ASX / Media Release
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Invex Receives IND Approval from the FDA for Presendin™ and to Commence the IIH EVOLVE Phase III Clinical Trial in the US

Key Highlights:

- US FDA IND approval received for Presendin™ and for commencement of the IIH EVOLVE Phase III clinical trial in the US
- Invex is progressing with the opening of leading clinical sites across the US to support the IIH EVOLVE trial, with robust engagement from IIH clinicians willing to participate
- Invex on-track to recruit first patient into the trial during the second half of CY2022

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 Company has received United States (US) Food and Drug Administration (FDA) Investigational New Drug Application (IND) approval for Presendin™ and for the commencement of the IIH EVOLVE Phase III clinical trial in the US for patients with Idiopathic Intracranial Hypertension (IIH).

Professor Alex Sinclair, Executive Director and Chief Scientific Officer of Invex commented "We are excited to have received the IND for Presendin™ and IIH EVOLVE from the US FDA, based on the study protocol where we have already secured regulatory clearances in the UK and Australia. We anticipate that a positive efficacy outcome of the study will facilitate further discussions with the FDA on the future registration requirements of Presendin™ for IIH patients in the US. Overall, I have been delighted with the level of engagement from my US clinical peers on our planned IIH EVOLVE trial and look forward to their participation in this important study in IIH."

The IIH EVOLVE Trial Steering Group Chairperson, Professor Michael Wall, Professor of Ophthalmology and Neurology at the University of Iowa College of Medicine and Director of the Iowa Visual Field Reading Center said "I congratulate Invex on the IND approval. A high calibre randomized controlled clinical trial such as IIH EVOLVE will answer many important clinical questions and better direct IIH patient care leading to potentially the first ever drug approval for IIH. Our team is looking forward to assisting Invex in the management of this important clinical trial."

Dr Jason Loveridge, Chairman of Invex said "The outcomes of this trial have the potential to transform the lives of thousands of IIH patients living with the significant burden of this disease, where there are no existing regulatory approved drug therapies for clinicians to offer, with many patients seeing their disease progress to a stage where invasive neurosurgical and ophthalmic surgeries are required to alleviate severe headaches and prevent permanent blindness."

Invex intends to open a number of clinical sites across the US to support the IIH EVOLVE trial and will now complete the necessary institutional contracts and human ethics committee approvals to facilitate patient recruitment in a timely manner. In addition, the IND now permits Invex to ship Presendin™ to intended US clinical investigators participating in the IIH EVOLVE clinical trial.

IIH EVOLVE has been designed to meet the requirements for market approval of Presendin™ for the treatment of IIH in the EU, UK and Australia.

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 19 August 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.