

R Cady,<sup>1</sup> SK Aurora,<sup>2</sup> JL Brandes,<sup>3</sup> J Rothrock,<sup>4</sup> JA Myers,<sup>5</sup> AW Fox,<sup>5</sup> SJ Farr<sup>5</sup>

<sup>1</sup>Headache Care Center, Springfield, MO; <sup>2</sup>Swedish Headache Clinic, Seattle, WA; <sup>3</sup>Nashville Neuroscience Group, Nashville, TN;

<sup>4</sup>The University of Alabama School of Medicine, Birmingham, AL; <sup>5</sup>Zogenix Inc., Emeryville and San Diego, CA

## Introduction

- Patients' satisfaction with and confidence in migraine therapy predict medication adherence, which is necessary for optimizing clinical and economic outcomes.
- The primary determinant of satisfaction with migraine therapy is rapid, complete relief in which patients can be confident.
- Among the triptans, subcutaneous sumatriptan offers the most rapid, complete relief from migraine symptoms; however, parenteral therapies typically require a needle, usually with an autoinjector requiring assembly.
- SUMAVEL® DosePro® (a registered trademark of Zogenix, Inc.) is a needle-free, subcutaneous product that does not require assembly and that confers relief as early as 10 minutes after dosing in some patients.

## Objective

To evaluate patient satisfaction with and confidence in SUMAVEL DosePro (needle-free subcutaneous sumatriptan) among current triptan users administering SUMAVEL DosePro for up to 4 migraine attacks

## Methods

- SUMAVEL DosePro was self-administered for ≤4 migraine attacks with moderate or severe pain over a ≤60-day period by adults with migraine meeting International Headache Society criteria and currently treated with triptans (any form, any dosage) in this open-label, multicenter study.
- Treatment satisfaction was measured at baseline and the end of the treatment period with the validated Patient Perception of Migraine Questionnaire, revised (PPMQ-R).

## Results

- 212 patients administered SUMAVEL DosePro to treat ≥1 migraine attack for a total of 669 treated attacks (Table).
- PPMQ-R Overall Satisfaction (primary endpoint) increased significantly from baseline to the end of treatment (p=0.0007), an improvement that met the criterion for clinical significance (Figure 1).
- PPMQ-R scores significantly improved from baseline to the end of treatment for Efficacy (p<0.0001), Functionality (p<0.0001), and Tolerability (p=0.02) but declined for Ease of Use (p<0.0001) (Figure 1).
- The % patients *satisfied* or *very satisfied* increased from baseline to the end of treatment for all global satisfaction domains including Overall Satisfaction, Satisfaction with Medication Effectiveness, and Satisfaction with Side Effects (Figure 2) as did the percentage who were *confident* or *very confident* in treating repeated migraine attacks (baseline: 41.0%, 90% confidence interval [CI] 35.4, 46.9); end of treatment: 64.6%, 90% CI 58.9, 70.1) (Figure 3).

Table. Demographics and Clinical Characteristics

|   | Per Protocol Population (N=212) |
|---|---------------------------------|
| Mean (SD) age, years                          | 43.5 (10.74)                    |
| Female, n (%)                                 | 175 (82.5)                      |
| Race, n (%)                                   |                                 |
| Asian   | 3 (1.4)                         |
| Black or African American                     | 14 (6.6)                        |
| Native Hawaiian or Other Pacific Islander     | 1 (0.5)                         |
| White   | 193 (91.0)                      |
| Multiple                                      | 1 (0.5)                         |
| Mean (SD) weight, kg                          | 74.96 (18.43)                   |
| Mean (SD) age at migraine onset, years        | 21.1 (11.26)                    |
| Primary migraine type, n (%)                  |                                 |
| Migraine without aura                         | 147 (69.3)                      |
| Migraine with aura                            | 24 (11.3)                       |
| Composite (with and without aura)             | 41 (19.3)                       |
| Prior use of self-injected sumatriptan        |                                 |
| Yes   | 89 (42.0)                       |
| No  | 123 (58.0)                      |
| Triptans within 8 weeks of study start, n (%) |                                 |
| Any oral                                      | 210 (99.1)                      |
| Any injectable                                | 36 (17.0)                       |
| Any intranasal                                | 9 (4.2)                         |

Figure 2. Results for Global Satisfaction Items Expressed as % Patients Satisfied/Very Satisfied (N=212)

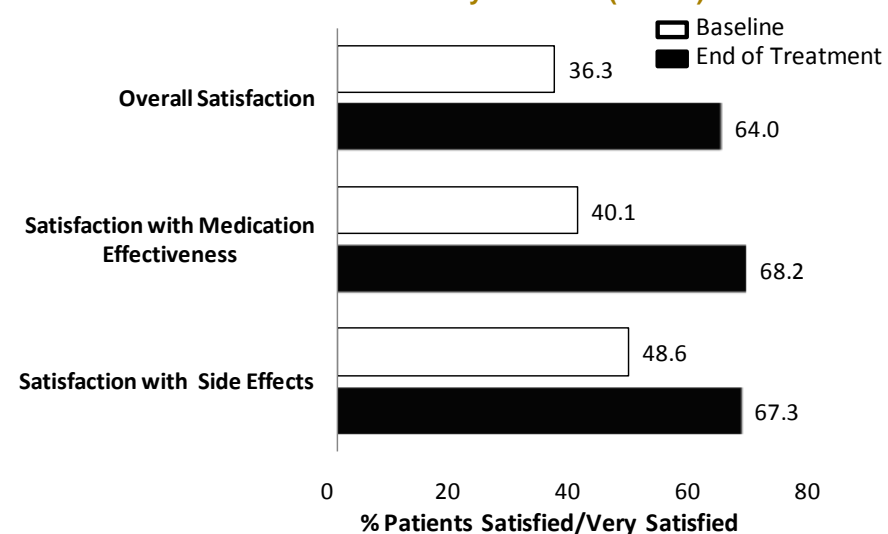


Figure 1. Mean PPMQ-R Scores. Higher scores reflect greater satisfaction.

