ASX / Media Release
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HREC and TGA Approval for Commencement of IIH EVOLVE Phase III Clinical Trial in Australia

Key Highlights:

- Major milestone allowing patient recruitment to commence in Australia for the IIH EVOLVE Phase III clinical trial
- Private Hospital Ethics committee approval via HREC process and TGA approval both secured
- Invex targeting clinical sites (private and public) in Australia

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 receipt of Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) to commence the IIH EVOLVE Phase III clinical trial in Australia, for patients with Idiopathic Intracranial Hypertension (IIH).

Professor Alex Sinclair, Executive Director and Chief Scientific Officer of Invex said "We are delighted to receive the approvals from the HREC and TGA to commence this ground-breaking study in IIH. We believe the lack of approved therapies for IIH and the associated unmet medical need in this study population augers well for strong clinician support, efficient patient enrolment and execution of this high quality randomised controlled clinical trial."

Associate Professor Celia Chen, Director at Vision SA, Consultant Ophthalmologist at Flinders Medical Centre and a Principal Investigator for IIH EVOLVE in Australia commented "Our group is excited to be part of this important clinical trial in IIH. As a practicing clinician who observes the significant quality of life impacts on patients suffering from IIH, the goal of developing safe and effective treatments for these patients by way of a large randomised clinical trial like IIH EVOLVE is of paramount importance."

The HREC approval covers a number of private hospital sites in Australia that will conduct the trial, with Invex shortly to file an additional separate HREC application for a single public hospital in Australia. Invex has commenced the initiation of Australian IIH EVOLVE clinical trial sites and remains on track to commence patient recruitment once separate institutional authorisations are completed.

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 4 July 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.