



## **IMPEL NEUROPHARMA ANNOUNCES FIRST PATIENT DOSED IN PHASE 3 TRIAL EVALUATING INP104 FOR THE TREATMENT OF ACUTE MIGRAINE HEADACHE**

*Safety and Tolerability of POD-DHE (STOP-301) Trial to Explore Safety and Tolerability of Long-Term Intermittent Use of Intranasal Dihydroergotamine Mesylate Delivered via Precision Olfactory Delivery (POD®) Device*

*STOP-301 Trial Recruiting More Quickly Than Expected, Company On-Track With 2019 NDA Filing*

SEATTLE, August 22, 2018 — Impel NeuroPharma, a Seattle-based, privately-held biopharmaceutical company focused on therapies for the treatment of central nervous system (CNS) disorders, today announced the first patient has been dosed in the Company's Phase 3, open-label safety and tolerability study evaluating long-term, intermittent use of INP104 for the treatment of migraine headache. INP104 is a novel dihydroergotamine (DHE) product dosed via Impel's proprietary Precision Olfactory Delivery, or POD®, intranasal delivery device.

The "STOP-301 Trial" (**S**afety and **T**olerability of **POD**-DHE) will evaluate the safety and tolerability of long-term, intermittent use of INP104 for 24-week and 52-week data points and will also collect efficacy data of INP104 as assessed by change from baseline in migraine measures during the course of the study. Pending complete review of the clinical study data and as a result of rapid recruitment, the Company expects to be in a position to file a New Drug Application (NDA) for INP104 in the second half of 2019.

"We are very pleased with the speed of recruitment to the STOP-301 study and anticipate that this reflects the level of unmet need in the market and enthusiasm for novel treatments," said Jon Congleton, Chief Executive Officer of Impel NeuroPharma. "We believe that INP104 stands to provide a gold-standard migraine therapy in a device that offers rapid and optimized bioavailability."

Migraine affects more than 36 million people in the United States, but only five million people are treating their migraine with a prescription medication. Over 70 percent of treated patients report dissatisfaction with currently-available treatments in controlling

their acute migraines. Further details of the INP104-301 study can be found at [ClinicalTrials.gov](https://clinicaltrials.gov).

### **About INP104**

INP104 is a drug-device combination product being studied for acute migraine headache. It is comprised of an intranasal formulation of dihydroergotamine (DHE) and Impel's novel Precision Olfactory Delivery, or POD, device. The POD is a novel, simple-to-use device designed to deliver consistent and predictable doses of drug. INP104, an investigational new drug, delivers DHE to the richly-vascularized upper nasal cavity, offering rapid and optimized bioavailability without injection. DHE is an established and highly-effective treatment option for acute migraine treatment.

### **About Acute Migraine**

Migraine is a common and debilitating neurological disease characterized by recurrent episodes of severe head pain and associated with nausea, vomiting, sensitivity to light and to sound. Migraine affects more than 36 million people in the United States and over 90 percent of these have acute migraines averaging less than four migraine days per month.<sup>1,2,3</sup> The majority of people that suffer from acute migraines are either untreated or dissatisfied with currently-available treatments.<sup>4</sup> They are seeking treatments that offer rapid and durable control of their pain.

### **About Impel NeuroPharma**

Impel NeuroPharma, Inc., is a privately-held, Seattle-based biotechnology company devoted to creating life-changing, innovative therapies for central nervous system (CNS) diseases. Impel NeuroPharma is currently investigating INP104 (POD-DHE) for acute migraine headache, INP103 (POD-levodopa) for reversal of OFF episodes in Parkinson's disease, INP105 (POD-olanzapine) for acute agitation in schizophrenia and bipolar disorders as well as INP102 (POD-insulin) for Alzheimer's disease in a series of trials currently funded by the NIH.

Impel's products utilize its novel, nasal drug-delivery Precision Olfactory Delivery, or POD, device technology to deliver liquid or dry powder forms of drug to the upper nasal cavity in a consistent and predictable manner.

IMPEL, POD and the IMPEL Logo are trademarks of Impel NeuroPharma, Inc. To learn more about Impel NeuroPharma, please visit our website at <http://impelnp.com>.

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<sup>1</sup> American Migraine Foundation. <https://americanmigrainefoundation.org>

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<sup>2</sup> Lipton RB, Manack Adams A, Buse DC, Fanning KM, Reed ML. A Comparison of the Chronic Migraine Epidemiology and Outcomes (CaMEO) Study and American Migraine Prevalence and Prevention (AMPP) Study: Demographics and Headache-Related Disability. *Headache*. 2016;56(8):1280-1289. doi:10.1111/head.12878.

<sup>3</sup> Migraine prevalence, disease burden, and the need for preventive therapy. R. B. Lipton, M. E. Bigal, M. Diamond, F. Freitag, M. L. Reed, W. F. Stewart. *Neurology* Jan 2007, 68 (5) 343-349; DOI: 10.1212/01.wnl.0000252808.97649.21

<sup>4</sup> Lipton, R. B., Buse, D. C., Serrano, D. , Holland, S. and Reed, M. L. (2013), Examination of Unmet Treatment Needs Among Persons With Episodic Migraine: Results of the American Migraine Prevalence and Prevention (AMPP) Study. *Headache: The Journal of Head and Face Pain*, 53: 1300-1311. doi:10.1111/head.12154