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Participants View Use of STS101 Favorably: Participant Impression Data From the Phase 3 Open-Label ASCEND Study

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Introduction

- Dihydroergotamine mesylate (DHE) exerts anti-migraine effects via a unique multi-modal mechanism of action involving interactions with both serotonergic and adrenergic receptors, has been used since 1946 for the acute treatment of migraine, and is recognized as a first-line treatment option.[1-3]
- STS101 is a novel investigational DHE product that combines a mucoadhesive nasal powder formulation delivered with an easy-to-use, easy-to-carry, pre-filled, single-use nasal delivery device (Figure 1).
- The STS101 advanced nasal powder and device technology maximizes deposition of DHE on the nasal mucosa, enhancing DHE absorption, increasing drug exposure and reducing pharmacokinetic variability in comparison with DHE liquid nasal sprays.[4]

Objective

- To report the participant impression and satisfaction of STS101 5.2 mg in the acute treatment of migraine attacks with or without aura over 12 months of the ASCEND study.

Methods

Study design and treatment intervention

- ASCEND was a multi-center, multi-dose, open-label, 12-month study of STS101 in adults aged 18–65 years with migraine (NCT04406649).
- After establishing eligibility, participants could self-administer STS101 5.2 mg as needed (PRN), for up to 2 doses within 24 hours to treat a single migraine attack, and up to 12 doses/month for 12 months.

Participants

- Study participants must have ≥1-year history of migraine (with or without aura) according to the International Classification of Headache Disorders, 3rd edition,[5] including:
  - Migraine onset before age of 50 years
  - 4–12 migraine attacks/month in each of the 3 months prior to screening
  - <15 headache days/month in each of the 3 months prior to screening
- Exclusion criteria included diagnosis of non-migraine headache, history of cerebrovascular disease, and ≥2 cardiovascular risk factors.
- Participants must have had an intact nasal mucosa at baseline (i.e., no ulceration or bleeding; no or mild erythema, swelling, and rhinorrhea).

Outcomes and analyses

- Patient global impression, ease-of-use impression, likelihood of use, and comparison of STS101 with previously used migraine medication for the 3-, 6-, and 12-month timepoints.
- Participants' ratings were assessed using a 5-point Likert scale, with response options dependent on the question (Table 1).

Results

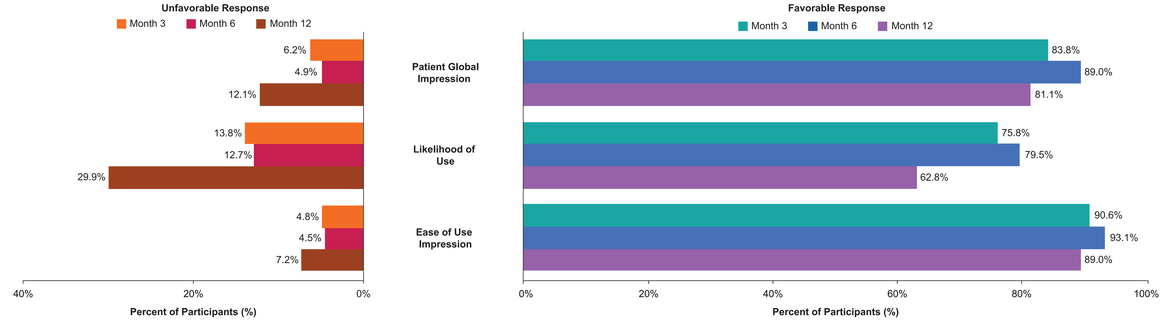
- A total of 446 participants were enrolled and used 11,390 doses of STS101 to treat 9,091 migraine attacks.
- Overall, large percentages of participants had favorable impressions of STS101, which was consistent across the assessments at 3-, 6-, and 12-month timepoints.
- STS101 was considered "good" or "very good" by 83.8% of subjects after 3 months, 89.0% after 6 months, and 81.1% after 12 months of use (Figure 2).
- At Month 3, 90.6% of participants considered STS101 easy or very easy to use, increasing to 93.1% at Month 6 and sustaining at 89.0% at Month 12 (Figure 2).
- After 3, 6, and 12 months of use, 75.8%, 79.5%, and 62.8% of participants, respectively, indicated they were likely or very likely to use STS101 if it was available (Figure 2).
- When asked at the 3-, 6-, and 12-month assessments to compare STS101 to their usual migraine medication, respectively:
  - 66.2%, 74.1%, and 61.1% of participants agreed or strongly agreed that STS101 helped them return to normal faster than their usual medication (Figure 3)
  - 64.7%, 66.7%, and 60.2% of participants agreed or strongly agreed that STS101 worked faster than their usual medication (Figure 3)
  - 69.3%, 74.2%, and 63.4% of participants agreed or strongly agreed that STS101 worked more consistently than their usual medication (Figure 3)
- At the 3-, 6-, and 12-month assessments, respectively, 62.2%, 71.3%, and 57.6% of participants agreed or strongly agreed that STS101 kept their migraines from coming back (Figure 3).

