ASX / Media Release
4 November 2021

Notice of Webinar & Investor Presentation

Invex Therapeutics Ltd (**Invex**, **ASX:IXC,** or **the Company**) a clinical-stage biopharmaceutical company focused on the development and commercialisation of Presendin™ (once weekly extended release Exenatide) for neurological conditions relating to raised intracranial pressure (ICP), will today host an investor/analyst interactive webinar with presentation (attached) to discuss the Regulatory and Clinical Strategy, as announced to ASX today.

The investor webinar will take place at **5.00pm AEDT today (6.00am BST (London) time)**, with the following Invex executives, who will provide an overview of the Strategy followed by a question and answer session with investors:

- Dr Tom Duthy, Executive Director (Host/Moderator)
- Dr Jason Loveridge, Chairman and
- Professor Alex Sinclair, Executive Director and Chief Scientific Officer

Investors are required to register for the Webinar prior to the commencement via Zoom at: https://zoom.us/webinar/register/WN_rfRVjfywQm6Xe8M-y22Fsw

Webinar ID: **985 3315 6472**

As an attendee, investors can ask questions in the Q&A, however, both audio and video functions will be disabled except for the presenters. The Q&A panel will be open when you join. Select 'Q&A' at the bottom of the pane if you wish to ask a question. Type your question in the compose box, and then select Send icon. A question can be asked anonymously, if required.

- ENDS -

This release dated 4 November 2021 has been authorised for lodgement to ASX by the Board of Directors and lodged by Narelle Warren, Company Secretary.

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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.

Invex Therapeutics

CLINICAL & REGULATORY UPDATE

4 November 2021
ASX Code: IXC

invex
THERAPEUTICS

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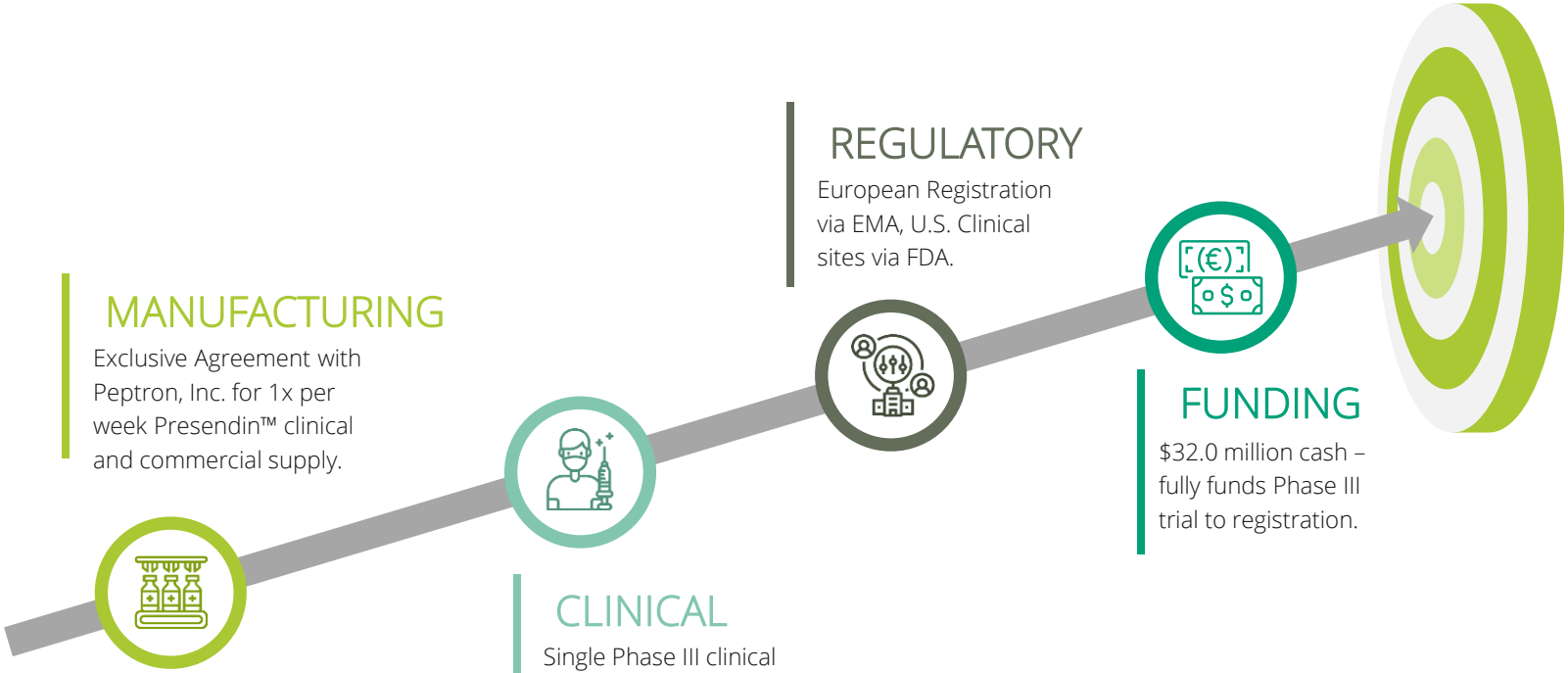
Critical Components for Invex's Success



