Invex Therapeutics

Bell Potter Healthcare Conference

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invex THERAPEUTICS

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Company Snapshot

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

Capital	
Shares on Issue	**75.2 million**
Unlisted Options	**3.9 million**
Cash (30 Sep-20)	**$33.9 million**
Market Capitalisation (11 Nov-20) [1]	**$63.9 million**
Enterprise Value (11 Nov-20)	**$30.0 million**

Major Shareholders	
Directors / Management	16.8%
Tattarang	11.8%
Tisia Nominees Pty Ltd	5.3%
JK Nominees Pty Ltd	5.0%
University of Birmingham	2.7%
Top 20 Shareholders	**63.8%**

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

[1] Based on closing price of $0.85

A clinician's perspective on Idiopathic Intracranial Hypertension (IIH)

Professor Alexandra J. Sinclair

MBChB, MRCP, PhD

- Institute of Metabolism and Systems Research
- Professor of Neurology, University of Birmingham
- Chief Scientific Officer & Executive Director Invex Therapeutics

Invex Therapeutics - Executive Summary

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

Attractive Market Dynamics

- IIH Total Addressable Market (TAM) in the US and Europe of **A$1.6 billion** per annum and growing at **3.4% per annum**
- 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 - clear statistical and clinical evidence of efficacy in primary and secondary endpoints demonstrating a strong and sustained drug effect in the IIH population
- No significant safety concerns over 12 weeks of treatment
- Plan to commence Phase III registration trial in 1H CY2021

Significant Barriers to Competition

- Orphan drug designation in US (7 years exclusivity) and Europe (10 years exclusivity)
- Issued and pending patents for use of Exenatide in IIH. Formulation patents filed Q1 2020

What is Idiopathic Intracranial Hypertension (IIH)?

The Disease[1]

- >90% of cases are overweight women of childbearing age, with no known cause (idiopathic): approx. 4.7 per 100,000
- >90% suffer headaches that are progressively more severe and frequent: major cause of morbidity
- Up to 25% suffer permanent vision loss due to elevated intracranial pressure (ICP) effect on optic nerve function

The Impact[2]

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

The Solution

- Prof. Alex Sinclair (Invex CSO & Exec. Director) first to demonstrate glucagon like peptide 1 (GLP-1) receptor agonists commonly used in diabetes treatment (Exenatide formulated as Byetta® or Bydureon®) act on the choroid plexus in the brain to lower cerebral spinal fluid secretion and as a consequence, ICP
- Exenatide - strong scientific basis for benefit, well defined mechanism of action, patents secured - re-purposing opportunity to improve safety & efficacy → Presendin™
- Invex Phase II study in IIH - first clear demonstration of safety & efficacy in IIH

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 Phase II trial – design & outcomes

Study Purpose

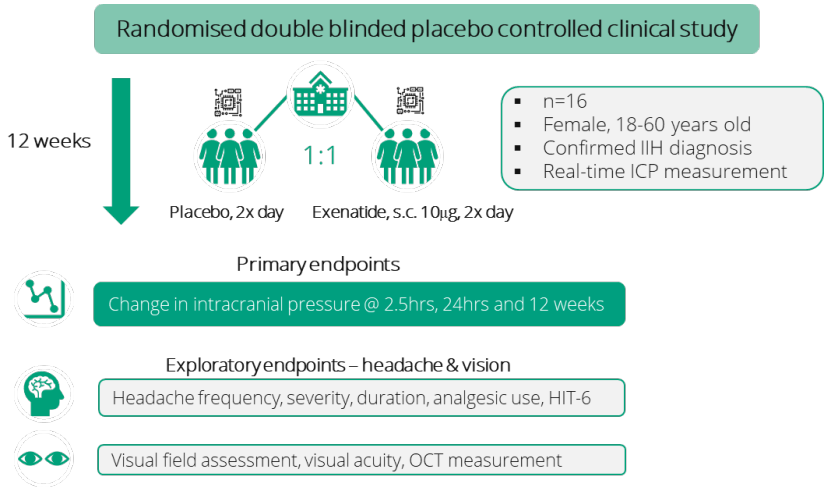
- Obtain first clinical proof of concept for Exenatide in IIH and provide a basis to move into pivotal Phase III trial by leveraging orphan drug status in Europe and the United States

