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Invex Granted Type C Meeting with 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 US Food and Drug Administration (FDA) Division of Neurology has granted Invex's meeting request to discuss the planned Phase III clinical program for Presendin™ (Exenatide) for the treatment of Idiopathic Intracranial Hypertension (IIH).

Invex is seeking FDA guidance on the design of the planned Phase III trial, including the proposed clinical endpoints and statistical analysis methods.

Based on the statement of purpose, objectives, and proposed agenda, the FDA considers the meeting a Type C meeting. In addition, the FDA determined that written responses only (WRO) to questions posed by Invex would be the most appropriate means for responding as part of the Type C meeting. The FDA retains absolute discretion in electing the meeting format by either face-to-face, teleconference or WRO. The WRO from the FDA is expected by mid-June 2021.

Dr Jason Loveridge, Chairman of Invex Therapeutics said "We are pleased the FDA has granted Invex a Type C meeting, which allows the Company to gain guidance on the development path for Presendin™ as we plan our Phase III program in IIH. Our clinical trial plans seek to examine several important neurological measures including intracranial pressure and headache as clinical endpoints, hence the Division of Neurology's input will provide invaluable feedback for the Company as our development progresses in this important market, where treatment options for IIH patients are limited."

The FDA retains the right to cancel or reschedule the agreement to provide written responses to the proposed Phase III development of Presendin™ in IIH. As previously indicated, the Company submitted a proposed study protocol and statistical analysis plan as part of its written request with the FDA.

A Type C meeting is any meeting other than a Type A or Type B meeting between the Center for Drug Evaluation and Research (CDER) and a sponsor or applicant regarding the development and review of a product and are scheduled to occur within 75 days of FDA receipt of the written meeting request.

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This release dated 22 April 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.