Invex Therapeutics

2022 Annual General Meeting

22 November 2022

ASX Code: IXC

Invex Therapeutics

Chairman Address and Presentation

Dr Jason Loveridge

invex THERAPEUTICS

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Invex Therapeutics - Executive Summary

Late-stage drug development Company targeting the orphan disease - Idiopathic Intracranial Hypertension (IIH)

The Disease[1]

- Dysregulation of cerebral spinal fluid secretion in the brain, leading to high intracranial (brain) pressure (ICP)
- >90% of cases overweight women of childbearing age with no known cause
- >90% suffer headaches that are progressively more severe and frequent
- Up to 25% suffer permanent vision loss due to elevated ICP impact on optic nerve

The Impact[2]

- Invasive surgical and/or device interventions to temporarily lower ICP and preserve vision (sig. side effects)
- 40% of patients have repeat hospital admissions, with average stays of 2.7 days
- Sig. impact on quality of life and rapidly rising healthcare costs e.g., £462M in UK by 2030 (5x increase on 2017)

A Potential Solution

- Exenatide: a GLP-1 receptor agonist: link to IIH established by Prof. Sinclair (IXC Director, CSO)
- Strong scientific basis for benefit with a well defined mechanism of action
- Patent protection secured: use of Exenatide in IIH & other indications
- Presendin™ - once weekly dosing improves compliance and safety

1. Corbett JJ, et al. Arch Neurol. Visual loss in pseudotumor cerebri. Follow-up of 57 patients from five to 41 years and a profile of 14 patients with permanent severe visual loss; Markey et al., Understanding idiopathic intracranial hypertension: mechanisms, management, and future directions (2016).
2. Mollan et al., EYE. The expanding burden of idiopathic intracranial hypertension (2019)

Invex Therapeutics - Executive Summary

Late-stage drug development company targeting the orphan disease - Idiopathic Intracranial Hypertension (IIH)

Attractive Market Dynamics

- IIH Total Addressable Market (TAM) in the US and EU/UK of **A$1.6 billion per annum** (~A$1 billion EU/UK, ~A$0.6 billion US) and growing at 3.4% p.a.
- Unencumbered drug therapy market – no approved treatments, no new treatments in clinical trials
- Urgent market need, chronic administration required

