ASX / Media Release
30 November 2022

Invex to Present at the MST Financial Late Stage Development Biotech Virtual Forum

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 an upcoming presentation by Dr Thomas Duthy, Executive Director at the MST Financial Late Stage Development Biotech Virtual Forum, to be held on Thursday 1 December 2022 at 3.20pm Australian Eastern Daylight Time (AEDT).

Investors who wish to register for the event can do so at the following link:
https://mstfinancial-au.zoom.us/webinar/register/WN_gql-TGwYSfK82CjeFBadwQ

A copy of the presentation is attached.

- ENDS -

This release dated 30 November 2022 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 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 the IIH EVOLVE Clinical Trial

The Phase III IIH EVOLVE trial is a randomised, placebo-controlled, double-blind, multi-centre trial that will randomise 240 patients with newly diagnosed IIH to determine the efficacy and safety of Presendin™ versus placebo, administered once weekly. Patients with a confirmed diagnosis of IIH will be randomised on a 1:1 basis to either Presendin™ or placebo for 24 weeks.

The primary endpoint of the trial is the change in intracranial pressure (ICP), as measured by lumbar puncture, at baseline and at 24 weeks. Secondary endpoints include the change in perimetric mean deviation (PMD), papilloedema and monthly headache days over 24 weeks.

IIH EVOLVE is designed to meet the requirements for market approval of Presendin™ for the treatment of Idiopathic Intracranial Hypertension (IIH) in the European Union (EU), United Kingdom (UK) and Australia.

Further study details can be found at clinicaltrials.gov website under Identifier **NCT05347147** or by visiting: https://clinicaltrials.gov/ct2/show/NCT05347147.

Invex Therapeutics

MST Financial Late Stage Development Biotech Virtual Forum

Dr Tom Duthy
Executive Director

1 December 2022
ASX Code: IXC

invex
THERAPEUTICS

Disclaimer

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Company Snapshot

Company	
Repurposed, Proven Drug	Presendin™ (SR-Exenatide)
Clinical Stage	Phase III (Single Trial)
Orphan Disease Focus	Idiopathic Intracranial Hypertension (IIH)
Orphan Designation Granted	USA + EU/UK
Total Addressable Market	$1.6 billion annually (USA/EU/UK)
Valuation Drivers	Clinical, regulatory, patent

Capital	
Shares on Issue	75.2 million
Unlisted Options	4.6 million
Ave. Quarterly Cash Burn (12 mth trailing)	$1.15 million
Cash (30 Sep-22)	$27.3 million
Market Capitalisation (25 Nov-22) [1]	$41.4 million
Enterprise Value (25 Nov-22)	$14.1 million

[1]Based on a closing price of $0.55

Major Shareholders (as at 1 November 2022)	
Directors / Management	16.8%
Tattarang	11.8%
Tisia Nominees Pty Ltd	5.3%
JK Nominees Pty Ltd	4.0%
Anthony Grist	3.7%
University of Birmingham	2.7%
Top 20 Shareholders	58.0%

Board of Directors	
Dr Jason Loveridge	Non-Executive Chairman
Professor Alexandra Sinclair	Executive Director & Chief Scientific Officer
Dr Tom Duthy	Executive Director
Mr David McAuliffe	Non-Executive Director
Dr Megan Baldwin	Non-Executive Director

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

IIH Total Addressable Market (TAM)

Key Inputs[1-5]


~24,000 EU/UK patients


~16,000 US patients


60% Diagnosed


90% Drug Treatable


4.3 year disease duration
~92k active patients


A$1,500 cost per month*
*Example only (ref. drug pricing) – final market price for Presendin™ TBD

Market Size (Annual)[6]


