)</th>
<th>Overall (N=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaska native</td>
<td>0</td>
<td>1 (0.7)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (3.3)</td>
<td>2 (1.5)</td>
<td>6 (2.4)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>3 (2.5)</td>
<td>4 (3.0)</td>
<td>7 (2.7)</td>
</tr>
<tr>
<td>White</td>
<td>110 (91.7)</td>
<td>126 (93.3)</td>
<td>236 (92.5)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (2.5)</td>
<td>2 (1.5)</td>
<td>5 (2.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PSVT confirmation duration, years</th>
<th>Placebo (N=120)</th>
<th>Etripamil (N=135)</th>
<th>Overall (N=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>1.7 (3.8)</td>
<td>2.2 (5.3)</td>
<td>2.0 (4.7)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>0.5 (0.0, 32.2)</td>
<td>0.3 (-0.7, 30.7)</td>
<td>0.4 (-0.7, 32.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PSVT episodes in past year</th>
<th>Placebo (N=120)</th>
<th>Etripamil (N=135)</th>
<th>Overall (N=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>10.8 (22.9)</td>
<td>6.3 (13.9)</td>
<td>8.4 (18.8)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>5.0 (0.0, 200.0)</td>
<td>3.0 (0.0, 150.0)</td>
<td>4.0 (0.0, 200.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lifetime emergency department visits for PSVT</th>
<th>Placebo (N=120)</th>
<th>Etripamil (N=135)</th>
<th>Overall (N=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>3.9 (11.2)</td>
<td>4.6 (15.5)</td>
<td>4.3 (13.6)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>2.0 (0.0, 120.0)</td>
<td>2.0 (0.0, 160.0)</td>
<td>2.0 (0.0, 160.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concomitant medications, n (%)</th>
<th>Placebo (N=120)</th>
<th>Etripamil (N=135)</th>
<th>Overall (N=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta blocker or calcium channel blocker</td>
<td>80 (66.7)</td>
<td>86 (63.7)</td>
<td>166 (65.1)</td>
</tr>
<tr>
<td>Beta blocker only</td>
<td>40 (33.3)</td>
<td>45 (33.3)</td>
<td>85 (33.3)</td>
</tr>
<tr>
<td>Calcium channel blocker only</td>
<td>29 (24.2)</td>
<td>30 (22.2)</td>
<td>59 (23.1)</td>
</tr>
<tr>
<td>Beta blocker and calcium channel blocker</td>
<td>11 (9.2)</td>
<td>11 (8.1)</td>
<td>22 (8.6)</td>
</tr>
</tbody>
</table>
Primary Endpoint: Conversion of Adjudicated PSVT to NSR at 30 min

At 30 min., HR = 2.62 (95% CI, 1.659-4.147); p<0.001

Placebo 85 78 67 64 60 58 56
Etripamil 99 79 67 55 45 40 35

Number of Patients at Risk

*++* symbol on graph indicates censoring for signal loss (n=4 over 30 minutes). PSVT = paroxysmal supraventricular tachycardia. NSR = normal sinus rhythm. HR = hazard ratio.
300-Minute Endpoint: Conversion of Adjudicated PSVT to NSR

"+" symbol on graph indicates censoring for signal loss (n=4 over 30 minutes). PSVT = paroxysmal supraventricular tachycardia. NSR = normal sinus rhythm. HR = Hazard Ratio

At 300 min.: HR = 1.70 (95% CI, 1.213-2.383); p<0.001
Median Time to Conversion of PSVT to NSR, Reduced in Etripamil Arm Compared to Placebo

"+" symbol on graph indicates censoring for signal loss (n=4 over 30 minutes). PSVT = paroxysmal supraventricular tachycardia. NSR = normal sinus rhythm.
Subgroup Analyses: Responders At 30 Minutes

