ASX / Media Release
14 December 2022

Invex Receives Approval for Paediatric Investigation Plan from the EMA

Key Highlights:

- Paediatric Investigation Plan (PIP) accepted for paediatric development of Presendin™ in IIH
- The PIP includes a decision adopting a waiver for Invex from conducting a trial in pre-pubertal males and females (typically <12 years of age)
- The PIP also includes a deferral, allowing for a pediatric trial to commence after the receipt of positive data from Invex's IIH EVOLVE Phase III clinical trial in the adult IIH population
- A successful outcome to the proposed paediatric trial would permit an additional market authorisation (MAA) in Europe for IIH, expanding market access to the pediatric population

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 Paediatric Committee (PDCO) of the European Medicines Agency (EMA) has accepted the Company's PIP for the development of Presendin™ for Idiopathic Intracranial Hypertension (IIH) in pubescent boys and girls aged less than 18 years.

Professor Alex Sinclair, Executive Director and Chief Scientific Officer of Invex said "This approval from the PDCO of the EMA will allow Invex to develop Presendin™ for adolescent patients who have reached puberty and suffer from the devastating effects of IIH. Presendin™ represents a potentially safe and effective new treatment option in these patients where there is a substantial unmet clinical need and approved therapies lacking. We look forward to this new trial commencing following a positive outcome to IIH EVOLVE."

In the UK, overall paediatric IIH incidence is approximately 0.7 per 100,000 of population with increasing incidence linked to age and weight to 4.18 and 10.7 per 100,000 in obese boys and girls aged 12–15 years.[1]

In the European Union, sponsors must possess a compliant PIP prior to applying for marketing approval of new drugs. A successful clinical trial in adolescents will allow Invex to file for an additional market authorisation (MAA) in Europe, thereby expanding market access in an adolescent population where the incidence of IIH continues to climb and associated healthcare costs are high.

[1] Matthews Y, Dean F, Lim MJ, et al. Pseudotumor cerebri syndrome in childhood: incidence, clinical profile and risk factors in a national prospective population-based cohort study. Archives of Disease in Childhood 2017;102:715-721.

The proposed pediatric trial will be a randomised, placebo-controlled, double-blind, multi-centre trial recruiting at least 40 post-pubertal males and females with IIH who are <18 years of age (as described above) and an additional number of adult IIH patients for treatment with either Presendin™ or placebo over 24 weeks. The primary endpoint will be determined by the change in papilloedema (swelling of the optic disc) assessed by optical coherence tomography over 24 weeks. Intracranial pressure (ICP) will not need to be measured in the agreed pediatric trial given that the positive effect of Presendin™ on ICP will have already been established in the IIH EVOLVE trial. Key secondary endpoints for the trial will include perimetric mean deviation, headache evaluation and visual acuity at 24 weeks, along with safety assessments and concomitant medication use throughout the study. The final trial design will be guided by clinical outcomes from the IIH EVOLVE Phase III clinical trial.

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This release dated 14 December 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.