Real-World Assessment of Concomitant Medication Use in 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]
- 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 published[1]
- A post hoc analysis of exploratory efficacy data from the STOP 301 study demonstrated numerical improvements in self-reported pain and most bothersome symptom freedom at 2 hours post-INP104, with most of the concomitant migraine preventive groups (eg, none, topiramate, erenumab, and "other") analyzed and safety measures found to be similar in patients who did or did not use concomitant migraine preventive medications over 24 weeks of treatment[3]
- These results suggest that INP104 may be an effective and well-tolerated acute therapy for migraine in patients who are concurrently using preventive therapies; however, real-world data are needed to understand medication utilization patterns of patients who use INP104 to determine how INP104 fits into the migraine treatment paradigm[1]

Objective

- To report concomitant acute and preventive medication use among patients with migraine prior to and after initiating INP104 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
  - 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
- The baseline period was defined as the 12 months prior to the index date (not including the index period), and the follow-up period was 12 months after the index period (and including the index period). Preliminary results for the 90-day follow-up period are reported here (Figure 1, see Figure 2 for patient disposition)

Figure 1. Study Design

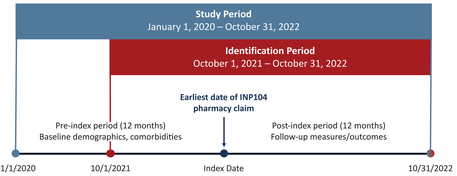
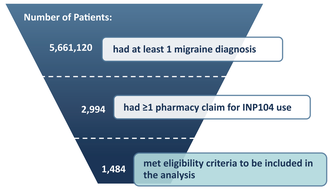


Figure 2. Patient Disposition



Results

Baseline and Concomitant Preventive Medication Use for Migraine

- During the 12-month baseline period, 49.7% of patients used a migraine preventive medication (Figure 3)
  - 32.2% used a gepant (22.0% rimegepant or 3.7% atogepant), 24.5% used an anticonvulsant, 18.4% used a beta-blocker, 15.0% used an anti-calcitonin gene-related peptide (CGRP) monoclonal antibody, 11.7% used topiramate, and 11.5% used a selective serotonin reuptake inhibitor (SSRI; >10% in each category)
- During the 90-day follow-up period, 42.5% of patients used a concomitant migraine preventive medication with INP104
  - 23.3% used a gepant (12.5% rimegepant or 7.3% atogepant), 17.9% used an anticonvulsant, 14.9% used an anti-CGRP monoclonal antibody, 9.8% used a beta-blocker, 8.3% used an SSRI, and 6.8% used topiramate
- No patients used onabotulinumtoxinA during the baseline or follow-up period

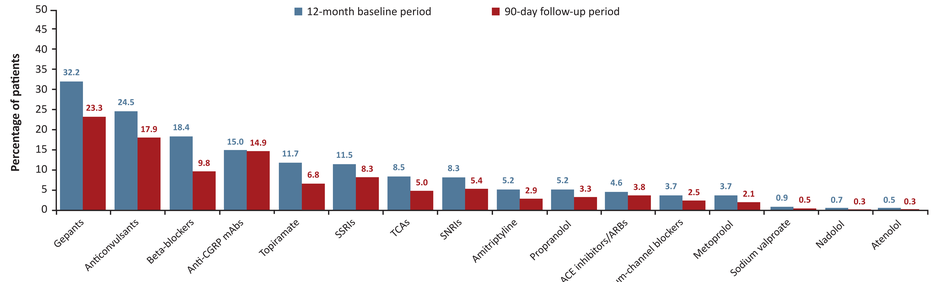
Baseline and Concomitant Acute Medication Use for Migraine (Figure 4)

- During the 12-month baseline period, 32.2% used a gepant (14.5% ubrogepant or 22.0% rimegepant), 28.4% used a nonsteroidal anti-inflammatory drug (NSAID), 21.5% used a triptan, 18.4% used an opioid, 5.0% used a ditan, 4.7% used a barbiturate, and 2.0% used acetaminophen
- During the 90-day follow-up period with INP104 use, 23.3% used a gepant (8.5% ubrogepant or 12.5% rimegepant), 15.4% used an NSAID, 9.9% used a triptan, 8.1% used an opioid, 3.1% used a barbiturate, 2.6% used a ditan, and 0.4% used acetaminophen
- During the 12-month baseline period, 0.7% of patients used DHE or ergot derivative

Baseline and Concomitant Other Medication Use for Migraine

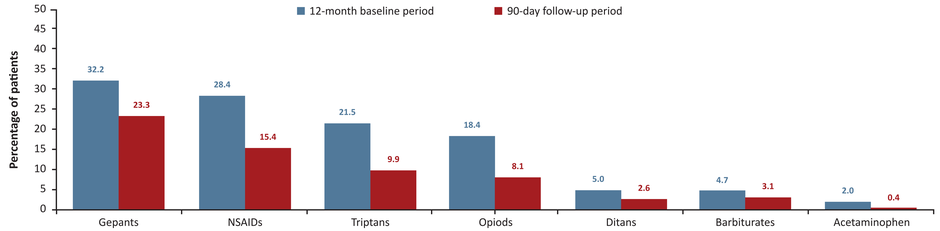
- During the 12-month baseline period, 23.0% of patients used an antinausea or antiemetic medication, which decreased to 9.9% during the 90-day follow-up period with INP104 use
- Other medications used during the 12-month baseline period were antihypertensive drugs (5.9%), antidiabetic drugs (3.9%), and combination treatments (eg, ergotamine-caffeine, cambia, etc; 2%), which decreased to 4.4%, 3.1%, and 1.0%, respectively, during the 90-day follow-up period. No patients used domperidone.

Figure 3. Concomitant Preventive Medication Use During the 12-Month Baseline Period and 90-Day Follow-Up Period



ACE=angiotensin converting enzyme; ARB=angiotensin II receptor blockers; CGRP=calcitonin gene-related peptide; mAb=monoclonal antibody; SNRI=serotonin-norepinephrine reuptake inhibitor; SSRI=selective serotonin reuptake inhibitor; TCA=tricyclic antidepressant.

Figure 4. Concomitant Acute Medication Use During the 12-Month Baseline Period and 90-Day Follow-Up Period



NSAID=nonsteroidal anti-inflammatory drug.

Conclusion

- Real-world evidence in patients with migraine suggests a treatment gap may remain, with approximately half of patients not receiving appropriate preventive medication
- Most patients were not using DHE prior to INP104 use
- Following INP104 use, concomitant preventive (with the exception of the anti-CGRP monoclonal antibody class) and acute medication use generally decreased between the 12-month baseline and 90-day follow-up period, which suggests that INP104 may be an effective acute therapy for managing migraine
- Importantly, an increase in antinausea medications was not observed following INP104 use, whereas these medications are commonly used with DHE administered intravenously
- This study is preliminary and based on claims data; therefore, clinical relevance is to be further elucidated

References

1. Smith TR, et al. *Headache.* 2021; 61(8):1214-1226. **2.** TRUDHESA®. Package insert. Impel Pharmaceuticals; 2021. **3.** Grant J, et al. Presented at: AHS; June 9-12, 2022; Denver, CO, USA.

Disclosures and Acknowledgments

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