Efficacy Outcomes

- **Primary Endpoint (reduction in ICP) Met** – 18-21% reduction across three time points; statistically significant and clinically meaningful
- **Secondary Endpoint (Headache) Met** – statistically significant & clinically meaningful reduction in headache days (7.7 days / 37% versus placebo)
- **Secondary Endpoint (Vision) Met** – statistically significant & clinically meaningful improvement in visual acuity (0.1 logMAR improvement at 12 weeks, equivalent to one line of visual acuity)

Safety Results

- No serious adverse events (SAEs) were observed related to the use of Exenatide
- Overall, adverse events were relatively low, with nausea the most common seen in >85% of patients treated with Exenatide
- Nausea is a known and the most frequent AE of sub-cutaneous administration of this formulation of Exenatide (Byetta®)



Conclusion

- **Strength of the outcomes for both primary & key secondary clinical endpoints from the Phase II study implies a clear & strong drug effect in the IIH population & supports progression to a Phase III clinical trial for registration in the USA and Europe.**

Regulatory update

Strength of the outcomes for both primary & key secondary clinical endpoints from the Phase II study implies a clear & strong drug effect in the IIH population & supports progression to a Phase III clinical trial for registration in the USA and Europe

European Medicines Agency (EMA)

July 2020: First Response to Protocol Assistance

- One well controlled study providing compelling evidence of safety and efficacy required for marketing authorisation application (MAA) in EU
- CHMP[1] recommended ICP as primary endpoint versus placebo
- Noted headache would also be a clinically meaningful endpoint
- Broad acceptability of Invex's pre-clinical package and human PK study plans

October 2020: Second Protocol Assistance Request

- Follow up submission for advice lodged in October 2020
- Ascertain acceptability of headache based primary endpoint for Phase III trial
- Following feedback in late Q4 CY2020, Invex intends to submit a Clinical Trial Application (CTA) within select European countries in 1H CY2021
- Single pivotal clinical trial for registration of Presendin™ in EU expected to commence thereafter

US Food and Drug Administration (FDA)

July 2020: First Response to Protocol Assistance

- Initial submission asked for advice on either headache or vision as the preferred primary endpoint – reviewed by Division of Ophthalmology
- Requested a complete protocol and statistical analysis plan prior to detailed scientific advice
- Reduction in headache days of moderate to severe headaches a clinically meaningful endpoint
- Broad acceptability of Invex's pre-clinical package

Q1 2021: Pre-IND Meeting

- Detailed protocol assistance to be sought post-response from CHMP
- Although outside Invex's control, with headache-based endpoint, it is logical to expect a pre-IND / type B meeting with Division of Neurology
- Pre-IND meeting expected Q1 CY2021

CHMP[1] – Committee for Medicinal Products for Human Use

Summary & Outlook

- Large, growing market for IIH with no approved medical interventions
- **Orphan Drug Designation in the USA and EU** provides expedited, cost-effective clinical trial recruitment, reporting and approval/registration as well as commercial exclusivity for up to 10 years
- Strong Phase II clinical data established
- **Financial:**
  - **$33.9M** in cash following capital raise in Q2 CY2020 – expected to fully fund completion of a Phase III clinical trial in IIH
  - Very attractive **$30.0M** Enterprise Value (EV) considering stage of development and market attributes
  - Large EV discount to ASX-listed orphan (ASX:CUV, ASX:NEU, ASX:RAC), ophthalmic (ASX:OPT) and re-purposing (ASX:PAR) companies
- **12 Month Milestones:**
  - Response from EMA expected late Q4 CY2020
  - Final Formulation Q4 CY2020
  - Appointment of contract manufacturer Q4 CY2020
  - Pre-IND Submission / Type B Meeting with FDA expected Q1 CY2021
  - Subject to availability of GMP Presendin™
    - Human PK study to commence 1H CY2021
    - Animal tolerability study to commence 1H CY2021
    - Filing of a CTA in Europe for Phase III clinical trial 1H CY2021

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Thank you

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