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Invex Receives Written Response from FDA on Type C Meeting

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 announced the receipt of written responses from the US Food and Drug Administration (FDA) Division of Neurology relating to its proposed Phase III clinical trial design for Presendin™ (Exenatide) for the treatment of Idiopathic Intracranial Hypertension (IIH).

On 31 March 2021 the Company submitted a full Phase III study protocol and statistical analysis plan, as requested by the FDA in its response to Invex's initial meeting (23 July 2020), along with a number of questions. The documents submitted by Invex sought the FDA's guidance on the overall study design, and in particular, intracranial pressure and headache as key endpoints. The FDA, having reviewed the submission, provided written responses to the Type C meeting granted to Invex.

The FDA recommended Invex consider a clinically meaningful effect on visual function, such as Perimetric Mean Deviation (PMD) – a measure of change in the patient's visual field - as a primary endpoint to support an indication for Presendin™ in IIH. The FDA was open to Invex providing proposals for establishing the clinically meaningful effect of Presendin™ on visual function.

For intracranial pressure (ICP), the FDA considered this measure as an appropriate secondary endpoint of a study, but not a primary endpoint that would support approval of Presendin™ in IIH. This advice contrasts with that from the European Medicines Agency (EMA), which considered a lowering of ICP as an appropriate primary endpoint for a Phase III study in IIH. The FDA had very few specific comments relating to the Company's planned measure of monthly headache days and other key headache measures but did recommend an abbreviated headache severity scale as an alternative assessment.

Dr Jason Loveridge, Chairman of Invex Therapeutics said "We thank the FDA for their written feedback on the Company's proposed Phase III trial, which further informs Invex of a potential approval pathway for Presendin™ as a treatment for IIH in the US. Our clinical trial protocol and statistical analysis plan submitted to the FDA sought to harmonize and gain a broad consensus between the EMA and FDA by incorporating assessments of headache and ICP as key endpoints - as recommended by EMA – which would best reflect both the signature of the disease and the very broad impact of headache on the quality of life of all IIH patients. In its response, the Division of Neurology repeated the original Division of Ophthalmology feedback that visual function should be a key outcome measure of a study seeking approval of a drug for the treatment of IIH in the US."

The Company now intends to meet with its key regulatory and clinical advisors in the coming weeks to better understand the Type C meeting response from FDA, and in particular, to determine the best direction and design for a Phase III study of Presendin™ in IIH. The Company's current Phase III study protocol was developed to meet the EMA's requirements for a single Phase III study for registration of Presendin™ for IIH in the European Union.

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This release dated 15 June 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.