Scores for Overall Satisfaction and the 4 subscales (Efficacy, Functionality, Ease of Use, Tolerability) were calculated from item scores and transformed to scores ranging from 0 to 100, with higher scores indicating greater satisfaction or tolerability. The Overall Satisfaction score came from the global satisfaction domain of the PPMQ-R. The total score was a composite of the subscale scores for Efficacy, Functionality, and Ease of Use.

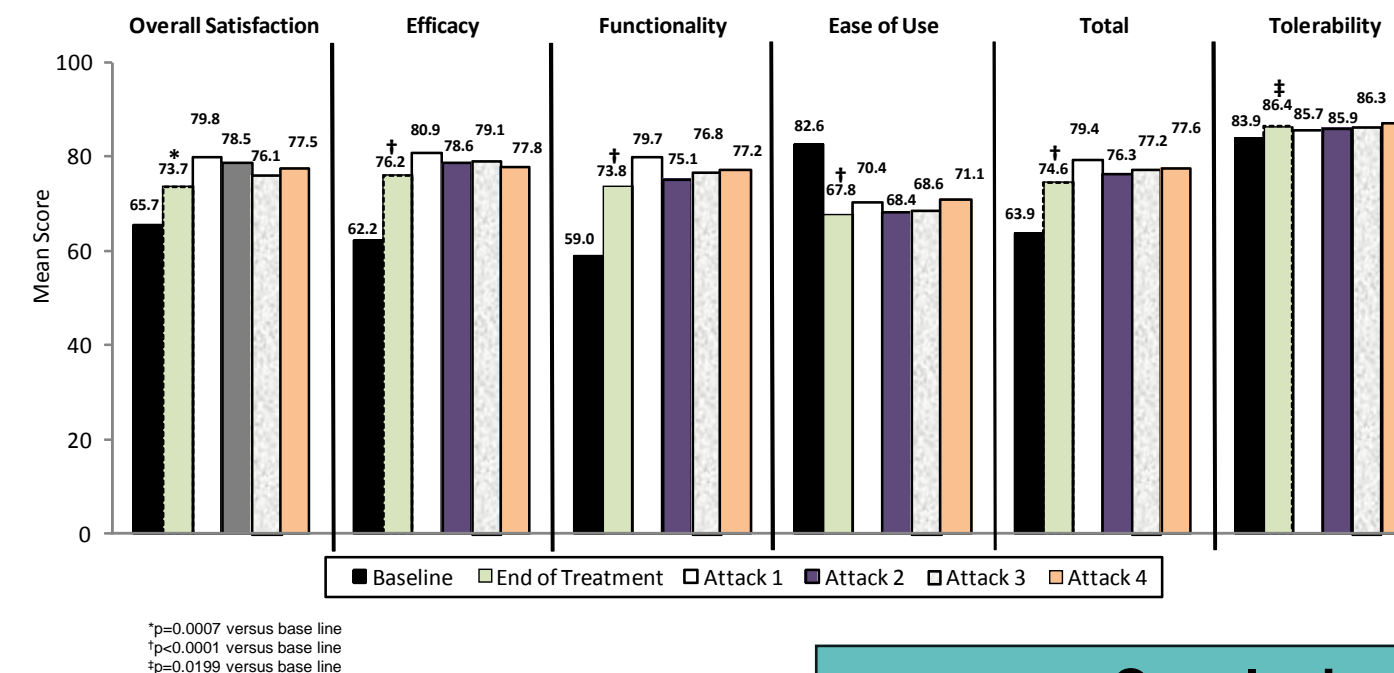
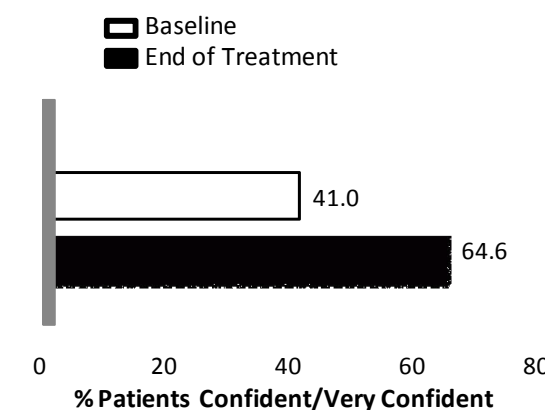


Figure 3. % Patients Confident/Very Confident in Treating Repeated Migraine Attacks (N=212)



## Conclusions

- Patients currently treated with triptans experienced a clinically and statistically significant increase in satisfaction with therapy and enhanced confidence in treatment after trying SUMAVEL DosePro for up to 4 migraine attacks.
- The findings suggest that SUMAVEL DosePro should be viewed as one essential component of the patient's anti-migraine toolbox.
- By providing patients with the tools to tailor treatment to the attributes of individual migraines and particular contexts, doctors help patients to implement the treatment strategies most effective in minimizing pain and disability and engage patients in their own management as recommended by treatment guidelines.