~A$1.0 Billion


~A$0.6 Billion


~A$1.6 Billion


3.4% growth

Market Drivers


Increasing obesity rates


Increasing awareness


10% ↑ in diagnosis rate =
↑ A$300 million in TAM

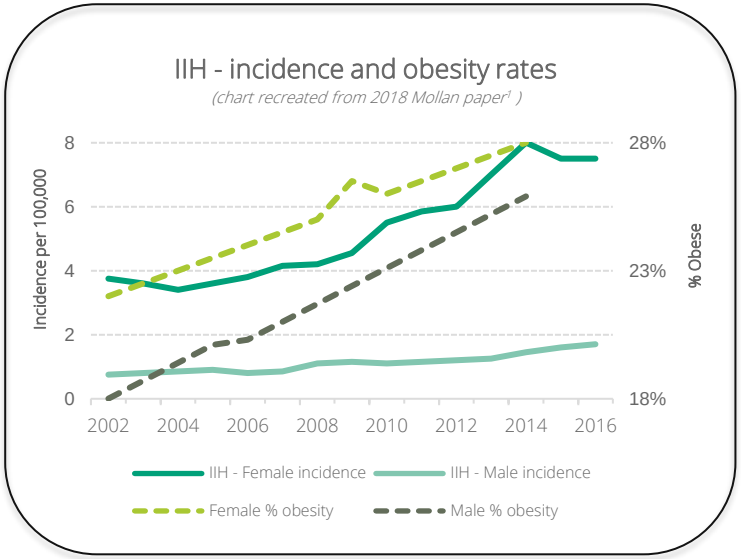

>A$2.3 Billion market by 2030

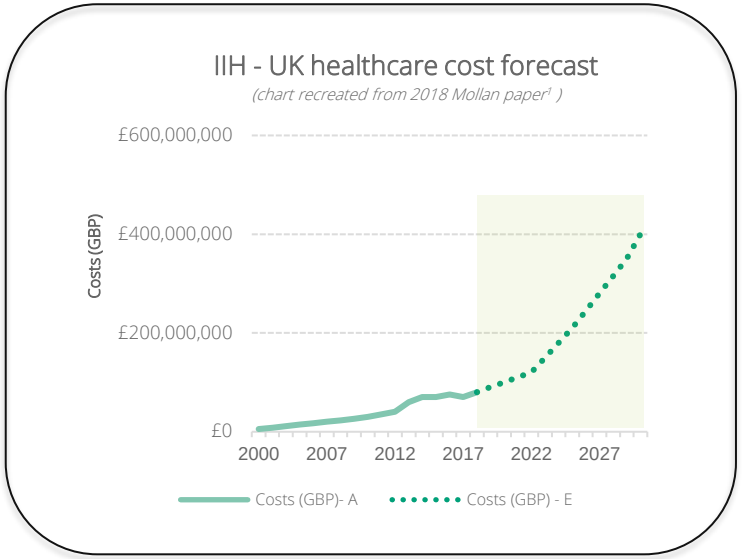
invex THERAPEUTICS | INITIAL TARGET MARKETS – EU, UK, AU

1. Mollan et al., EYE. The expanding burden of idiopathic intracranial hypertension (2019) incidence rate of 4.7/100,000 general population, n =23,182 . Targets markets are EU 27(& UK) + USA
2. Mollan SP, et al. Idiopathic intracranial hypertension: consensus guidelines on management (2018) ; Invex estimate re % presenting headache severity
3 Simoens et al., "what price do we pay for repurposing drugs for rare diseases"? (2016) – average 66x & Invex initial pricing analysis => pricing subject to change
4. D. Friesner et al., Idiopathic intracranial hypertension in the USA: the role of obesity in establishing prevalence and healthcare costs (2010)
5. Assumes average of obesity growth rates in UK (https://www.oecd.org/els/health-systems/Obesity-Update-2017.pdf) and historical incidence growth rate
6. Data as at 2020 estimates.

IIH is a Rapidly Rising Cost to the Healthcare System

- IIH is a rapidly growing orphan indication driven by changing demographics[1]
- **90%** of IIH patients are women of childbearing age[1]
- By 2030 IIH is projected to cost hospitals in England alone +**£400m** p.a[1], similar trend in USA[2]
- Key cost driver - ~**40%** of IIH patients have repeat hospital admissions[1]



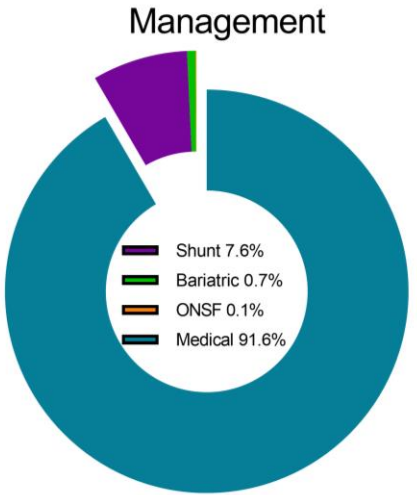


1. Mollan et al., The expanding burden of idiopathic intracranial hypertension (2018), 'Incidence and obesity rate' – Graphs recreated from Mollan et al. paper
2. Friesner et al., Idiopathic intracranial hypertension in the USA: the role of obesity in establishing prevalence and healthcare costs (2010)

