ASX / Media Release
7 May 2021

Formulation & Manufacturing Update

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 provides an update on the selection of a preferred Presendin™ formulation of Exenatide and the appointment of a contract manufacturing organisation (CMO) to produce current Good Manufacturing Practice (cGMP) material for planned human clinical trials in Idiopathic Intracranial Hypertension (IIH).

Despite the challenges during 2020 in completing the formulation selection due to COVID-19 related delays, the Company successfully identified several preferred formulation candidates for Presendin™ that exhibited a release profile that was supportive of a once per day sub cutaneous administration in humans.

The Company has proactively solicited and evaluated a number of CMOs who specialise in the formulation of peptides for clinical and commercial purposes. Several detailed proposals have been received for the manufacture of Presendin™ for late-stage clinical trial purposes and commercial supply which meet the stringent regulatory requirements of the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) pertaining to the manufacture and supply of human therapeutics under cGMP.

The Company has also undertaken detailed additional analyses relating to cost per unit at commercial scale volumes and potential pricing structures, taking account of market access dynamics such as government/private payers and overall patient acceptability, which is important when committing to long term manufacturing/supply agreements.

The proposals and contract discussions are well-advanced and in the process of further legal and commercial review. Invex will update the market once the manufacturing selection process has been completed and a binding manufacturing agreement signed.

The Company remains in a strong financial position, with cash of $33.2 million as at 31 March 2021 and a quarterly operating cash burn that has averaged $0.49 million on a trailing 12 month basis.

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This release dated 7 May 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.