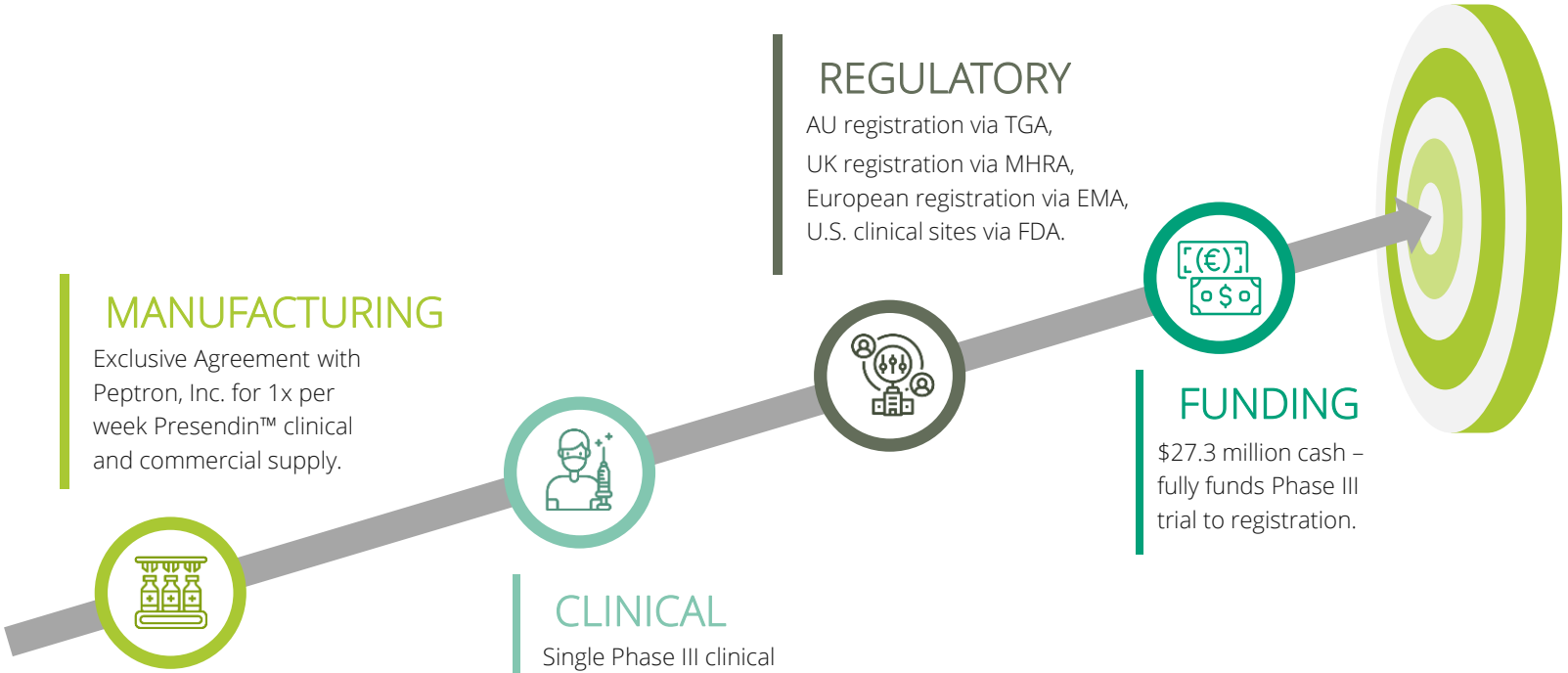
Supportive Clinical Data

- Strong Phase II clinical data - efficacy demonstrating a strong and sustained (3 months) drug effect in the IIH population
- No significant safety concerns over 12 weeks of treatment
- Single Phase III clinical trial targeting registration of Presendin™ (sustained-release (SR) Exenatide) in the EU, UK and Australia

Significant Barriers to Competition

- Orphan drug designation in US (7 years exclusivity) and Europe (10 years exclusivity)
- Issued patents for use of Exenatide in IIH in US, EU and Japan out to beyond 2035
- Additional patents pending

Critical Components for Success



MANUFACTURING

Exclusive Agreement with Peptron, Inc. for 1x per week Presendin™ clinical and commercial supply.

CLINICAL

Single Phase III clinical trial designed with expert input.

REGULATORY

AU registration via TGA,
UK registration via MHRA,
European registration via EMA,
U.S. clinical sites via FDA.

FUNDING

$27.3 million cash – fully funds Phase III trial to registration.

