

## **ASX Announcement**

October 15, 2019

# Phase II Recruitment Completed

**Invex Therapeutics Ltd (Invex**, ASX: **IXC**, or the **Company**) is pleased to announce that the 16<sup>th</sup> and final patient has been recruited and dosed for its Phase II clinical trial targeting the treatment of Idiopathic Intracranial Hypertension (IIH) with Exenatide.

Invex has significantly progressed the clinical trial having enrolled and dosed the last four patients with a clinical diagnosis of IIH in the month of October 2019, well ahead of schedule. Patients enrolled in the Phase II trial are each dosed with either placebo or Exenatide for 12 weeks, and monitored in real-time for changes in intracranial pressure.

The purpose of the Phase II clinical trial is to demonstrate that Exenatide can significantly reduce intracranial pressure in IIH patients, and to gather data which will be necessary to design a subsequent trial to gain regulatory approval for the Company's reformulated Exenatide in IIH.

Having completed recruitment and dosing ahead of schedule the Company is pleased to confirm the last patient is likely to receive the final dose in early 2020. If that remains the case then the Company will report full results of the Phase II clinical trial in the first half of calendar year 2020 as previously stated.

Chairman Dr Jason Loveridge commented: "This is a very important study for Invex and the fact that we have executed ahead of forecast just underlines the very significant patient need for new safe and effective therapies in IIH. We now look forward to viewing the data from the study in early 2020 and, if positive, initiating discussions with the relevant regulatory bodies regarding next steps in moving our first drug to market."

#### **ENDS**

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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. <a href="https://www.invextherapeutics.com">www.invextherapeutics.com</a>

#### 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.

### **Idiopathic Intracranial Hypertension (IIH)**

- IIH features severely raised intracranial pressure which causes disabling daily headaches and can compress the optic nerve, causing permanent vision loss in 25% of those affected.
- 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.