ASX / Media Release
21 November 2022

First Patient Randomised in IIH EVOLVE Phase III Clinical Trial

Key Highlights:

- First Idiopathic Intracranial Hypertension (IIH) patient randomised into IIH EVOLVE Phase III clinical trial
- Clinical trial sites are now active and open for patient recruitment in Australia and the UK
- Additional sites are planned to open and commence patient recruitment with additional regulatory or site approvals to commence IIH EVOLVE pending in Europe, US, Israel and New Zealand

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 announces the first IIH patient has been randomised into the IIH EVOLVE Phase III clinical trial at VisionSA in Adelaide, South Australia.

Dr Jason Loveridge, Non-Executive Chairman of Invex said "The first patient randomised under our clinical trial marks a significant milestone for the Company and IIH patients generally. We certainly thank Associate Professor Chen and her clinical team at VisionSA for their interest and participation in this very important clinical trial. Given the clinical results we have achieved to date, we believe Presendin™ has the potential to improve clinical outcomes and the quality of life for these IIH patients in a safe and effective manner, where current therapies remain lacking."

IIH EVOLVE is a randomised, placebo-controlled, double-blind trial that will randomise 240 patients with newly diagnosed IIH to determine the efficacy and safety of Presendin™ versus placebo, administered once weekly over 24 weeks. The primary endpoint of the trial is the change in intracranial pressure from baseline, with key secondary endpoints related to vision and headache outcome measures. Invex intends to open up to 40 clinical sites globally. Information on the trial is available at clinicaltrials.gov under Identifier **NCT05347147**.

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This release dated 21 November 2022 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

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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 the 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.

Further study details can be found at clinicaltrials.gov website under Identifier **NCT05347147** or by visiting: https://clinicaltrials.gov/ct2/show/NCT05347147.