

JL Brandes,<sup>1</sup> J Rothrock,<sup>2</sup> R Cady,<sup>3</sup> SK Aurora,<sup>4</sup> JA Myers,<sup>5</sup> AW Fox,<sup>5</sup> SJ Farr<sup>5</sup>  
<sup>1</sup>Nashville Neuroscience Group, Nashville, TN; <sup>2</sup>The University of Alabama School of Medicine, Birmingham, AL;  
<sup>3</sup>Headache Care Center, Springfield, MO; <sup>4</sup>Swedish Headache Clinic, Seattle, WA; <sup>5</sup>Zogenix Inc., Emeryville and San Diego, CA

## Introduction

- A top priority in managing migraine is rapid, sustained relief that allows return to normal functioning.
- Subcutaneous sumatriptan has been shown in double-blind, placebo-controlled trials to provide the fastest relief of all the triptans as well as prompt return to normal daily activities. To date, parenteral therapy with sumatriptan has required a needle, typically within an autoinjector requiring assembly.
- SUMAVEL® DosePro® (registered trademark of Zogenix, Inc.) (Figure 1) is a needle-free, single-use, subcutaneous product that does not require assembly and that confers relief as early as 10 minutes after dosing in some patients.

## Objective

To evaluate multiple-attack efficacy and tolerability of SUMAVEL DosePro (needle-free subcutaneous sumatriptan) among current triptan users

## Methods

- Adults with migraine treated with triptans administered SUMAVEL DosePro for ≤4 migraine attacks over ≤60 days in this open-label, multicenter study.
- Efficacy was assessed as the proportion of attacks with pain relief 15 and 30 minutes and 1, 2, and 24 hours postdose and the proportion with sustained relief (no recurrence) at 24 hours. Pain-free response and relief of associated symptoms were also assessed at these time points.
- Adverse events were the primary tolerability measure.

## Results\*

- 242 patients administered ≥1 dose of SUMAVEL DosePro and were included in the Safety Population; 212 administered SUMAVEL DosePro to treat ≥1 migraine attack and were included in the Per-Protocol Population (Table).
- The % attacks with pain relief was 33.0% at 15 minutes, 70.1% at 30 minutes, 84.6% at 1 hour, 85.9% at 2 hours, and 81.3% at 24 hours (Figure 2). Results for nausea, photophobia, and phonophobia were similar (Figure 3).
- Sustained 24-hour pain relief (response maintained from 1-24 hours with no use of a second dose or rescue medication) was observed in 66.3% of attacks; sustained 24-hour pain-free response was observed in 35.4% of attacks (Figure 4).
- Results were consistent across attacks. 75.8% of those treating 4 attacks (n=113) reported pain relief 2 hours postdose in ≥3 of 4 attacks (Figure 5).
- The % attacks requiring a second dose was 24.5% across all attacks and remained stable throughout the study. The mean±SD time between the first and second doses ranged from 10.9±9.1 to 15.4±12.2 hours across attacks.
- The most common adverse events (% patients) were administration site reactions, (namely minor and transient bleeding [13.2%], hematoma [12.8%], pain [12.0%], swelling [10.7%], erythema [7.4%]); nausea (7.4%); and dizziness (7.0%).

Table. Demographics and Clinical Characteristics

	Per Protocol Population (N=212)	Safety Population (N=242)
Mean (SD) age, years	43.5 (10.74)	43.2 (10.75)
Female, n (%)	175 (82.5)	196 (81.0)
Race, n (%)		
Asian	3 (1.4)	3 (1.2)
Black or African American	14 (6.6)	16 (6.6)
Native Hawaiian/Pacific Islander	1 (0.5)	1 (0.4)
White	193 (91.0)	220 (90.9)
Multiple Races Checked	1 (0.5)	2 (0.8)
Mean (SD) weight, kg	74.96 (18.43)	76.06 (19.96)
Mean (SD) age at migraine onset, years	21.1 (11.26)	20.8 (10.99)
Primary migraine type, n (%)		
Migraine without aura	147 (69.3)	165 (68.2)
Migraine with aura	24 (11.3)	29 (12.0)
Composite (with and without aura)	41 (19.3)	48 (19.8)
Prior use of self-injected sumatriptan		
Yes	89 (42.0)	97 (40.1)
No	123 (58.0)	145 (59.9)
Triptans within 8 weeks of study, n (%)		
Any oral triptan	210 (99.1)	227 (93.8)
Any subcutaneous triptan	36 (17.0)	36 (14.9)
Any nasal triptan	9 (4.2)	10 (4.1)

