ASX / Media Release
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Invex Receives MHRA Approval to Commence IIH EVOLVE Phase III Clinical Trial in the UK

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 Medicines and Healthcare products Regulatory Agency (MHRA) has approved the Company's Clinical Trial Authorisation (CTA) to commence the IIH EVOLVE Phase III clinical trial in the United Kingdom (UK), for patients with Idiopathic Intracranial Hypertension (IIH). In addition, Invex has received a favourable ethical opinion from a Research Ethics Committee (REC), which was also a requirement prior to commencing the trial.

Professor Alex Sinclair, Executive Director and Chief Scientific Officer of Invex said "The approval of our CTA from the MHRA and favourable opinion from a UK REC, is an important step for our global Phase III trial initiatives, which will allow access for newly diagnosed IIH patients in the UK to potentially participate in the IIH EVOLVE clinical trial. In my clinic in Birmingham, I routinely observe the devastating effects of IIH on patients, their caregivers, and the associated healthcare costs to manage their disease, where standard drug therapies are lacking."

Professor Sinclair continued "Our research group has modelled the economic cost of IIH for England to be almost £500 million by 2030. In Scotland for example, the incidence of IIH has also materially increased to approximately 40 per 100,000 in obese females aged 15–44, which is a direct consequence of the increasing levels of obesity[1]. IIH EVOLVE is therefore an important and timely clinical trial to understand the clinical efficacy and safety of our proprietary once per week IIH treatment Presendin™ in these patients."

Invex intends to open a number of clinical sites across the UK and will now rapidly progress institutional contracts to facilitate the commencement of patient recruitment.

The Company continues to advance the necessary preparative activities for the IIH EVOLVE trial including additional regulatory filings to commence the study and expects to further update investors in early July as part of the Quarterly Activities Report and Appendix 4C disclosures. The interaction with the MHRA has allowed Invex to better harmonise the IIH EVOLVE trial design across regulatory agencies, including ethics/regulatory clearance in Australia and Invex remains confident that all necessary approvals in Australia will be completed during the September quarter.

[1] Goudie C, Shah P, McKee J, Foot B, Kousha O, Blaikie A. The incidence of idiopathic intracranial hypertension in Scotland: a SOSU study. Eye (Lond). 2019;33(10):1570-1576.

Dr. Jason Loveridge, Non-Executive Chairman commented "Through seeking regulatory approvals sequentially, Invex has achieved a more efficient and cost-effective execution of the global IIH EVOLVE Phase III clinical trial and we now expect the first IIH patient to be randomised and dosed after 30 June 2022."

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 29 June 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.