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

European Registration via EMA, U.S. Clinical sites via FDA.

FUNDING

$32.0 million cash – fully funds Phase III trial to registration.

Manufacturing

Dr Jason Loveridge
Chairman

Presendin™ Manufacturing Partnership

Exclusive Collaboration & Manufacturing Agreement with Peptron Inc. (South Korea)

- Executed 27 September 2021
- Worldwide collaboration, manufacturing and supply agreement for Presendin™ in Idiopathic Intracranial Hypertension (IIH)
- A 1x per week, sustained-release (SR) Exenatide microsphere formulation, originally developed by Peptron
- Exclusive manufacturing and supply to Invex for IIH in all major markets
- Peptron gains exclusive commercial rights for Presendin™ in South Korea for IIH
- Contract expires at the later of either the expiry of the last relevant Peptron patent or ten years following first commercial sale

Key Financial Terms

- Fixed price per dose for supply of Presendin™ and placebo for all Invex's clinical studies in IIH
- Fixed price per dose for supply of Presendin™ for commercial sale by Invex
- No royalties payable
- No upfront or milestone payments

Benefits of Partnering for Manufacturing

STRATEGIC PARTNER

Establishes a long term strategic partner for Invex

TIME & RISK REDUCTION

Significant clinical and non-clinical data package provided by Peptron

12 months of lead-in activities no longer required to be performed by Invex

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

PEPTRON EXPERTISE

Invex receives the benefit of Peptron's expertise and ongoing product development activities

FINANCIAL

~$3M in Invex cost savings

Strong economics

- no royalties
- no milestone payments

MANUFACTURING

Financially robust

Commercial-scale capacity

PATIENTS

Once weekly dosing

Clinical

Professor Alexandra Sinclair
Executive Director & Chief Scientific Officer

Clinical

IIH EVOLVE - a Phase III clinical trial evaluating the safety and efficacy of Presendin™ in IIH .
Designed based on substantial data analysis from previous IIH trials, extensive expert clinical and regulatory input, patient outreach, as well as scientific / protocol advice received from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA)