Figure 1. STS101 Administration

Table 1. Response Options for the 5-point Likert Scale

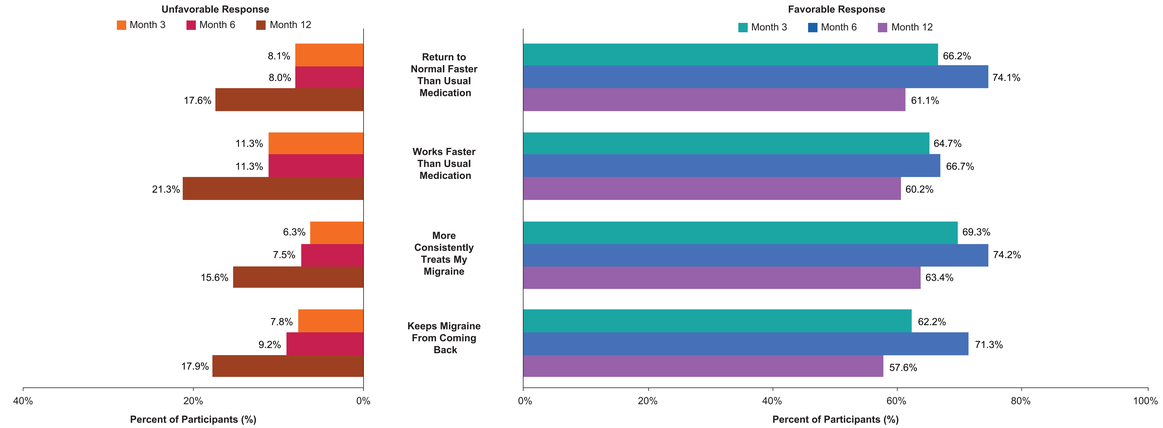
	Response Options		
	Unfavorable	Neutral	Favorable
Patient Global Impression	Very Poor, Poor	No Opinion	Good, Very Good
Likelihood of Use	Very Unlikely, Unlikely	No Opinion	Likely, Very Likely
Ease of Use Impression	Not Easy at All, Not Easy	No Opinion	Easy, Very Easy
Return to Normal Faster Than Usual Medication	Strongly Disagree, Disagree	Neutral	Agree, Strongly Agree
Works Faster Than Usual Medication			
More Consistently Works Than Usual Medication			
Keeps Migraine From Coming Back			

Figure 2. Participant Impressions of STS101



Sample sizes ranged 289–290 at Month 3, 244 at Month 6, and 371 at Month 12 across assessments.

Figure 3. Participant Impressions of Effect on Migraine



Sample sizes ranged 283–284 at Month 3, 240 at Month 6, and 342–347 at Month 12 across assessments.

Conclusions

- Participant impression data through 12 months of treatment in the open-label ASCEND study indicate STS101 is viewed very favorably across multiple attributes.
- Most participants considered STS101 easy to use and indicated they would be likely to use the product if it were available.
- In comparison to their usual migraine medications, participants indicated that STS101 worked faster and more consistently, and enabled them to more rapidly return to normal.

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Dr. Charleston has received personal compensation for serving as a consultant for AllerganAbbVie, Biohaven, Lundbeck, and Teva; serves on the advisory panel of Ctrl M Health (stock); is an Associate Editor with *Headache*; and serves as a Board Member at Large with Alliance for Headache Disorders Advocacy.

Dr. Strom is an employee of Satsuma Pharmaceuticals and was a stockholder at the time of study conduct.
Dr. Albrecht was an employee and stockholder of Satsuma Pharmaceuticals at the time of study conduct and is now a consultant and stockholder for Satsuma Pharmaceuticals.

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