



ASX / Media Release  
20 March 2023

## Competent Authority Clearance for IIH EVOLVE Trial in Germany

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**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 approval to commence the IIH EVOLVE Phase III clinical trial has been received from the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) in Germany for patients with Idiopathic Intracranial Hypertension (IIH). In addition, Invex has secured Central Ethics Committee (CEC) approval for commencement of the IIH EVOLVE trial. Both BfArM and CEC approval are required to commence a clinical trial in Germany.

Professor Alex Sinclair, Executive Director and Chief Scientific Officer of Invex said “This approval from the BfArM German competent authority represents our first national regulatory clearance in Europe for our study. We are now completing the necessary institutional agreements for our intended clinical sites. Germany is expected to make a solid contribution to our overall patient recruitment profile and will help facilitate our plans for European Medicines Agency (EMA) approval for Presendin™, subject to clinical trial success.”

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](https://clinicaltrials.gov) under Identifier **NCT05347147**.

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*This release dated 20 March 2023 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.*

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## About Invex Therapeutics Ltd

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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](http://www.invextherapeutics.com).

## About Idiopathic Intracranial Hypertension (IIH)

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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™

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Presendin™ is a once per week, sub-cutaneous, sustained-release (SR) Exenatide microsphere formulation originally developed by Pepton, Inc. (KOSDAQ: 087010). In September 2021 Invex entered into an exclusive collaboration, manufacturing and supply agreement with Pepton 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

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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](https://clinicaltrials.gov) website under Identifier **NCT05347147** or by visiting: <https://clinicaltrials.gov/ct2/show/NCT05347147>.