Research as a Service

Invex Therapeutics Ltd

Entering Phase III

Pharmaceuticals, Biotechnology & Life Sciences

9th September 2022

Invex Therapeutics (ASX:IXC) is a clinical-stage biopharmaceutical company focused on the repurposing of an already approved drug, Exenatide, for the treatment of neurological conditions resulting from raised intracranial pressure (ICP). These conditions include Idiopathic Intracranial Hypertension (IIH), acute stroke and traumatic brain injuries. Invex has trademarked its repurposed sustained-release (SR) Exenatide as Presendin™ and has received US Food and Drug Administration (FDA) Investigational New Drug Application (IND) approval, Medicines and Healthcare products Regulatory Agency (MHRA) approval, Therapeutic Goods Administration clearance and Human Research Ethics Committee (HREC) approval, and Clinical Trial Notification (CTN) scheme clearance to commence its IIH EVOLVE Phase III clinical trial in the US, UK and Australia. IIH EVOLVE is a randomised, placebo-controlled, double blind trial on 240 patients with newly-diagnosed IIH to determine the efficacy and safety of Presendin™ against placebo, administered once-weekly over 24 weeks. The primary goal of the trial is to change the intracranial pressure from baseline, with key secondary endpoints related to vision and headache outcome measures. The company is well-funded to proceed with its Phase III trial with $29.3m cash in hand.

Business model

Invex Therapeutics is focused on developing treatments for neurological conditions resulting from or involving raised intracranial pressure, which can occur due to several conditions including traumatic brain injury, blood clots and blockages, brain tumours, stroke and infections leading to meningitis. Invex is currently focused on ICP caused by idiopathic intracranial hypertension (IIH), a rare but increasing condition found most often in women with obesity aged from 15 to 60 years. This condition currently has no treatment options but can result in debilitating daily headaches and permanent loss of sight for the patient. Invex was founded to advance research conducted at the University of Birmingham by Professor Alexandra Sinclair in intracranial pressure-related neurological disorders.

Greenlighted to commence IIH EVOLVE Phase III in the US

The company announced in August that it had received IND approval from the US FDA for Presendin™ and for commencement of the IIH EVOVLE Phase III clinical trial in the US. Invex noted that it was on-track to recruit its first patient into the trial during the second half of CY2022 and that it was progressing the opening of leading clinical sites across the US to support the trial. The IIH EVOLVE trial is a randomised, placebo-controlled, double-blind trial that will select 240 patients with newly diagnosed IIH to determine the efficacy and safety of Presendin™ against placebo, administered once weekly over 24 weeks. The primary endpoint of the trial is the change of intracranial pressure from the baseline, with key secondary endpoints being vision and headache outcome measures. Invex expects to operate the trial across 40 clinical sites globally.

Peers are other companies seeking to repurpose drugs

Companies at a similar stage in their journey include Island Pharmaceuticals (ASX:ILA) and Paradigm Biopharmaceuticals (ASX:PAR). ILA is a mid-clinical stage antiviral drug development company focused on its Phase IIa clinical trials. Paradigm is a late-stage drug development company undertaking to develop and commercialise Pentosan polysulfate sodium for the treatment of pain associated with musculoskeletal disorders. Both companies are seeking to repurpose an already approved drug. It is worth noting that companies seeking to repurpose drugs generally bring them to market quicker due to their prior safety approval, however, a downside risk is that repurposed drugs generally have less patent protection, although Invex has secured orphan drug designation in the US and Europe in IIH for Exenatide, providing 7 and 10 years market exclusivity, respectively, in these markets.

Share Details

ASX code	IXC
Share price (8-Sept)	$0.63
Market capitalisation	$47.4M
Shares on issue	75.2M
Net cash at 30-Jun-2022	$29.3M
Free float	~57.7%

Share Performance (12 months)

Upside Case

- Successful Phase III trial on IIH EVOLVE
- Fully funded to proceed with Phase III trial
- Strong management team with commercial experience

Downside Case

- No guarantee that a reformulated Exenatide will receive regulatory approval
- Limited company history
- IIH EVOLVE trial fails to meet endpoint goal

Catalysts

- Outcome of Phase III clinical trial in US
- Further approvals in Australia and NZ

Comparable Companies (Aust/NZ)

Island Pharmaceuticals (ASX:ILA), Paradigm Biopharmaceuticals (ASX:PAR)

Board and Management

Dr Jason Loveridge	Non-Executive Chair
Prof. Alexandra Sinclair	Executive Director/CTO
Dr Thomas Duthy	Executive Director
Dr Megan Baldwin	Non-Executive Director
David McAuliffe	Non-Executive Director

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FINANCIAL SERVICES GUIDE

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