ASX / Media Release
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Invex Receives European Orphan Drug Designation for Exenatide in Traumatic Brain Injury

Invex Therapeutics Ltd (**Invex**, **ASX:IXC,** or **the Company**) a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (sustained release Exenatide) for neurological conditions relating to raised intracranial pressure, today announces the granting of orphan drug designation (ODD) from the European Medicines Agency (EMA) for Exenatide in the treatment of moderate to severe Traumatic Brain Injury (TBI). This is the second ODD for Exenatide in Europe, with Invex receiving an ODD for Idiopathic Intracranial Hypertension (IIH) in 2017, alongside an ODD from the US Food and Drug Administration (FDA), also for IIH.

The EMA provides a range of incentives in the European Union (EU) for medicines that have been granted an orphan designation, including ten years market exclusivity from the date of approval, clinical trial protocol assistance, access to the centralised authorisation procedure in Europe, and certain fee reductions.

TBI affects adult and paediatric population globally and remains one of the major cause of traumatic death and disability across all ages worldwide. Overall, 57,000 TBI-related deaths and 1.5 million hospitalisations occur every year in the European Union.[i] Management of intracranial pressure (ICP) elevation is considered critical in patients with moderate to severe TBI, however, at present, there are no EMA or FDA approved therapies specifically for the treatment of intracranial hypertension in this patient population.

Invex is currently investigating Presendin™, a once per week, sub-cutaneous, sustained-release (SR) Exenatide microsphere formulation in a randomised, double-blind, placebo-controlled Phase III clinical trial (IIH EVOLVE) in 240 IIH patients across the globe. Invex believes Presendin™ will be able to reduce ICP in a number of conditions associated with elevated ICP, including moderate and severe traumatic brain injury.

Dr Thomas Duthy Executive Director of Invex said “Since we first discovered the potent ICP lowering effects of Exenatide in pre-clinical models and within our completed Phase II Pressure IIH trial, the Company has explored other elevated intracranial pressure disorders, including TBI. Securing a European ODD for Exenatide is an important initial step in protecting the commercial opportunity in moderate to severe TBI, which is forecast to represent an annual market opportunity of US$2.45 billion by 2027, growing 9% per annum.[ii]”

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This release dated 23 June 2023 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 Presendin™

Presendin™ is a once per week, sub-cutaneous, sustained-release (SR) Exenatide microsphere formulation originally developed by Peptron, Inc. (KOSDAQ: 087010). In September 2021 Invex entered into an exclusive collaboration, manufacturing and supply agreement with Peptron for Presendin™ in IIH for all major markets, with the exception of South Korea.

Exenatide is a small peptide and a synthetic version of the GLP-1 agonist exendin-4, which is currently approved for the treatment of type 2 diabetes. In 2017, Invex received orphan drug designation for Exenatide in IIH from the US Food and Drug Administration and European Medicines Agency.

About Traumatic Brain Injury (TBI)

Traumatic brain injury (TBI) has been defined as an alteration in brain function, or other evidence of brain pathology, caused by external force. TBI affects adult and paediatric population globally and remains one of the major cause of traumatic death and disability across all ages worldwide. In the general population, TBI is more prevalent among those under 25 years of age and those older than 75 years, with the mean age for women higher than for men. There are no approved therapies to treated raised intracranial pressure in TBI patients.

[i] www.centre-tbi.eu
[ii] https://www.marketdataforecast.com/market-reports/traumatic-brain-injury-market