ASX / Media Release
31 March 2021

Invex Files Pre-IND/Type B Meeting Request with US FDA

Invex Therapeutics Ltd (**Invex**, **ASX:IXC,** or **the Company**) a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (Exenatide) for neurological conditions relating to raised intracranial pressure, today announces the filing of a pre-Investigational New Drug Application (pre-IND) / Type B meeting request with the US Food and Drug Administration (FDA) seeking further protocol assistance on a proposed Phase III clinical trial of Presendin™ (Exenatide) versus placebo in Idiopathic Intracranial Hypertension (IIH) patients.

The Company is seeking advice on the proposed endpoints of the trial which include monthly headache days and intracranial pressure (ICP), two key measures that harmonise with European Medicines Agency (EMA) protocol advice received by Invex in December 2020 under the Company's orphan drug designation. In addition, as previously requested by the FDA following initial scientific advice received in July 2020, Invex has also submitted a complete proposed study protocol and statistical analysis plan (SAP) for the proposed trial.

Commenting on the submission, Invex Chairman Dr Jason Loveridge said "The filing of this request with the FDA represents an important milestone for the Company. The completion of a study protocol and SAP within approximately three months of obtaining final EMA feedback is testament to the commitment of the Invex team, our expert medical/scientific and regulatory advisors and study statisticians to our IIH development program for Presendin™."

Dr Loveridge continued "The feedback sought from the FDA will be an important consideration as the Company contemplates the filing of an IND following the official minutes of the meeting, expected in Q3 CY2021. We are certainly excited by the opportunity to share our plans with the FDA upon the granting of our proposed meeting request. This represents an important trial for IIH sufferers, who are unable to rely on any regulatory cleared therapeutic agents to effectively manage high ICP and materially improve their quality of life by positively impacting important clinical outcomes such as a reduction in headaches."

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This release dated 31 March 2021 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 Exenatide

Exenatide is a small peptide and a synthetic version of the GLP-1 agonist exendin-4, which received approval in the US and Europe for the treatment of type 2 diabetes in 2005 and 2006 respectively. Professor Alexandra Sinclair's research showed that GLP-1 receptors are expressed in the choroid plexus in the brain and that Exenatide can bind to these receptors and reduce secretion of cerebrospinal fluid. Current Exenatide dosage forms are not optimised for IIH.