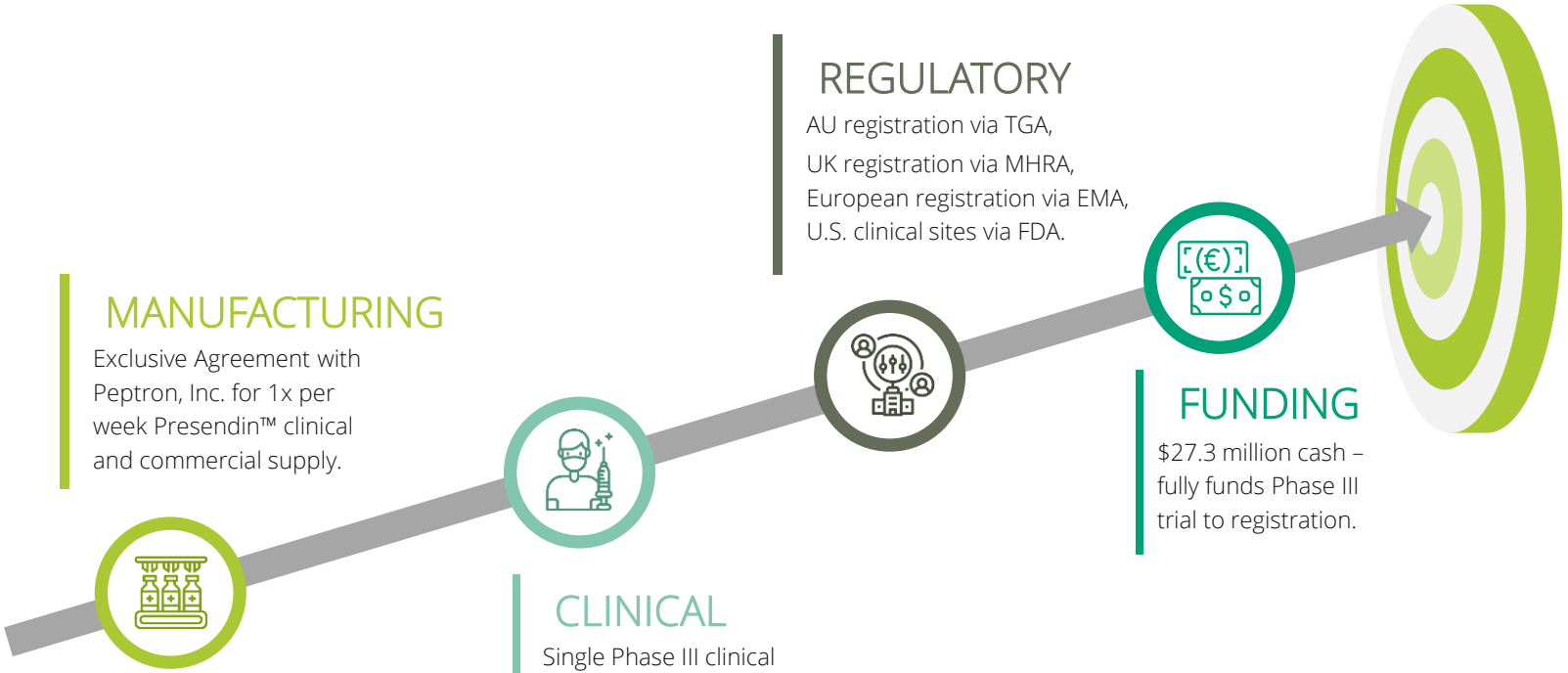
Urgent Need to Identify New Treatments

Idiopathic Intracranial Hypertension (IIH) is a growing neurological disorder

- No regulatory approved treatments
- No new therapeutic interventions in clinical trials
- For patients at risk of vision loss, invasive & high risk surgical interventions are the only alternative
- Patients live with the daily debilitating effects of IIH



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.

Manufacturing

STRATEGIC PARTNER PEPTRON

Established a long-term strategic partner for Invex (Sep 2021)

Listed on South Korean KOSDAQ Exchange (KS:087010)