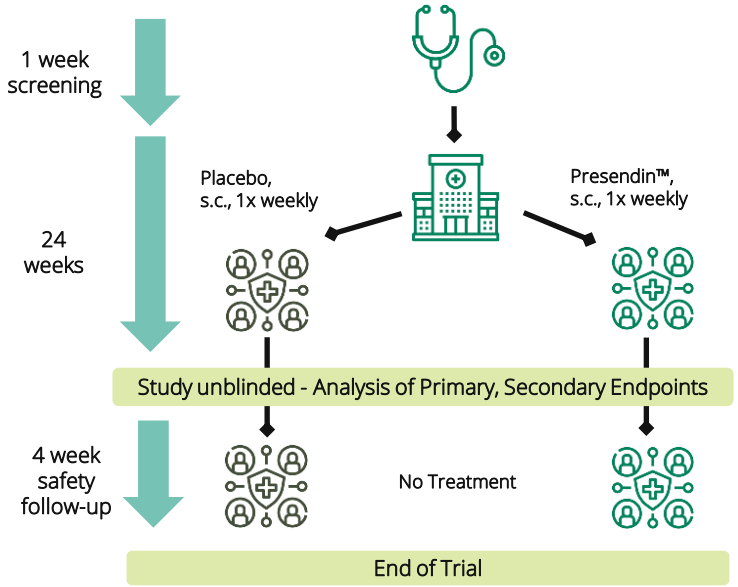
- Randomised double-blinded, placebo controlled, multi-centre clinical trial to determine efficacy and safety of Presendin™ in IIH
  - ~37 centres planned to participate across Europe, the UK, the US and Australia
    - Investigational New Drug Application (IND) to be filed in the US
  - 240 patients with IIH to be randomised 1:1 versus placebo
  - Patients self-medicate with either a once weekly PLGA formulation of Exenatide (Presendin™) or placebo
  - Appointment of Key Trial Committees and Overall International Lead Investigator to be announced shortly
  - Recruitment anticipated to take up to 24 months
- Designed to meet the regulatory requirements for market approval of Presendin™ in the EU, UK and Australia
- Based on the Company's analysis of proprietary clinical data in IIH, the endpoints in IIH EVOLVE trial have sufficient statistical power to meet the primary outcome of Intracranial Pressure (ICP) along with the secondary endpoints of Perimetric Mean Deviation (PMD), papilloedema and Monthly Headache Days (MHD)
- Fully funded from Invex's existing cash on hand

IIH EVOLVE

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

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, PK and general lab measures
Quality of Life	Patient reported outcomes (SF-36, ED-5D-5L, VFQ-25), monthly patient diary

Phase III Schematic



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

Key Inclusion Criteria

- ≥ 18 years of age, recently diagnosed IIH (females + males)
- Lumbar pressure > 25cm H_2O at baseline / bilateral papilloedema
- PMD with vision loss between -2 to -7 decibels (dB)
- ≥3 headache days per week over one week measurement period

Global Reach, Expert Participation

- ~37 centres across Europe, UK, US and Australia
- Initial feasibility assessment positively endorsed trial plans
- Globally recognised IIH experts & centres targeted for recruitment
- Lead International Investigator appointment in the near term

Key Exclusion Criteria

- Brain-associated venous blood clots by MRI/CT venogram scans
- Previous neurosurgical / bariatric or ophthalmic IIH surgeries
- Able to reliably perform the visual tests
- Past ophthalmic history that may affect interpretation
- Taken or received GLP-1 agonists
- Treatments to lower ICP within 1 week prior to screening

Statistical Considerations

- Sufficient statistical power to detect a change from baseline over 24 weeks for primary and secondary endpoints
- Minimal clinically important change (MCIC) changes sought for:
  - ICP @ 24 weeks
  - PMD @ 24 weeks
  - Papilloedema @ 24 weeks
  - MHD @ 24 weeks

IIH EVOLVE Endpoint Assessment

Why ICP is Important

- A reduction in ICP is a requirement for approval by EMA
- Pure physical measurement
- Direct measurement of the mechanism of action of Presendin™
- Key diagnostic criteria of IIH

Why MHD is important

- >90% of IIH patients suffer from chronic headaches
- MHDs accepted clinically relevant endpoint by all regulators
- Headache has a detrimental effect on patient quality of life
- Headache management is an unmet need in IIH

Why PMD is Important

- Clinically meaningful measure used in prior IIH interventional trials as a primary endpoint
- Accepted clinically relevant endpoint by all regulators
  - PMD MCIC in IIH established by the Neuro-Ophthalmology Research Disease Investigator Consortium and the IIH Treatment Trial (IIHTT)
- Vision loss is the primary concern of all IIH clinicians

Why Papilloedema is important

- Measuring papilloedema is a vital measure clinically
- Key diagnostic criteria of IIH
- Change in papilloedema has been used by all randomised control trials in IIH to date to determine clinical improvement
- Measurement by OCT accepted in clinical practice and routinely used to monitor IIH patients all over the world – fast, objective