IIH EVOLVE Phase III

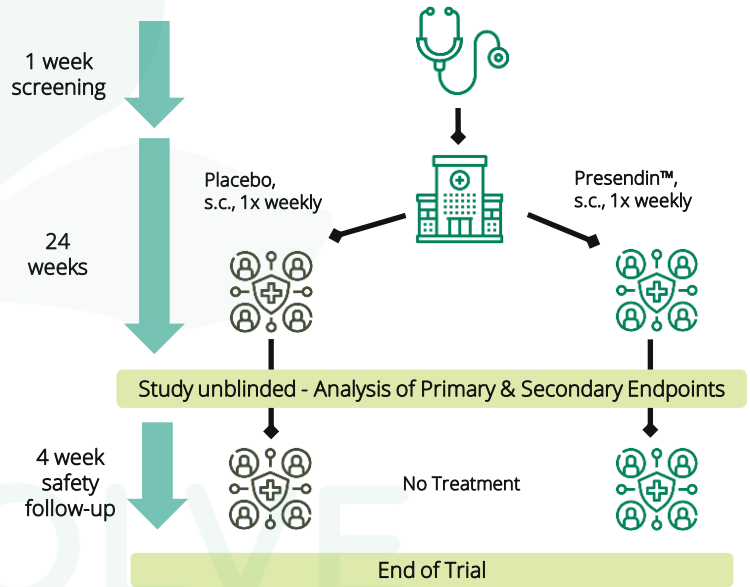
IIH EVOLVE

Randomised double-blinded, placebo controlled multi-centre clinical trial to determine safety and efficacy of Presendin™ in IIH

40 centres across EU, UK, Australia, NZ, Israel and the US | 240 patients | 24 months recruitment

Primary Endpoint	Change in Intracranial Pressure (ICP) from baseline at 24 weeks
Secondary Endpoint	Change in Perimetric Mean Deviation (PMD) from baseline over 24 weeks
Secondary Endpoint	Papilloedema (optic nerve swelling) by change in OCT[1] measures over 24 weeks
Secondary Endpoint	Change in Monthly Headache Days (MHD) from baseline over 24 weeks
Safety	Adverse events rate, anti-drug antibodies and general lab measures
Quality of Life	Patient reported outcomes (SF-36, ED-5D-5L, VFQ-25), monthly patient diary

Phase III Schematic



Designed to meet registration (approval) requirements in the UK, EU and Australia; data to inform US FDA registration next steps

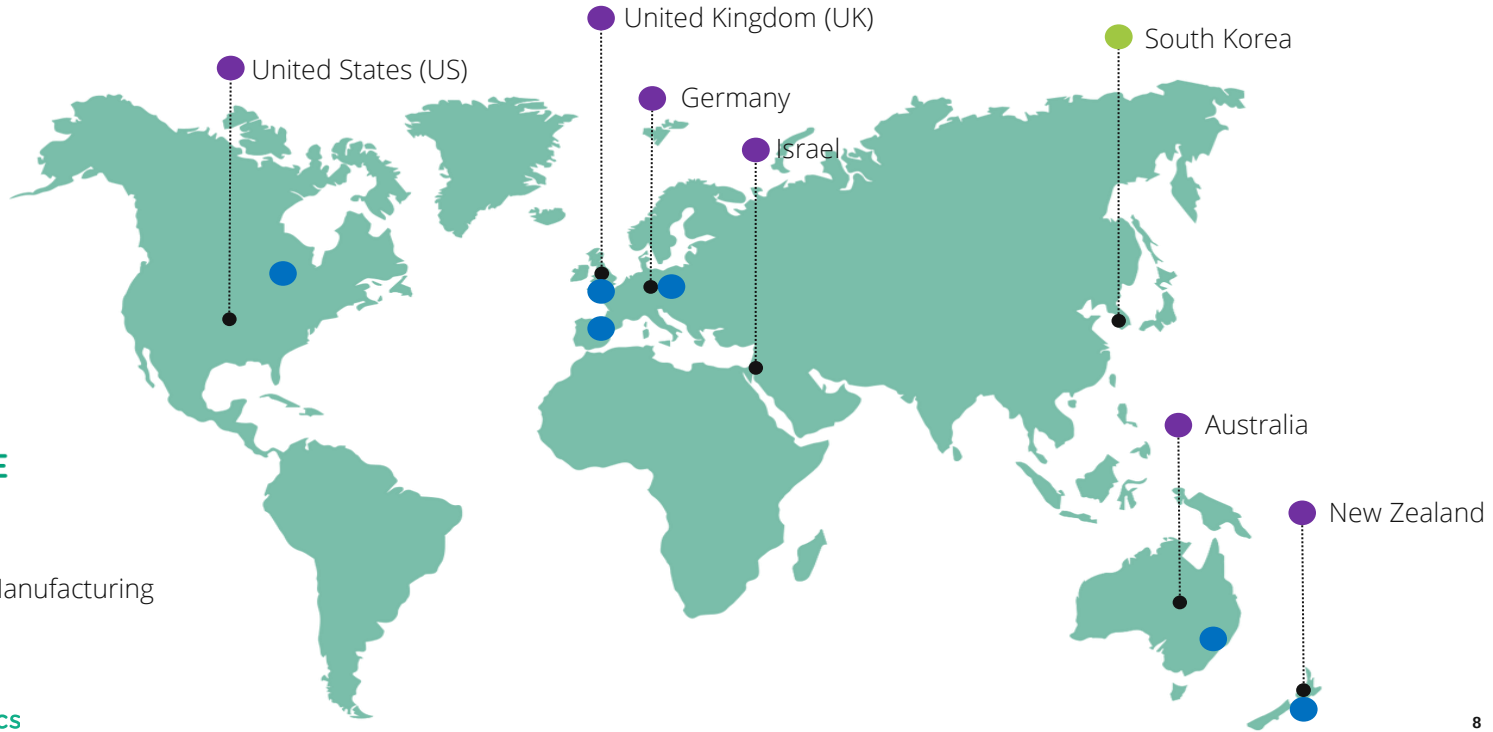
1. OCT – Optical Coherence Tomography is an imaging tool accepted by professional bodies for monitoring papilloedema in IIH by measuring different aspects of the optic nerve. The optic nerve head size and retinal nerve fibre layer (RNFL) are measurements that both reflect swelling of the optic nerve and hence the extent of papilledema. Optic nerve head measures on OCT correlate with visual field sensitivity loss.
2. s.c. – sub cutaneous

