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PATIENT ACCEPTABILITY OF A NOVEL UPPER NASAL DELIVERY SYSTEM FOR DHE – USING THE PRECISION OLFACTORY DELIVERY (POD®) DEVICE (INP104)

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Introduction: DHE is an effective acute treatment for episodic migraine, but from 1946–1996 was only available as an injection. Nasal DHE (Migranal®) introduced in 1996 as a much desired needle-free alternative has shown variable efficacy which may be due to loss of the drug product out of the nose onto the upper lip, or down the throat, leading to inconsistent absorption of the remaining drug from the lower/anterior nasal space. Delivery of drugs to the upper nasal space may provide greater, more consistent absorption, reduce response variability and provide more reliable relief similarly without the need for an injection. Assessing the safety and tolerability of delivery to this previously unexplored area is important – but so too is understanding how acceptable patients find drug delivery to this space with the POD device.

Objectives: To assess patient acceptability of INP104 (POD DHE) over 24/52 weeks in the pivotal STOP 301, safety trial.

Methods: In an open label, Phase 3 safety study of INP104 (STOP 301), conducted at 38 centers in the US, patients were asked to complete a questionnaire (PAQ) at the end of 24/52 weeks after using the INP104 product, a self-administered, single use, propellant-enabled device delivering a previously approved formulation of DHE mesylate as required for self-recognized migraine. Subjects were asked to score Strongly Disagree; Disagree; Neutral; Agree; Strongly Agree to the following series of 6 questions once they had completed the study: (1) Study drug is easy to carry, (2) Study drug allows me to return to normal faster, (3) Study drug more consistently treats my migraine, (4) Study drug works faster than previous treatment, (5) Study drug keeps my migraine from coming back and (6) Study drug is easy to use.

Results: 324 subjects who entered the 24-week treatment period completed the PAQ. Results are presented in a tabular format. Neutral, Agree or Strongly Agree was noted by: 65% that the device was easy to carry; 78% that it allowed them to return to normal activities faster than previous medication; 76% that it worked more consistently than their previous best usual care; 77% that it worked faster than their previous best usual care; 82% that it kept their migraine from coming back; and 94% that it was easy to use.

Conclusion: The results suggest DHE delivered to the upper nasal space with POD may provide an effective, well tolerated alternative to acute oral treatments for migraine. The majority of study subjects reported INP104 was easy to carry and use, faster and more consistently provided benefit with longer lasting relief and allowed them to return to normal activities faster than previous medications they had used.

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