



## **IMPEL NEUROPHARMA ANNOUNCES LAST PATIENT ENROLLED IN PHASE 3 TRIAL EVALUATING INP104 FOR THE TREATMENT OF ACUTE MIGRAINE**

*Top-line Results of the STOP-301 Trial Evaluating the Safety and Tolerability of Long-term,  
Intermittent Use of INP104 Anticipated Early 2020*

*Pending Complete Review of the Data, Submission of a  
New Drug Application Anticipated in Second Half of 2020*

SEATTLE, September 3, 2019 — Impel NeuroPharma, a late-stage biopharmaceutical company focused on the development and commercialization of transformative therapies for patients living with central nervous system (CNS) disorders with high unmet medical needs, today announced the last patient has been enrolled in “STOP-301” (Safety and Tolerability of POD-DHE), the Company's pivotal open-label Phase 3, multi-use, long-term safety and tolerability of INP104 for the treatment of acute migraine.

STOP-301 is evaluating the safety 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. Following a four-week screening period, a total of 360 patients have been enrolled in the study. A subset of 73 patients will continue into a 28-week treatment extension period and a two-week post-treatment follow-up period. There are currently 36 sites in the United States with patients enrolled in the study.

“INP104 has the potential to provide IV-like dihydroergotamine (DHE) effects in the home with rapid onset and long-lasting benefits because it reaches the vascular rich upper nasal cavity, an emerging new area of the body for drug administration,” said Stephen B. Shrewsbury, M.D., Chief Medical Officer of Impel NeuroPharma. “Although the use of DHE has been limited due to route of administration, it remains a trusted treatment for acute migraine in headache clinics. Importantly, because INP104 is designed to provide consistent delivery of DHE, it can be used anytime and anywhere by the patient. We look forward to sharing the top-line results of STOP-301 in early 2020.”

INP104 is a DHE product dosed via Impel's proprietary Precision Olfactory Delivery, or POD<sup>®</sup>, nasal drug delivery device. DHE was first introduced in 1946, and over time, has demonstrated to be a safe and effective treatment for acute migraine, with a consistent response to intravenous administration. Based on discussions with the FDA, this pivotal Phase 3 safety study for INP104 and a previously completed comparative bioavailability trial between INP104, IV DHE and Migranal are the final clinical requirements to file a New Drug Application (NDA) for INP104. Pending complete review of the clinical study data, the Company expects to be in a position to file a NDA in the second half of 2020.

### **About INP104**

INP104 is a drug-device combination product being studied for the treatment of acute migraine. It is comprised of a nasal formulation of dihydroergotamine (DHE) and Impel's proprietary Precision Olfactory Delivery, or POD<sup>®</sup>, device. The family of POD devices are patient-friendly, simple-to-use and designed to deliver consistent and predictable doses of drug. INP104, an investigational new drug, delivers DHE to the richly vascularized upper nasal cavity, offering the potential for rapid and consistent biodistribution 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 approximately 39 million people in the United States. Of those diagnosed, only four million are on prescription treatment. While triptans account for almost 70 percent of migraine therapies, approximately 30 to 40 percent of patients do not respond adequately to triptans and up to 79 percent of the treated patients report being dissatisfied with their current treatment and willing to try a new therapy.

### **About Impel NeuroPharma**

Impel NeuroPharma, Inc., is a privately-held, Seattle-based biopharmaceutical 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) and INP107 (POD-carbidopa/levodopa) for reversal of OFF episodes in Parkinson's disease and INP105 (POD-olanzapine) for acute agitation in schizophrenia and bipolar I disorder.

Impel's product candidates are delivered via its proprietary Precision Olfactory Delivery, or POD<sup>®</sup>, technology which targets the richly vascularized upper nasal cavity with the goal of achieving enhanced bioavailability of therapeutic molecules.

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### **About Precision Olfactory Delivery or POD<sup>®</sup> Devices**

Impel NeuroPharma's proprietary POD® nasal drug delivery device is designed to deliver drugs to the richly-vascularized upper nasal cavity to improve biodistribution and bioavailability of both small molecules and biologic drugs. By consistently and predictably delivering therapeutics to the upper nasal cavity, the POD device may improve overall bioavailability of drugs without IV injection. Impel has developed dry powder and liquid compatible POD devices to improve upon current treatment options for central nervous system (CNS) disorders.

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