IIH EVOLVE Phase III

Manufacturing

Clinical Sites

Trial Steering Committee (TSC)



IIH EVOLVE

- TSC Members
- Presendin™ Manufacturing
- Clinical Sites

Trial Steering Committee – Global Leaders in IIH

Professor Michael Wall – Chair

Professor of Neurology and Ophthalmology at the University of Iowa. Director of the Iowa Visual Field Reading Center.

Associate Professor Clare Fraser – Member

Assoc. Professor Neuro-ophthalmology, University of Sydney. Consultant Visiting Medical Officer at both Sydney Eye Hospital and Liverpool Hospital.

Professor Patricia Pozo-Rosich – Member

Professor Pozo-Rosich is a Head of Section in the Neurology Department at Vall d'Hebron University Hospital in Barcelona and Director of the Migraine Adaptive Brain Centre.

IIH EVOLVE

Professor Susan Mollan – Member

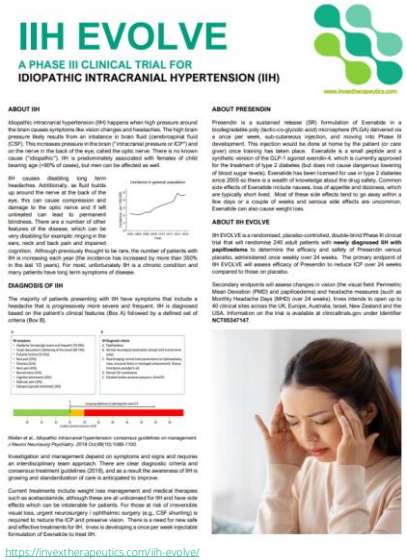
Professor Mollan is Honorary Professor at the University of Birmingham and a Consultant Neuro-ophthalmologist at University Hospitals Birmingham (UHB). Lead author IIH consensus treatment guidelines (2018/9).

Professor Helen Danesh-Meyer– Member

Professor Danesh-Myer is Professor, Faculty of Medical and Health Sciences, Ophthalmology, Sir William and Lady Stevenson Chair in Ophthalmology, Head of Academic Neuro-ophthalmology and Glaucoma, University of Auckland and a Director of the Eye Institute.

