MTIS2020

Migraine - acute therapy

MTIS2020-229

A LONG TERM, OPEN LABEL STUDY OF SAFETY AND TOLERABILITY OF PRECISION OLFACTORY DELIVERY OF DHE IN ACUTE MIGRAINE (STOP 301): CLINICAL RESULTS

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Introduction: Migraine is a common neurological disease impacting at least 12% of the US population. Despite several recent approvals, high unmet need and patient dissatisfaction remains for early and sustained efficacy with reduced recurrence. Intravenous dihydroergotamine (DHE) mesylate has a rapid onset and sustained effect. Similar plasma levels of DHE from 20 minutes with INP104, a novel drug-device combination product that delivers DHE to the upper nasal space, using a Precision Olfactory Delivery (POD®) device have been reported.

Objectives: To report the long term safety, tolerability, patient acceptability and exploratory efficacy of INP104.

Methods: STOP 301 was a multicenter, open-label, 24-week study, with a subset extending treatment to 52-weeks; (NCT0355733). Patients completed a daily diary and a migraine diary with every attack during a 28-day screening (on “best usual care”) and then on treatment. Patients were allowed to self administer up to 3 doses/week of INP104 nasally with migraine attacks (1.45 mg). The primary safety focus was on change in nasal mucosa and olfactory function. Exploratory objectives included efficacy measures compared to best usual care, patient acceptability by a questionnaire (PAQ), and heathcare utilization and quality of life measures (MIDAS and HIT-6).

Results: 360 patients entered the 24-week treatment period, with 185 and 354 patients in the Primary and Full Safety Sets (PSS and FSS) respectively, while 55 and 73 patients composed the respective 52-week data sets. 36.7% of patients reported AEs, with 6.8% of patients discontinuing due to AEs (FSS). No significant olfactory mucosal integrity issues or functional disturbance was found by upper nasal endoscopy, nasal related TEAEs, or University of Pennsylvania Smell Identification Test (UPSIT) scores. Most common TEAEs were nasal congestion (15.0%), nausea (6.8%), nasal discomfort and unpleasant taste (5.1% each) with all other TEAEs being reported by < 3%. There were no treatment related Serious AEs, cardiac TEAEs or deaths. 4,515 migraines were treated with INP104 over 24-weeks (FSS). Pain- and most bothersome symptom-freedom were reported by 33.1% and 49.1% of patients at 2 hours post-INP104 (Weeks 21-24, PSS) compared to 26.2% and 43.9% on best usual care at baseline, respectively. Sustained pain freedom through 24 hours was reported by 98.4% of patients (Weeks 21-24). The PAQ demonstrated that the majority of patients agreed or strongly agreed that INP104 was easy to use (~84%) and preferred over current therapy (FSS).

Conclusion: INP104 provides well tolerated, rapid and effective symptom relief, predictably and consistently, without injection. No new safety signals were observed following delivery to the upper nasal space. These data suggest INP104 may be a promising acute treatment for patients suffering from migraine.

Disclosure of Interest: S. Aurora Conflict with: Employee and stock holder of Impel NeuroPharma, M. Jeleva Conflict with: Employee and stock holder of Impel NeuroPharma, J. Hocevar-Trnka Conflict with: Employee and stock holder of Impel NeuroPharma, J. Hoekman Conflict with: Employee and stock holder of Impel NeuroPharma, S. Shrewsbury Conflict with: Employee and stock holder of Impel NeuroPharma