IIH EVOLVE

Summary

- Phase III trial designed to achieve approval of Presendin™ in IIH in the EU, UK and Australia
- Designed with significant input from IIH clinicians, regulatory experts and IIH patients as well as informed by analysis of published and proprietary clinical data from previous clinical studies in IIH
- Selection of the primary and key secondary endpoints based on scientific advice from EMA, determined as the lowest risk pathway to potential market approvals relative to an integrated EMA/FDA trial design
- Study powering and endpoint ranking based on detailed external analysis and evaluation of published and proprietary IIH clinical data
- If successful, Presendin™ would be first pharmaceutical intervention shown to be safe and effective in IIH in a large, prospective randomised clinical trial
- If approved, Presendin™ will become the first and only approved drug for IIH on the market in the UK, Europe and Australia
- Potential for rapid incorporation of Presendin™ into IIH treatment guidelines
- UK/EU market represents a A$1 billion annual opportunity, growing 3.4% per annum
- IIH EVOLVE includes an economic evaluation to facilitate the health technology assessment (HTA) process – advantages with an orphan designation

Regulatory

Dr Jason Loveridge
Chairman

Regulatory

The Invex Phase III IIH EVOLVE clinical trial for Presendin™ is intended to support a European Medicines Agency (EMA), Medicines & Healthcare products Regulatory Agency (MHRA) and Therapeutic Goods Administration (TGA) approval for the treatment of IIH

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicines & Healthcare products Regulatory Agency

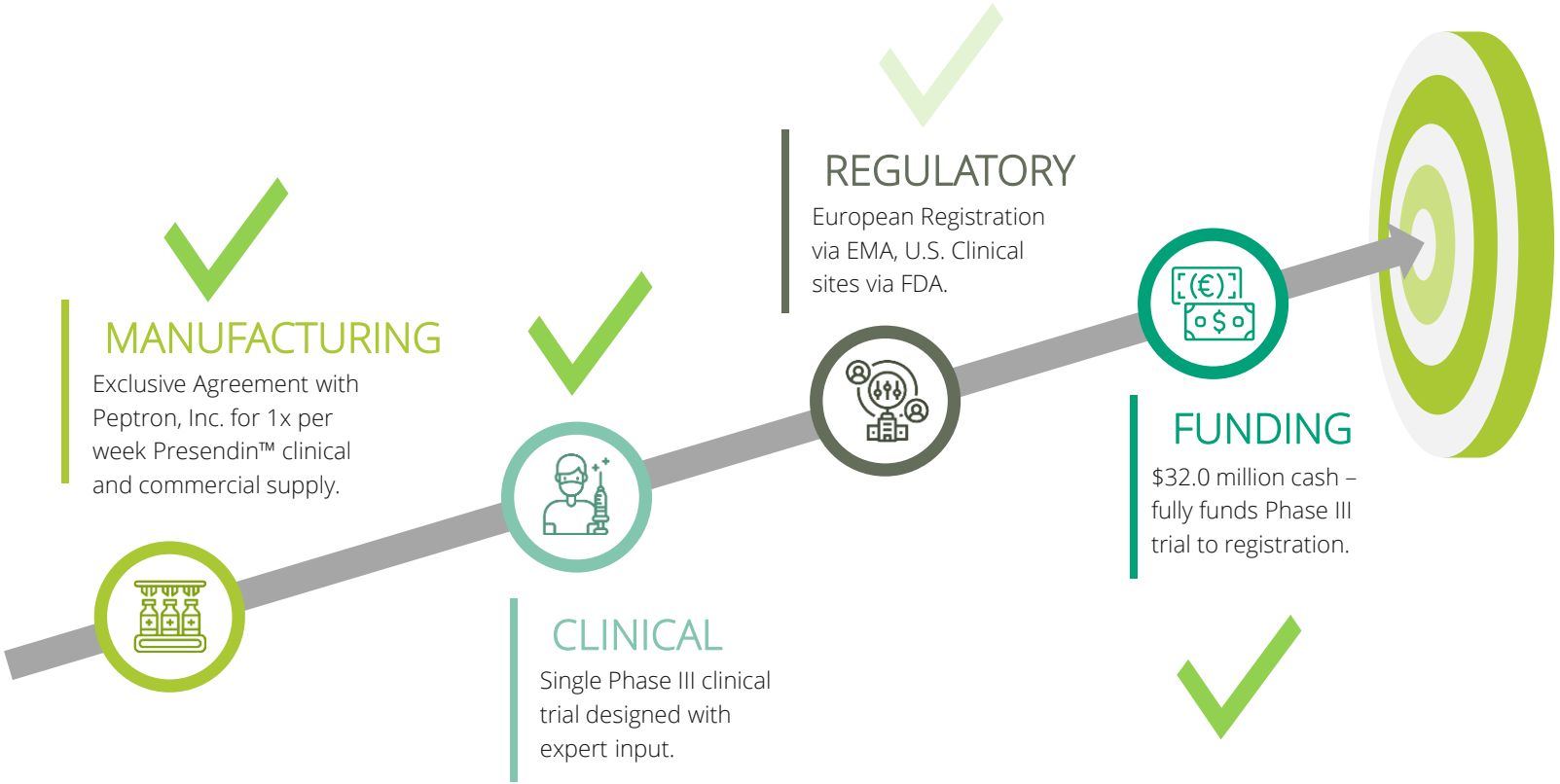
Australian Government
Department of Health
Therapeutic Goods Administration