Professor Dr Wolf Lagrèze – Member

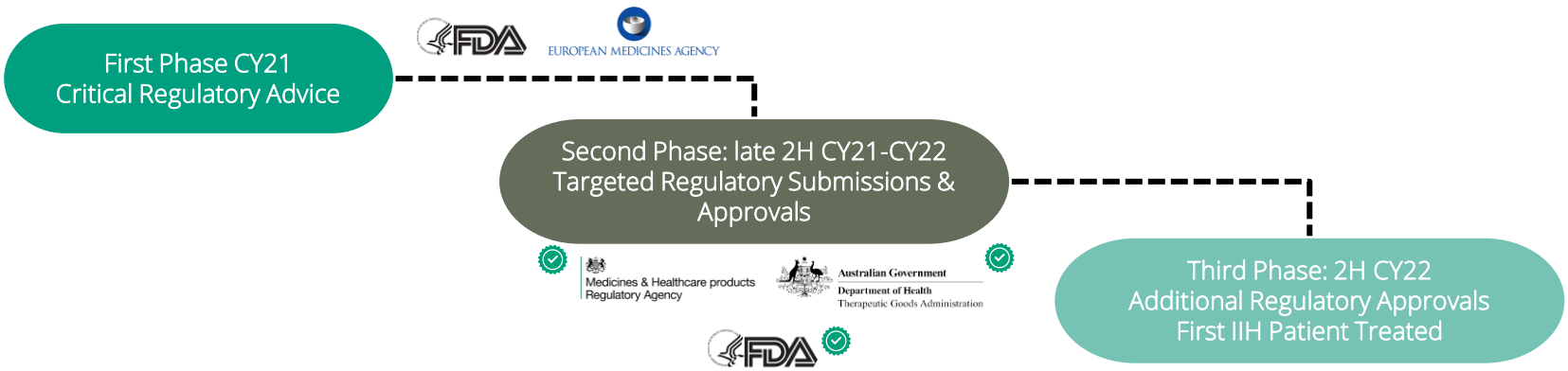
Professor Lagrèze is Professor of Ophthalmology at the University Medical Center Freiburg, Germany, where he holds the Chair of Neuro-ophthalmology and Pediatric Ophthalmology.



https://invextherapeutics.com/iih-evolve/

Regulatory

Phase III IIH-EVOLVE clinical trial for Presendin™ is intended to initially support: EMA, TGA & MHRA approval for treatment of IIH ($1Bn TAM)



- Efficient
- Cost-Effective
- Clinical Harmonisation

Milestones for Q4 CY22

- Completion of additional regulatory filings and/or approvals:
  - Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA) – achieved August 2022
  - HREC approval (public hospital) Australia – achieved September 2022
  - Medsafe Approval - New Zealand
  - Hospital Clearance / Ministry of Health – Israel (filing)
  - National Competent Authorities – Europe (filing)
- Progressive opening of clinical sites - Australia and UK launched in October 2022
- First patient recruited into IIH EVOLVE – achieved 21 November 2022

Summary & Outlook

- Single Phase III trial designed to support Presendin™ market approvals in the EU, UK and Australia - $1 billion+ unencumbered TAM
- Potential for rapid incorporation of Presendin™ into IIH treatment guidelines
- IIH-EVOLVE includes an economic evaluation to facilitate the health technology assessment (HTA) process
- Data generated from trial will inform discussions with FDA to understand regulatory requirements for future clinical trials/approval
- Potentially first-ever regulatory approved drug for IIH in any jurisdiction world-wide
- Fully funded Phase III program (IIH EVOLVE) - **$27.3 million cash (Q1 FY23)**
    - exited FY22 with annualised corporate costs (ex R&D, share-based payments) of **~$1 million per annum**

Contacts

INVESTORS

Dr Tom Duthy
Executive Director

+61 402 493 727
tduthy@invextherapeutics.com

MEDIA

Margie Livingston
Ignite Communications

+61 438 661 131
margie@ignitecommunications.com.au

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