Figure 2. % Attacks with Pain Relief or Pain-Free Response after Treatment with SUMAVEL DosePro (669 migraine attacks treated)

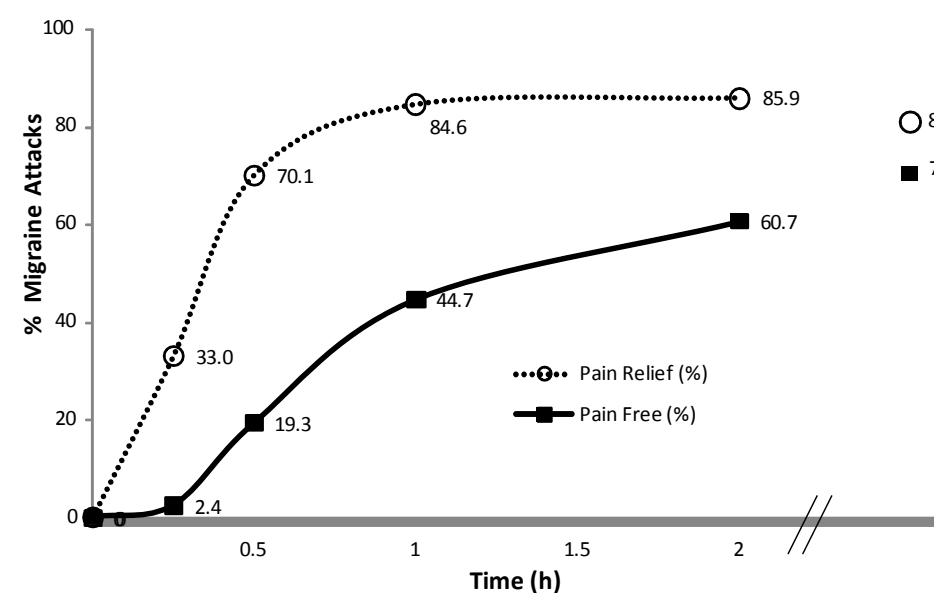


Figure 3. % Attacks with Nausea, Photophobia, or Phonophobia after Treatment with SUMAVEL DosePro (669 migraine attacks treated)

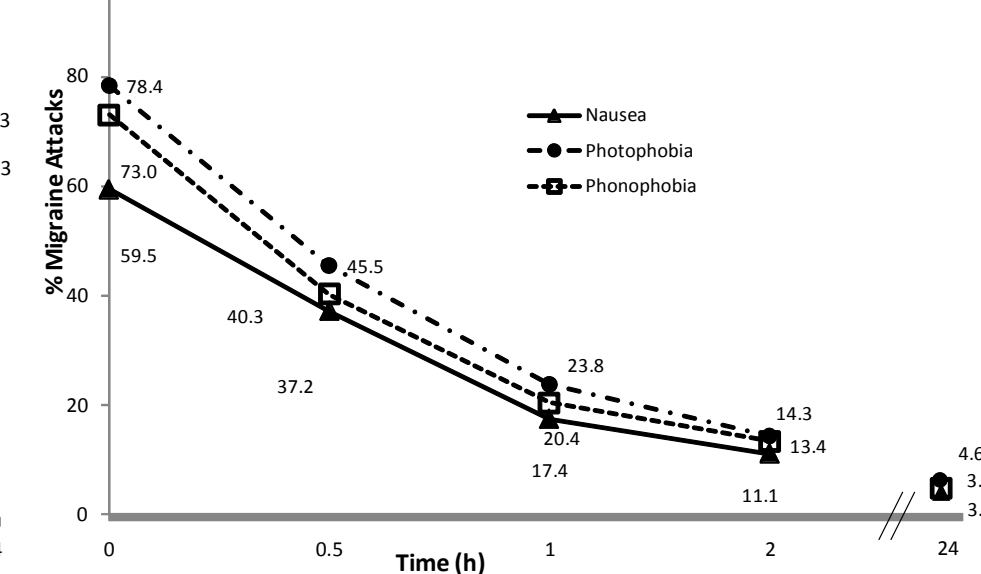


Figure 4. % Attacks with 24-Hour Sustained\* Pain Relief and Pain-Free Response (669 migraine attacks treated)

