



ASX / Media Release
17 December 2021

Professor Michael Wall appointed as Trial Steering Group Chairperson for the IIH EVOLVE Phase III Clinical Trial in IIH

Invex Therapeutics Ltd (Invex, ASX:IXC, or the Company) a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (sustained release Exenatide) for neurological conditions relating to raised intracranial pressure, today is pleased to announce that Professor Michael Wall, MD has been appointed as the Trial Steering Group Chairperson for the IIH EVOLVE Phase III clinical trial, comparing once weekly administration of Presendin™ to placebo in the treatment of Idiopathic Intracranial Hypertension (IIH).

Dr Wall is a Professor of Ophthalmology and Neurology at the University of Iowa College of Medicine and Director of the Iowa Visual Field Reading Center. He is considered a global key opinion leader in IIH, having made a significant contribution to the clinical and scientific literature pertaining to the diagnosis, treatment and management of this disease and has led a significant number of important IIH clinical trials.

Professor Alexandra Sinclair, Executive Director and Chief Scientific Officer of Invex said “We are delighted that Professor Wall has joined our global Phase III trial in IIH as the Trial Steering Group Chairperson. Professor Wall has a distinguished career in the field of IIH, has published widely, and has significant experience and expertise in the execution of clinical trials in neurology and ophthalmology for pharmaceutical companies undertaking studies in the United States and around the globe. We certainly welcome the opportunity to work with Professor Wall on this important Phase III clinical trial in IIH, where approved therapies are lacking.”

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This release dated 17 December 2021 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics and lodged by Narelle Warren, Company Secretary.

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About Invex Therapeutics Ltd

Invex is a biopharmaceutical company focused on the repurposing of an already approved drug, Exenatide, for efficacious treatment of neurological conditions derived from or involving raised intracranial pressure, such as Idiopathic Intracranial Hypertension (IIH), acute stroke and traumatic brain injury. Invex has trademarked its repurposed Exenatide as Presendin™. www.invextherapeutics.com.

About Idiopathic Intracranial Hypertension (IIH)

IIH features severely raised intracranial pressure which causes disabling daily headaches and can compress the optic nerve. The usual age of onset is 20-30 years, and it is most common in women who are obese. IIH is a rapidly growing orphan indication: its incidence has increased by more than 350% in the last 10 years.

About Presendin™

Presendin™ is a once per week, sub-cutaneous, sustained-release (SR) Exenatide microsphere formulation originally developed by Peptron, Inc. (KOSDAQ: 087010). In September 2021 Invex entered into an exclusive collaboration, manufacturing and supply agreement with Peptron for Presendin™ in IIH for all major markets, with the exception of South Korea.

Exenatide is a small peptide and a synthetic version of the GLP-1 agonist exendin-4, which is currently approved for the treatment of type 2 diabetes. In 2017, Invex received orphan drug designation for Exenatide in IIH from the US Food and Drug Administration and European Medicines Agency.

About IIH EVOLVE Clinical Trial

The Phase III IIH EVOLVE trial is a randomised, placebo-controlled, double-blind, multi-centre trial that will randomise 240 patients with newly diagnosed IIH to determine the efficacy and safety of Presendin™ versus placebo, administered once weekly. Patients with a confirmed diagnosis of IIH will be randomised on a 1:1 basis to either Presendin™ or placebo for 24 weeks.

The primary endpoint of the trial is the change in intracranial pressure (ICP), as measured by lumbar puncture, at baseline and at 24 weeks. Secondary endpoints include the change in perimetric mean deviation (PMD), papilloedema and monthly headache days over 24 weeks.

IIH EVOLVE is designed to meet the requirements for market approval of Presendin™ for the treatment of Idiopathic Intracranial Hypertension (IIH) in the European Union (EU), United Kingdom (UK) and Australia.