TIME & RISK REDUCTION

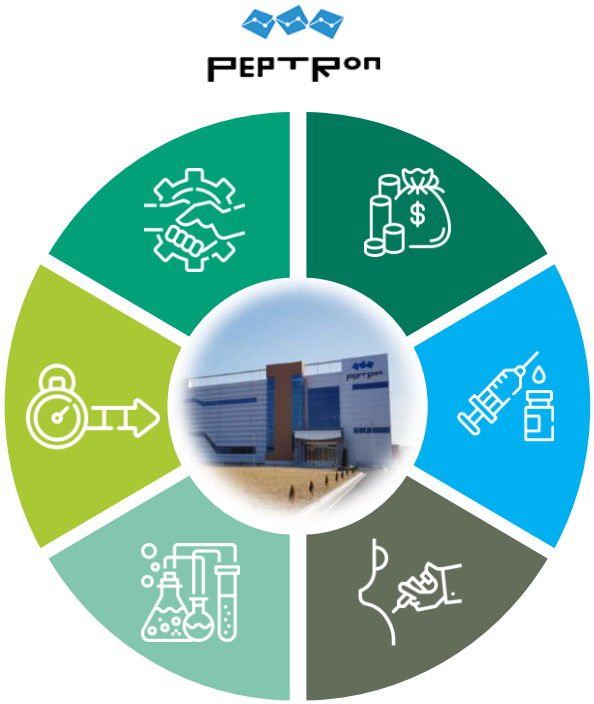
Significant clinical and non-clinical data package provided by Peptron

Significant de-risking of Invex's development of Presendin™ in IIH

PEPTRON EXPERTISE

Long-Acting Peptide Formulation specialists (SmartDepot™ Technology)