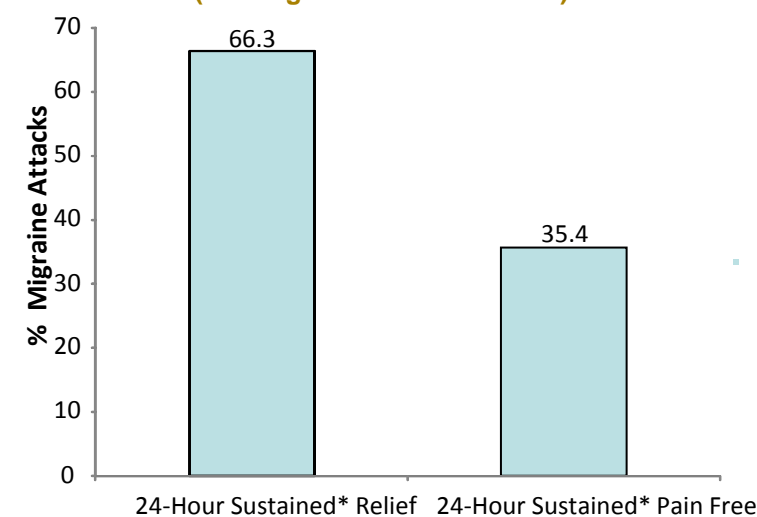


Figure 5. % Patients with Pain Relief 2 Hours Postdose in ≥3 of 4 Attacks

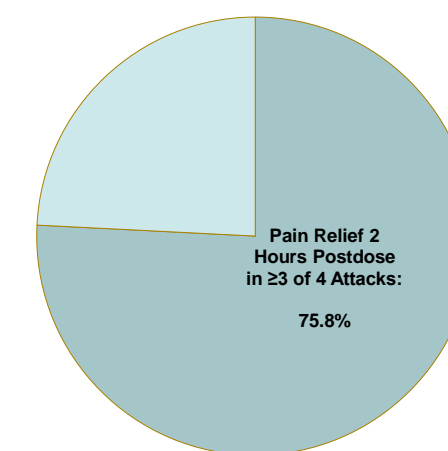
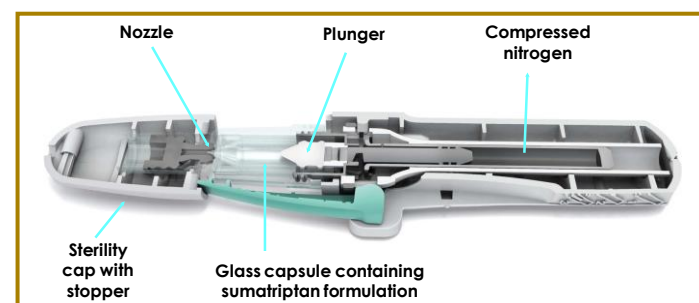


Figure 1. Cutaway View of SUMAVEL DosePro



\*Response maintained from 1 through 24 hours with no use of a second dose or rescue medication

## Conclusions

- Sumatriptan injection is the best option for triptan therapy when rapid, robust efficacy is important, but patients' dislike of needles has been a barrier to use of needle-based sumatriptan injection in formulation-based care.
- In this study, SUMAVEL DosePro (needle-free subcutaneous sumatriptan) was associated with rapid, sustained headache relief and was well tolerated in the treatment of migraine attacks among current triptan users, the majority of whom were using oral treatments.
- SUMAVEL DosePro consistently provided relief during use for multiple migraine attacks.
- The incidences of pain relief and pain-free response with SUMAVEL DosePro are consistent with those in previous double-blind, placebo-controlled clinical trials of needle-based subcutaneous sumatriptan.