- Strategy of seeking EU, UK and Australian market approvals ahead of the US based on a detailed risked based assessment following scientific advice and protocol assistance from both EMA and FDA
  - Informed by a detailed review of both published and proprietary IIH clinical data
- Selected approach is the lowest risk pathway
  - Global Phase III trial design difficult to achieve due to challenges in getting equivalence between the different regulatory agencies on endpoints and the definition of minimal clinical important change (MCIC)

- Outcomes from IIH EVOLVE will facilitate future discussions with the US FDA regarding registration of Presendin™ in the United States

FDA

Critical Pathways for Success



Funding

Dr Tom Duthy
Executive Director

Funding

- $26 million capital raise completed in May 2020
- Cash as at 30 September 2021: $32 million
- Corporate overheads remain low: 9 months YTD total cash outflows of $1.6 million with average quarterly cash burn of $0.5 million
- Phase III trial fully costed and to be funded from existing cash reserves
- Cash runway sufficient to complete Phase III & market approvals (subject to clinical success)
- Cash burn to increase in coming periods as Phase III commences and contracts executed
- No additional capital required to achieve these milestones

Summary & Outlook

- First clinical batches of Presendin™ from Peptron for IIH EVOLVE Phase III trial anticipated in Q4 CY2021
- Invex anticipates announcing the overall Lead International Investigator for the study and executing agreements with key service providers before the end of CY2021
- First CTA for IIH EVOLVE to be submitted in Q4 CY2021
- Single Phase III trial designed to support Presendin™ market approvals in the EU, UK and Australia
- Data generated from trial and inclusion of US sites will inform continued dialogue with FDA for future regulatory filings
- IIH EVOLVE fully funded from existing cash on hand ($32 million as at 30 September 2021)
- Potentially first-ever regulatory approved drug for IIH in any jurisdiction world-wide
- A $1 billion p.a. opportunity in the UK/EU and growing in-line with the obesity epidemic

Company Snapshot

Company	
Repurposed, Proven Drug	Presendin™ (SR-Exenatide)
Clinical Stage	Entering Phase III
Orphan Disease Focus	Idiopathic Intracranial Hypertension (IIH)
Orphan Designation Granted	USA + EU/UK
Total Addressable Market	$1.6 billion annually (US/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)	$0.49 million
Cash (30 Sep-21)	$32.0 million
Market Capitalisation (29 Oct-21) [1]	$49.3 million
Enterprise Value (29 Oct-21)	$17.3 million

[1]Based on a closing price of $0.655

Major Shareholders (as at 18 October 2021)	
Directors / Management	16.8%
Tattarang	11.8%
Tisia Nominees Pty Ltd	5.3%
Anthony Grist	4.0%
JK Nominees Pty Ltd	4.0%
University of Birmingham	2.7%
Top 20 Shareholders	59.4%

Board of Directors	
Dr Jason Loveridge	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

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Thank you

Q&A

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