Ongoing product development activities



FINANCIAL

Strong economics

- fixed price per dose
- no royalties
- no milestone payments

MANUFACTURING

Financially robust

Commercial-scale capacity

Established 16,000sqM GMP facility for exenatide formulation

PATIENTS

Once weekly dosing provides better compliance and convenience

IIH EVOLVE Phase III

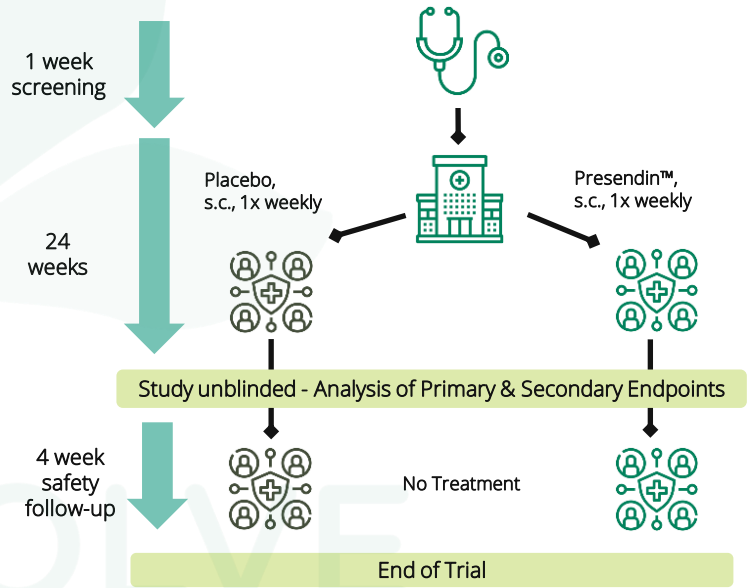
IIH EVOLVE

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

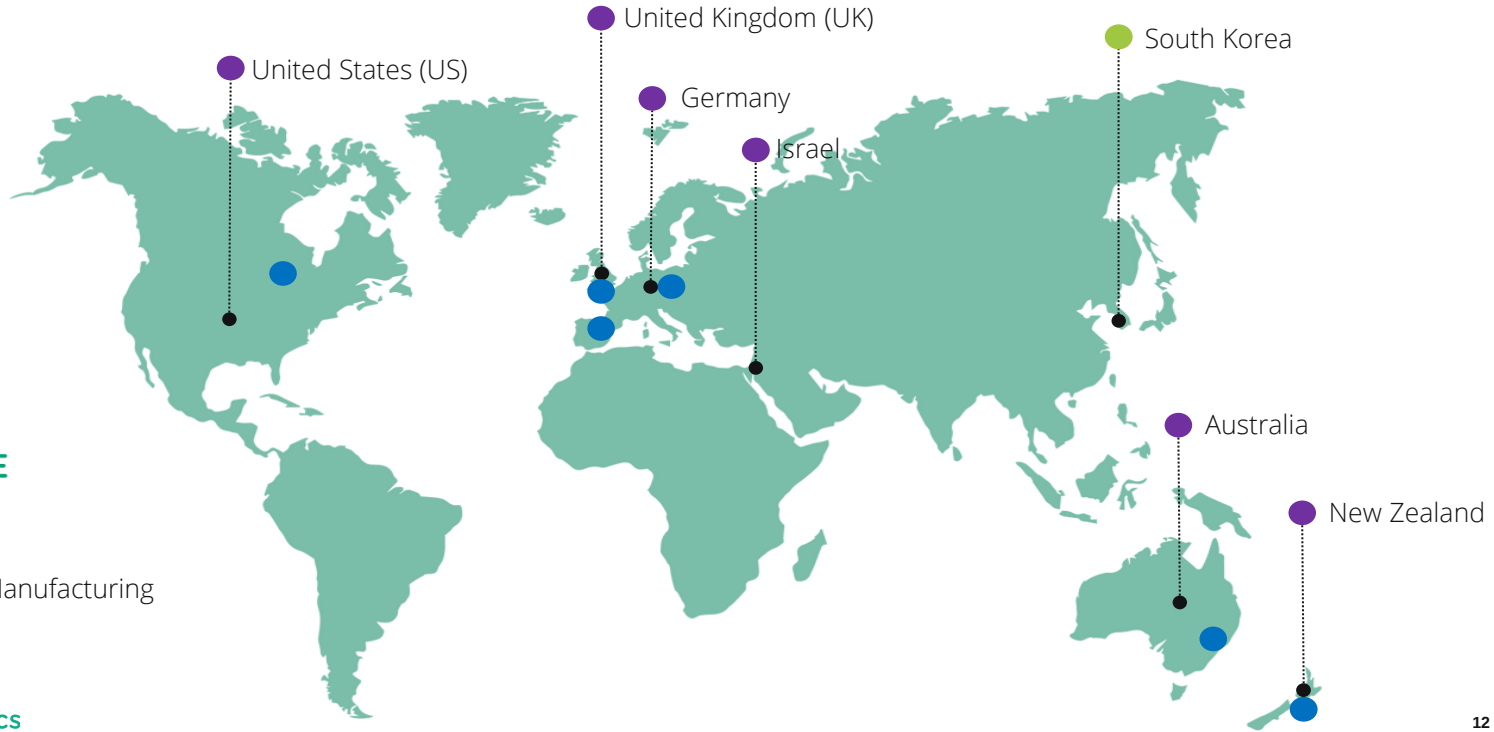
1. OCT – Optical Coherence Tomography is an imaging tool accepted by professional bodies for monitoring papilloedema in IIH by measuring different aspects of the optic nerve. The optic nerve head size and retinal nerve fibre layer (RNFL) are measurements that both reflect swelling of the optic nerve 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)

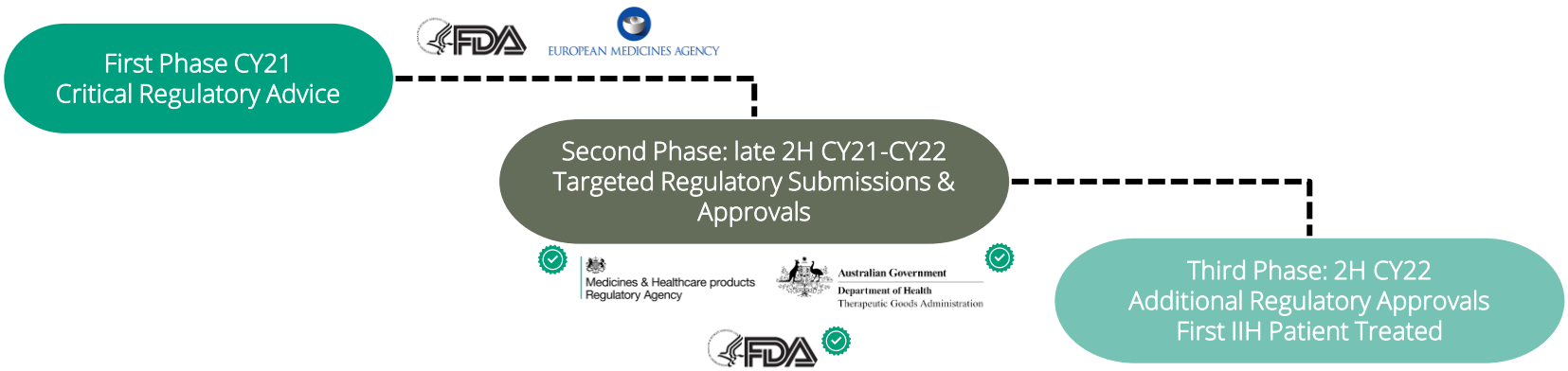


IIH EVOLVE

- TSC Members
- Presendin™ Manufacturing
- Clinical Sites

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 – achieved 25 November 2022
  - 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**

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