IMPEL NEUROPHARMA ANNOUNCES FDA CLEARANCE OF IND FOR PIVOTAL PHASE 3 STUDY OF INP104 FOR ACUTE TREATMENT OF MIGRAINE

SEATTLE, May 12, 2018 — Impel NeuroPharma, a Seattle-based, privately-held biotechnology company focused on therapies for the treatment of central nervous system (CNS) disorders, today announced that the U.S. Food and Drug Administration (FDA) has notified the Company that it may proceed with its clinical investigation of INP104, a novel, dihydroergotamine (DHE) product dosed via Impel’s proprietary Precision Olfactory Delivery, or POD®, intranasal delivery device for the treatment of acute migraine.

The notice to proceed was received following Impel’s submission of an investigational new drug (IND) application for this program. Impel expects to commence enrollment in the pivotal Phase 3 study evaluating the safety and tolerability of long-term, intermittent use of INP104 for the treatment of acute migraine in H2 2018.

“DHE is an effective, trusted cornerstone treatment for acute migraines, however current methods of administration by injection or traditional nasal spray devices have created barriers to its widespread use,” said Jon Congleton, Chief Executive Officer of Impel NeuroPharma. “We believe the consistent, reliable delivery of DHE via Impel’s POD intranasal device could provide a promising treatment option for both patients and their healthcare providers, and we look forward to progressing the development of INP104 as a potential acute migraine therapy.”

Migraine affects more than 36 million people in the United States with 24 million diagnosed, but only five million currently treat their condition with prescription medications. Over 70% of treated patients report dissatisfaction with currently-available treatments in controlling their acute migraines1.

About INP104
INP104 is an investigational new 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 delivers DHE to the richly vascularized upper nasal cavity, offering rapid 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% of these have acute migraines averaging less than four migraines per month. The majority of people that suffer from acute migraines are either untreated or dissatisfied with currently-available treatments. 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 the potential benefits of 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 National Institutes of Health (NIH).

Impel’s products utilize its novel, nasal drug delivery POD device technology, which is designed to deliver liquid or dry powder forms of drug to the upper nasal cavity in a consistent and predictable manner.

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