Responder = conversion of PSVT to normal sinus rhythm. Age groups are not inclusive of the lower bound: Q2 45-54, includes patients >45 years old; Q3 54-62, includes patients >54 years old. PSVT = paroxysmal supraventricular tachycardia; AVNRT = atrioventricular nodal reentrant tachycardia. Q = quartile.
Secondary Endpoints: Medical Interventions, Emergency Department Utilization

**Patients Seeking Medical Intervention**

- **NODE-301 Study**: n=49 (Placebo 14%, Etripamil 15%) - Chi-square test, P=0.0587
- **RAPID Study**: n=85 (Placebo 25%, Etripamil 15%) - Chi-square test, P=0.103
- **Pooled Analysis**: n=134 (Placebo 15%, Etripamil 15%) - Chi-square test, P=0.013

**Patients with Emergency Department Visits**

- **NODE-301 Study**: n=12 (Placebo 25%, Etripamil 13%) - Chi-square test, P=0.076
- **RAPID Study**: n=18 (Placebo 21%, Etripamil 14%) - Chi-square test, P=0.209
- **Pooled Analysis**: n=30 (Placebo 22%, Etripamil 14%) - Chi-square test, P=0.035

Pooling of data and analyses were prespecified in RAPID statistical analysis plan. Statistical analyses performed by Chi-square test for each study data set and pooled data set.
### RAPID Safety – Direct ECG CMS Reading

1 Expert cardiac electrophysiologist adjudication committee evaluated all ECG recordings for each patient in the Safety Population, pre- and post-drug administration. All adjudications performed blinded to treatment assignment.

2 Safety Population patients with full 5-hour ECG recordings available.

3 Blinded-expert ECG readings were indeterminate between supraventricular tachycardia with a wide-QRS vs. ventricular tachycardia; for conservatism, rated as the latter. Of note, this tachycardia was present prior to administration of placebo.

4 Cases of pauses observed only after rescue treatment with IV adenosine.

**CMS** = cardiac monitoring system.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Placebo Randomized Dose</th>
<th>Etripamil Randomized Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-sustained ventricular tachycardia</td>
<td>19 (16.4)</td>
<td>18 (14.1)</td>
</tr>
<tr>
<td>Sustained ventricular tachycardia (≥ 30 seconds)</td>
<td>1 (0.9)³</td>
<td>0</td>
</tr>
<tr>
<td>PSVT Recurrence</td>
<td>5 (4.3)</td>
<td>4 (3.1)</td>
</tr>
<tr>
<td>Atrial Fibrillation ≥ 30 seconds</td>
<td>4 (3.5)</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Atrial Tachycardia ≥ 30 seconds</td>
<td>1 (0.9)</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>Prolonged PR, for duration of ≥ 30 seconds</td>
<td>1 (0.9)</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>Pause ≥ 3 seconds</td>
<td>1 (0.9)⁴</td>
<td>1 (0.8)⁴</td>
</tr>
<tr>
<td>Atrial Flutter ≥ 30 seconds</td>
<td>1 (0.9)</td>
<td>0</td>
</tr>
<tr>
<td>Sinus Bradycardia ≤ 40 bpm</td>
<td>1 (0.9)</td>
<td>0</td>
</tr>
<tr>
<td>PVC greater than 6 PVCs within 45 seconds</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>2nd Degree AV Block - Mobitz I AV Block</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>2nd Degree AV Block - Mobitz II AV Block</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>3rd Degree AV Block</strong></td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Rapid Safety Analysis

<table>
<thead>
<tr>
<th></th>
<th>Placebo Randomized Dose&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Etripamil Randomized Dose&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=120</td>
<td>N=135</td>
</tr>
<tr>
<td>Subjects with any randomized-period TEAE, n (%)</td>
<td>20 (16.7)</td>
<td>68 (50.4)</td>
</tr>
<tr>
<td>Maximum severity, and n (%) of subjects with any randomized-period TEAE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>15 (75.0%)</td>
<td>46 (67.6%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>4 (20.0%)</td>
<td>21 (30.9%)</td>
</tr>
<tr>
<td>Severe</td>
<td>1 (5.0%)</td>
<td>1 (1.5%)</td>
</tr>
<tr>
<td>Subjects with SAE</td>
<td>1 (0.8)</td>
<td>0</td>
</tr>
<tr>
<td>Subjects with SAE related to study drug</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subjects with AE leading to death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subjects with Drug-related AE leading to study discontinuation</td>
<td>0</td>
<td>3 (2.2)&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>1</sup> Safety Population.

