



## **Impel NeuroPharma Announces First Patient Dosed in Phase 1 Clinical Trial of INP104 for Treatment of Acute Migraine Headache**

*Study to Explore Bioavailability and Safety of Novel, Intranasal Dihydroergotamine Delivered via Precision Olfactory Delivery™ Technology*

SEATTLE, October 31, 2017 -- 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 first patient was dosed in the recently-initiated Phase 1 clinical trial of INP104 for acute migraine headache. INP104 is a novel dihydroergotamine (DHE) product delivered via Impel's proprietary Precision Olfactory Delivery, or POD™, intranasal delivery platform.

This trial will investigate the comparative bioavailability of INP104 versus two approved DHE formulations – D.H.E. 45 (dihydroergotamine mesylate) intravenous (IV) injection (100% bioavailability), and Migranal® (dihydroergotamine mesylate, USP) Nasal Spray (reported ~32% bioavailability).

DHE is a drug often used in specialist headache clinics for acute migraines, but current methods of administration by injection or traditional nasal spray devices create barriers to their widespread use.

“We believe the consistent, reliable, dose-to-dose delivery of product via Impel's POD intranasal device holds the promise to improve systemic levels of DHE that were previously unachievable without injection,” said Jon Congleton, chief executive officer of Impel NeuroPharma. “Migraine affects more than 36 million people in the United States, and over a third of these have breakthrough acute migraines that are poorly addressed with currently-available treatments.”

“This Phase 1 bioequivalence trial will provide initial safety and tolerability data for INP104, and if predetermined, comparative bioavailability is proven, these data will serve as the basis for enabling a pivotal safety study of INP104 in 2018, with the intent to file a new drug application (NDA) in 2019,” commented John Hoekman, chief scientific officer and founder of Impel NeuroPharma.

## **About INP104**

INP104 combines a currently approved formulation of dihydroergotamine (DHE) for intranasal delivery with Impel's novel Precision Olfactory Delivery™ or POD™ technology. The POD device is designed to propel a narrow plume of aerosolized DHE to the upper nasal space. The device is a simple to use patient friendly system that does not require coordination of inhalation with actuation of the device.

This Phase 1 study, INP104-101, is Impel's first clinical study and is being conducted in Australia. The study will examine comparative bioavailability of three DHE arms, as well as explore safety and tolerability. Further details can be found on the ANZCTR website ([www.anzctr.org.au](http://www.anzctr.org.au))

## **About Precision Olfactory Delivery™ or POD™ Technology**

Impel NeuroPharma's proprietary POD intranasal drug delivery platform is designed to deliver drugs to the upper nasal cavity to achieve superior biodistribution and bioavailability of both small molecules and biologic drugs. By delivering therapeutics to the upper nasal cavity, the POD nasal delivery platform may improve overall bioavailability of drugs, and has the potential to target the brain via the olfactory and trigeminal nerves and to improve upon current treatment options for central nervous system (CNS) disorders. Impel has developed dry powder and liquid compatible POD technology.

## **About Impel NeuroPharma**

Impel NeuroPharma, Inc., is a privately-held, Seattle-based company devoted to creating life-changing, innovative therapies for central nervous system (CNS) diseases. Impel's products are based on a novel nasal drug delivery platform, the POD technology, that administers drug to the upper nasal cavity.

Impel NeuroPharma has is currently investigating INP104 (POD DHE) for acute migraine headache and INP103 (POD levodopa) for Parkinson's Disease, as well as INP102 (POD insulin) for Alzheimer's disease in an NIH funded trial.

Impel NeuroPharma's proprietary POD technology enables entirely new categories of drugs, including biologics, to be administered using a cost-effective, disposable, non-invasive intranasal drug delivery device. To learn more about Impel NeuroPharma, please visit our website at <http://impelnp.com>.

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