ASX / Media Release
30 September 2022

Second HREC Approval for IIH EVOLVE Phase III Clinical Trial

Key Highlights:

- A second HREC approval has been granted to Invex that covers three additional public hospitals in Melbourne (the Alfred Hospital) and Sydney (Liverpool Hospital / Sydney Eye Hospital)
- Sites expected to commence recruitment of patients following completion of institutional authorisations

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 a second Human Research Ethics Committee (HREC) approval to commence the IIH EVOLVE Phase III clinical trial in Australia, for patients with Idiopathic Intracranial Hypertension (IIH).

Associate Professor Clare Fraser, Consultant Neuro-Ophthalmologist, Sydney Eye Hospital, Liverpool Hospital, Macquarie University Hospital and the Save Sight Institute and Principal Investigator for IIH EVOLVE in Australia commented "I am delighted to be an Investigator on this important clinical trial in IIH, which will provide the necessary clinical evidence to potentially support a new drug therapy for IIH patients, where existing treatments are lacking and the clinical need significant."

Professor Alex Sinclair, Executive Director and Chief Scientific Officer of Invex said "We are pleased Dr Fraser is working with Invex on our clinical trial and has joined the IIH EVOLVE Trial Steering Committee as country lead. She is a neuro-ophthalmologist of high international standing, serving as Vice President of The Neuro-Ophthalmology Society of Australia, and is one of their Education Officers. She is also the Chair of the North American Neuro-Ophthalmology Society International Committee and is on the committee for the Neuro-Ophthalmology Virtual Education Library and on the editorial boards for a number of high impact ophthalmology journals."

Professor Sinclair continued "We are satisfied that with both the private hospital and public hospital HREC secured alongside the TGA approval, we have sufficient Australian sites that we can now initiate to ensure the timely commencement of patient recruitment for IIH EVOLVE during this half."

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**.

- ENDS -

This release dated 30 September 2022 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

For more information, please contact:

Company/Investors
Dr Thomas Duthy
Executive Director
tduthy@invextherapeutics.com
+61 402 493 727

Media
Margie Livingston
Ignite Communications
margie@ignitecommunications.com.au
+61 438 661 131

To subscribe to Invex email alerts, please visit www.invextherapeutics.com and follow us on Twitter **@InvexThera_ASX**

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.