Introduction

Exploratory endpoints included a patient acceptability questionnaire and nasal endoscopy and olfactory function assessments. The study was designed to assess whether differences in safety and tolerability were noted with INP104 compared to best usual care used during baseline, with information collected in a daily diary.

Methods

Study Design

This was a parallel Phase 3, international, open-label, single-group assignment study, assessing the safety, tolerability, and efficacy of INP104 for the treatment of acute migraine headache.

The study comprised 4-week screening period, a 26-week treatment period for all patients, with 1 patient receiving a dose of nasal DHE (INP104) every 2 weeks during the treatment period following futility (Figure 1).

Study Patients

For this study, a predefined diagnosis of migraine, defined as suffering in a minimum of 2 migraines per month with or without aura each month out not qual in chronic headaches during the previous year is required for the International Classification of Headache Disorders, 3rd edition.

Patients were aged 18 to 65 years, with a diagnosis of episodic or chronic migraine for at least 1 year and with at least 3 of the following: pain severity ≥ 5 on a 10-point scale, duration ≥ 4 hours, and interference with daily activities due to the migraine.

Sustained pain freedom through 24 hours was also reported in the majority of patients, with 98.4% of patients remaining relapse-free of their migraine after using INP104 (Weeks 21-24)

Studying the safety and efficacy of long-term intermittent usage of nasal DHE mesylate (INP104) self-administered every 2 weeks for 26 weeks.

Figure 1. Study Design

![Study Design](image)

![Table 1. STOP 301 Baseline Demographics Overview](image)

Table 1. STOP 301 Baseline Demographics Overview

<table>
<thead>
<tr>
<th>Demographic Baseline Overview</th>
<th>FSS (n=354)</th>
<th>IP (n=289)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, Yrs</td>
<td>41.3 (11.1)</td>
<td>41.3 (11.1)</td>
<td>0.926</td>
</tr>
<tr>
<td>Sex</td>
<td>F: 130 (36.7)</td>
<td>125 (43.1)</td>
<td>0.059</td>
</tr>
<tr>
<td>Gender</td>
<td>M: 124 (34.8)</td>
<td>114 (39.4)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>White: 272 (76.9)</td>
<td>245 (85.0)</td>
<td>0.078</td>
</tr>
<tr>
<td>2-hour Pain Freedom</td>
<td>35 (10.0)</td>
<td>30 (10.5)</td>
<td>0.686</td>
</tr>
<tr>
<td>Most Bothersome Symptom Freedom</td>
<td>23 (6.5)</td>
<td>19 (6.6)</td>
<td>0.935</td>
</tr>
</tbody>
</table>

Results

Patient Disposition and Baseline Characteristics

365 patients were screened and enrolled into the 26-week treatment period. 354 patients who took an average of 2 or more treatments with INP104 per the 28-day follow-up period (Figure 2).

Sustained pain freedom through 24 hours was also reported in the majority of patients, with 98.4% of patients remaining relapse-free of their migraine after using INP104 (Weeks 21-24)

Studying the safety and efficacy of long-term intermittent usage of nasal DHE mesylate (INP104) self-administered every 2 weeks for 26 weeks.

Figure 2. STOP 301 Baseline Medication Types (FSS Population)

![Figure 2. STOP 301 Baseline Medication Types (FSS Population)](image)

![Figure 3. 2-hour Pain Freedom and Most Bothersome Symptom Freedom (26-week FSS Population, n=354)](image)

![Figure 4. Pain Relief for First IPN104-Treated Migraine (24-week FSS, n=354)](image)

![Figure 5. Sustained Pain Freedom Through 24 Hours (26-week FSS Population)](image)

Conclusions

• STOP 301 was an open-label study of safety, tolerability, patient acceptability, and exploratory efficacy of long-term intermittent usage of nasal DHE mesylate (INP104) self-administered every 2 weeks for 26 weeks.

• There were no new safety signals following delivery of the upper nasal route, and with a patient acceptable by questionnaire. It is determined that the majority of patients found INP104 easy to use, and well tolerated over 26 weeks, and that the treatment was generally efficacious.

• Exploratory efficacy data suggest that INP104 is safe and efficacious in 36.7% of patients (2 of 2 patients), and used up to 5 or 6 times at 10% of patients at 26 weeks.

• Additionally, sustained pain freedom through 24 hours was also reported in the majority of patients, with 98.4% of patients remaining relapse-free of their migraine after using INP104 for 26 weeks.

• These results suggest that delivery to the upper nasal route may provide on effectiveness consistent, and well tolerated alternative to acute and episodic treatments for migraine, providing the potential efficacy, safety, and polypharmacy of the long-established DHE mesylate formulation.

References


Disclosures and Acknowledgments

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Figure 6. Patient Acceptability Questionnaires (24-week FSS, n=354)

![Figure 6. Patient Acceptability Questionnaires (24-week FSS, n=354)](image)