Real-World Assessment of Baseline Demographic and Clinical Characteristics Among Patients Using INP104 in the United States

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Introduction

- INP104 is a novel drug-device combination product that delivers dihydroergotamine mesylate (DHE) to the upper nasal space using Precision Olfactory Delivery (POD[®]) and was approved by the Food and Drug Administration for the acute treatment of migraine in September **2021**^{1,2}
- INP104 offers a non oral, non-invasive, and convenient alternative to DHE administered intravenously, (which can provide rapid symptom relief but can often cause nausea and vomiting and must be administered in a clinical setting) as well as superior pharmacokinetics compared to MIGRANAL (the first approved DHE mesylate nasal spray)^{1,3-5}
- The long-term safety and exploratory efficacy of INP104 in patients with migraine has been demonstrated in a Phase 3, open-label, study (STOP) 301), which has been previously published¹
- Real-world data are needed to understand characteristics and medication utilization patterns of patients who use INP104 to determine how it fits into treatment patterns for migraine relief

Objective

• To report the baseline demographic and clinical characteristics among patients who used INP104 over a 12-month period in a real-world setting

Methods

- This was a retrospective, longitudinal, observational study designed to assess demographic and clinical characteristics, identify baseline comorbidities and concomitant medication use, and assess treatment patterns among patients with migraine who were treated with INP104 based on medical and pharmacy claims in the United States from the STATinMED database
- Eligibility criteria (Figure 1, Figure 2)
- Diagnosis of migraine during the study period spanning January 1, 2020, through October 31, 2022
- − ≥18 years of age at index
- ≥ 1 pharmacy claim for INP104 use during a patient identification period spanning October 1, 2021, through October 31, 2022
- Continuous enrollment with both medical and pharmacy benefits for 12 months pre- and post-index period
- No diagnoses of malignant neoplasm at any body location (particularly the central nervous system) at any time during the study period

- Psychiatric disorders (depression, anxiety disorder, bipolar disorder, abuse, post-traumatic stress disorder)
- Cardiovascular diseases (stroke, myocardial infarction, angina)
- Other neurological conditions (not including epilepsy or seizure, migraine, other headache syndromes)
- Asthma
- Obesity
- Sleep disorders (restless leg syndrome, obstructive sleep apnea, insomnia)
- Autoimmune diseases (rheumatoid arthritis, hypothyroidism)
- Gastrointestinal (GI) disorders (irritable bowel syndrome, gastric ulcer/GI bleeding, gastroesophageal reflux disease, Helicobacter *pylori* infection, gastroparesis, hepatobiliary disorders, celiac disease)

- Other pain syndromes (fibromyalgia, neck pain, back pain) • Epilepsy

Figure 1. Study Design



01/1/2020

• The baseline period was defined as the 12 months prior to the index period (not including the index period)

Clinical characteristics:

 Quan-Charlson Comorbidity Index (CCI) score during baseline period: The most used index in health outcomes studies is the CCI, which assigns a weight ranging from 1 to 6 according to disease severity for 19 conditions. The index has since been revised; the Quan-CCI, which assesses 17 comorbidities, was used for this study. Quan-CCI score was assessed for the baseline period and can also be categorized as 0, 1, 2, 3, 4, and 5+ as a proxy for baseline severity

 Key baseline comorbidities during the baseline period: A binary variable was created using ICD-9/ICD-10-CM codes for patients diagnosed with the following comorbidities commonly associated with migraine:

Figure 2. Patient Disposition



Results

Patient Baseline and Clinical Characteristics

- Most patients were female (87.9%) with a mean age of 43.4 years (Figure 3)
- Regional distribution across the United States was mostly in the South (42.1%) (Figure 4)
- The payer channel was mostly commercial (86.5%; Figure 5)
- The mean (SD) Charlson Comorbidity Index score was 0.31 (0.83) (Table 1)
- The most common baseline comorbidities (>10%) included headache (25.9%), other pain disorders (24.8%), sleep disorders (18.8%), GI disorders (15.9%) and psychiatric disorders (11.5%; Figure 6, Table 2)

Table 1. Baseline Age and Sex Distribution

Baseline Characteristic	N=1484
Age, years Mean/SD Median	43.4 (11.8) 44
Sex, % Female Male	87.9% 12.1%

SD=standard deviation.

Figure 3. Baseline Age Distribution by Age Group



US=United States.

Figure 4. Baseline Patient Characteristics, Geographic Distribution



US=United States

Figure 5. Baseline Patient Characteristics, Payer Channel



Figure 6. Headache Related Comorbidities Present at Baseline



syndromes other than migraine (36.7%), other neurological conditions



Table 2. Baseline Comorbidities

	Current Study N=1484	AMPP Studies ^{6,7} Episodic Migraine
Other neurological conditions	25.9%	
Other pain disorders (fibromyalgia, neck pain, and back pain)	24.8%	~37% ^c
Sleep disorders	18.8%	
Gastrointestinal disorders	15.9% ^a	8% ^d
Psychiatric disorders	11.5% ^b	48-64% ^e
Autoimmune diseases	8.9%	6.5% ^f
Obesity	8.2%	21%
Asthma	7.2%	~17%
Epilepsy or seizure	5.6%	2.6% ^g
Mononeuropathies of upper or lower limb	3.4%	
Epilepsy	1.6%	
Other and unspecified disorders of the nervous system	0.4%	
Conversion disorder with seizures or convulsions	0.2%	
Post-traumatic seizures	0%	
Cardiovascular diseases	0.7%	6.3% ^h

^aIncludes irritable bowel syndrome (IBS), gastric ulcer/GI bleeding, gastroesophageal reflux disease (GERD), Helicobacter pylori infection, gastroparesis, hepatobiliary disorders, celiac disease). ^bIncludes anxiety, bipolar sorder, depression, post-traumatic stress disorder, and substance abuse. ^cChronic pain, rheumatoid arthritis pain. ^dLimited to ulcers of the stomach/intestines. ^eIncludes anxiety, bipolar disorder, and depression. ^fLimited to dermatitis/eczema. ^gIncluded seizures, epilepsy, fits, or convulsions. ^hLimited to heart disease/angina. AMPP=American Migraine Prevalence and Prevention.

Conclusions

- Real-world evidence demonstrates that most patients with migraine who used INP104 as an acute therapy are females between the ages of 36 and 45 years, and have comorbidities that include headache syndromes other than migraine, other neurological conditions, other pain disorders, sleep disorders, GI disorders, and psychiatric disorders
- In contrast to other epidemiological studies,^{8,9} in this real-world patient population, GI comorbidities were more common than those in the psychiatric category

References

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