Interim Analysis of Subject Impression Data for STS101 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 nasal powder formulation delivered via an easy-to-use, easy-to-carry, pre-filled, single-use device for intranasal administration that is currently in development.

Objective

- To report the subject impression and satisfaction questionnaire data from the ongoing, long-term, open-label, phase 3 ASCEND study, through 12 months of treatment with STS101 5.2 mg for the acute treatment of migraine attacks.

Methods

Study design and treatment intervention

- The ASCEND study is an ongoing, multi-center, multiple-dose, open-label, 12-month study of STS101 for the acute treatment of migraine in adults aged 18–65 years with migraine.
  - This interim analysis was conducted with a data cutoff date of June 30, 2022, and includes data reported for study drug exposure periods of up to 12 months
- After establishing eligibility, subjects could self-administer STS101 5.2 mg as needed (PRN), using up to 2 doses within 24 hours to treat a single migraine attack, and up to 12 doses/month (Figure 1).

Subjects

- Study subjects must have ≥1-year history of migraine (with or without aura) according to the International Classification of Headache Disorders, 3rd edition,[4] 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 a diagnosis of non-migraine headache, history of cerebrovascular disease, and ≥2 cardiovascular risk factors.
- Subjects must have an intact nasal mucosa at baseline (i.e., no ulceration or bleeding; no or mild erythema, swelling, and rhinorrhea).

Outcomes and analyses

- Interim analysis results of self-reported assessments are presented and include subject global impression, ease-of-use impression, subject likelihood of use, and comparison of STS101 with previously used migraine medication for the 3-, 6-, and 12-month timepoints.
- Subjects' ratings were assessed using a 5-point Likert scale, with response options dependent on the question (Table 1).

Results

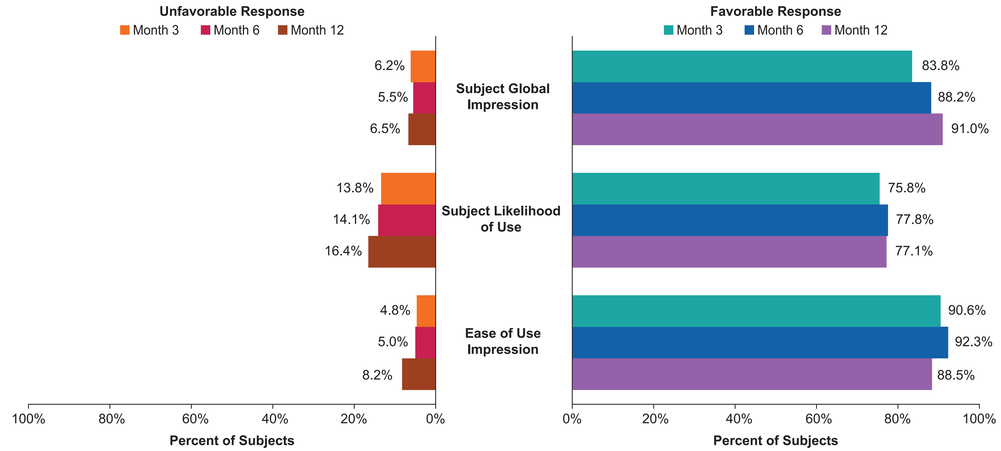
- A total of 446 subjects were enrolled and used study medication to treat 8027 migraine attacks.
- Overall, large percentages of subjects had favorable impressions of STS101, which was consistent across the assessments at 3-, 6-, and 12-month timepoints.
- STS101 was considered "good" or "very good" by 83.8% of subjects after 3 months, 88.2% after 6 months, and 91.0% after 12 months of use (Figure 2).
- At Month 3, 90.6% of subjects considered STS101 easy or very easy to use, increasing to 92.3% at Month 6 and sustaining at 88.5% at Month 12 (Figure 2).
- After 3, 6, and 12 months of use, 75.8%, 77.8%, and 77.1% of subjects, 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%, 72.3%, and 71.1% of subjects agreed or strongly agreed that STS101 helped them return to normal faster than their usual medication (Figure 3)
  - 64.7%, 64.4%, and 70.0% of subjects agreed or strongly agreed that STS101 worked faster than their usual medication (Figure 3)
  - 69.3%, 72.2%, and 73.6% of subjects 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%, 69.0%, and 66.7% of subjects 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 Scales

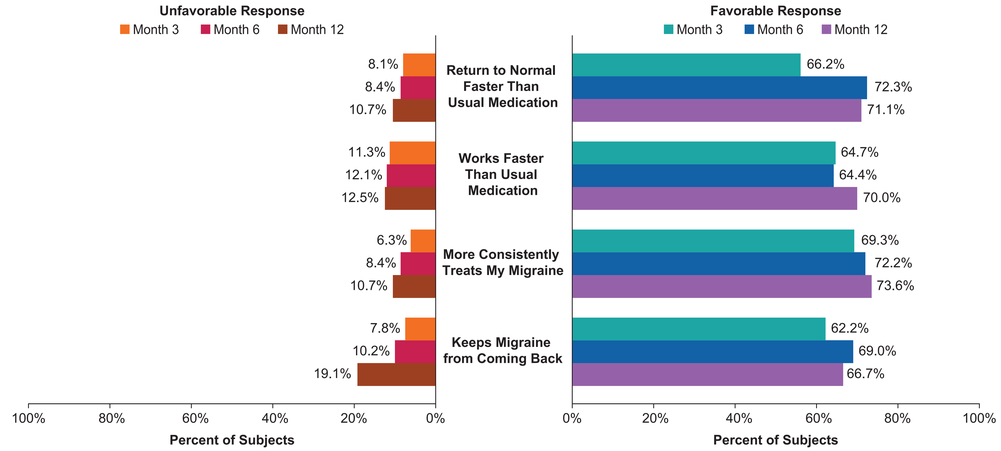
	Response Options		
	Unfavorable	Neutral	Favorable
Subject Global Impression	Very Poor, Poor	No Opinion	Good, Very Good
Subject Likelihood of Use	Very Unlikely, Unlikely	No Opinion	Likely, Very Likely
Ease of Use Impression	Not Easy at All, Not Easy	No Opinion	Easy, Very Easy
Return to Normal Faster Than 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. Subject Impressions of STS101



Sample sizes ranged 289–290 at Month 3, 220 at Month 6, and 122 at Month 12 across assessments.

Figure 3. Subject Impressions of Effect on Migraine



Sample sizes ranged 283–284 at Month 3, 216 at Month 6, and 120–121 at Month 12 across assessments.

Conclusions

- Subject impression data through 3-, 6-, and 12-months of treatment with STS101 from the ongoing open-label ASCEND study indicate STS101 is viewed very favorably by subjects on multiple attributes.
- The majority of subjects 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, subjects indicated STS101 not only worked faster and more consistently but also enabled them to more rapidly return to normal.

References

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Dr. Albrecht is an employee and stockholder of Satsuma Pharmaceuticals.

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