<sup>2</sup> Three events were: (a) frequent PVCs and couplets after PSVT termination; (b) non-sustained VT after PSVT termination (4 beats); and (c) possible allergic reaction, treated with oral Benadryl.

TEAE timing – up to 24 hours following drug administration. TEAE = treatment-emergent adverse event; SAE = serious adverse event; AE = adverse event; PVC = premature ventricular complex; PSVT = paroxysmal supraventricular tachycardia; VT = ventricular tachycardia.
## RAPID Safety – Adverse Events

### Subjects with Randomized-period TEAE, Incidence >5%, n (%)

<table>
<thead>
<tr>
<th>TEAE</th>
<th>Placebo Randomized Dose&lt;sup&gt;2&lt;/sup&gt; (n=120)</th>
<th>Etripamil Randomized Dose&lt;sup&gt;2&lt;/sup&gt; (n=135)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal discomfort</td>
<td>6 (5.0)</td>
<td>31 (23.0)</td>
</tr>
<tr>
<td>Nasal congestion</td>
<td>1 (0.8)</td>
<td>17 (12.6)</td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>3 (2.5)</td>
<td>12 (8.9)</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>2 (1.7)</td>
<td>8 (5.9)&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

### Subjects with Randomized-period TEAE,<sup>1</sup> n (%)

<table>
<thead>
<tr>
<th>TEAE</th>
<th>Placebo Randomized Dose&lt;sup&gt;2&lt;/sup&gt; (n=120)</th>
<th>Etripamil Randomized Dose&lt;sup&gt;2&lt;/sup&gt; (n=135)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syncope</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Loss of Consciousness</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Pre-Syncope</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.0</td>
<td>1 (0.7)&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

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<sup>1</sup> Adverse events specifically acquired as adverse events of interest, as potentially representing lowered blood pressure.

<sup>2</sup>Safety population.

<sup>3</sup>Six of 8 rated as mild, 2 of 8 rated as moderate.

<sup>4</sup>Rated as mild.

TEAE timing – up to 24 hours following drug administration.

TEAE = treatment-emergent adverse event.
RAPID Study: Summary and Conclusions

- RAPID study achieved primary efficacy endpoint of terminating PSVT with self-administered etripamil, using symptom-based optional repeat dosing (HR 2.62, \( p < 0.001 \))
  - Conversion of PSVT to sinus rhythm: 64.3% at 30 minutes, 73.5% at 60 minutes
- Median Time to Conversion, 17.2 minutes in Etripamil arm vs 53.5 minutes in Placebo arm
- Favorable safety and tolerability data are consistent with prior etripamil trials
  - No new safety signals or AEs with a 2nd dose of etripamil
  - Majority of AEs were mild, local, and transient
- Pooled analysis with NODE-301 showed a significant reduction in ED utilization and medical intervention
- Results demonstrate a potential management strategy for patients to self-treat episodes with etripamil in a medically unsupervised setting
- Ongoing analysis of RAPID open-label period and NODE-303 trial will provide more insights into the safety and efficacy of etripamil for recurrent episodes of PSVT
Acknowledgements

- Study Participants

- Participating study sites / Principal Investigators / Study Coordinators across 9 countries

- Adjudication Committee members
  
  José Dizon, MD, (Chair)
  Angelo Biviano, MD
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- Clinical Operational Support
  
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