

## **Incannex to develop IHL-216A formulation for use in pivotal clinical trials required for product registration**

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it has engaged Vectura Limited ('Vectura') to develop the specific formulation for IHL-216A required for clinical trials. IHL-216A is Incannex's proprietary inhaled drug for the treatment of traumatic brain injury ('TBI').

Vectura is a state-of-the-art contract development and manufacturing organisation (CDMO) that specialises in the development and manufacture of inhaled drugs and their associated delivery products. Vectura has contributed to the formulation and development of 13 successful inhaled medical products with partners and licensees that include Sandoz, Novartis and Bayer. In total, these products have cumulatively generated US\$11 billion in sales and have been used by 10 million patients since their launch and up until 2020<sup>1</sup>.

As part of the assignment, Vectura will:

- perform formulation screening studies,
- undertake manufacturing process optimisation studies,
- perform a stability assessment on the lead formulation, and
- manufacture a lab scale batch of IHL-216A in support of toxicology studies.

Vectura is also able to provide support services to navigate the regulatory process that involves the approval of both IHL-216A and its inhalation delivery mechanism.

Incannex previously announced on the 11<sup>th</sup> of March 2021 that it had partnered with the Monash Trauma Group at the Department of Neuroscience, Monash University to conduct a second and more-extensive *in vivo* study on the protective effect of IHL-216A in sports concussion. The model of TBI being used in this study was developed in collaboration with the US National Football League (NFL) and is a precursor to pivotal in-human trials required for drug registration, negating the need to complete an in-human proof-of-concept study, saving time and expense to the development program.

Appointing Vectura to develop the IHL-216A formulation in parallel with the *in vivo* study will ensure that Incannex is readied with the specific formulation and delivery mechanism required for advancement of pivotal clinical trials once the *in vivo* study is finalised.

### **About IHL-216A**

IHL-216A is a combination drug that combines CBD with any volatile anaesthetic agent, including isoflurane. IHL-216A has been designed to be administered soon after head trauma to reduce secondary brain injuries that lead to neurological deficits. Due to the product's potential therapeutic utility in contact sports, IHL-216A is designed to satisfy the World Anti-doping Authority (WADA) and Australian Anti-Doping Authority's

(ASADA) specifications for use by athletes at risk of TBI and Chronic Traumatic Encephalopathy, otherwise known as CTE.

CBD and isoflurane, when combined to create IHL-216A, have previously been found by Incannex to act synergistically to reduce neuronal damage, neuroinflammation and behavioural deficits that are consequences of TBI. In experiments, IHL-216A outperformed CBD at reducing neuronal damage in post-mortem Nissl staining analysis of brain tissue by 53% for CA1 and 60% for CA2 in the hippocampal region of the brain. IHL-216A reduced the Iba1 neuroinflammation marker by 35% more than CBD alone and 123% more than isoflurane administered alone.

An International Patent Application entitled “Compositions and methods for the treatment or prevention of traumatic brain injury” has been filed as part of the IHL-216A development program. The International Search Report and Opinion of the International Searching Authority has also been received by IHL. Pleasingly, the International Examiner considers that claims directed to IHL-216A and methods for the treatment of TBI using IHL-216A are novel, inventive and meet the requirements for industrial applicability.

#### **About Traumatic Brain Injury and Concussion**

TBI accounts for approximately 10 million deaths and/or hospitalizations annually in the world (Schuman et al., 2017). There are currently no registered pharmaceutical agents approved for the treatment of TBI. Current treatment of major TBI is primarily managed through surgical intervention by decompressive craniotomy (Bullock et al., 2006), which involves the removal of skull segments to reduce intracranial pressure.

#### **ENDS**

The release of this announcement has been approved for issue by IHL’s Board of Directors. For further details on the announcement, interested parties should contact:

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### **About Incannex Healthcare Limited (ASX: IHL)**

Incannex Healthcare Limited (IHL.ASX) is a clinical stage pharmaceutical development company developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of Generalised Anxiety Disorder (GAD), Obstructive Sleep Apnoea (OSA), Traumatic Brain Injury (TBI)/Concussion and Acute Respiratory Distress Syndrome (ARDS). FDA registration, subject to ongoing clinical success, is being pursued for each product and therapy under development.

Each indication represents major global markets and currently have no, or limited, existing registered pharmacotherapy (drug) treatments available to the public, raising the possibility of patients receiving Government subsidies for products that demonstrate suitable safety and efficacy profiles in clinical trials.

IHL has a strong patent filing strategy (as announced "IHL files cannabinoid patent over IHL-216A for TBI" 04th October 2019 and "IHL Files Patent over IHL-42X for OSA" 06th of December 2019) as it develops its products and therapies in conjunction with its medical advisory board.

Further to its clinical programs, Incannex has its Australian license to import, export and distribute medicinal cannabis products and has launched a line of cannabinoid oil products. The cannabis-based oils are sold under Incannex's product supply and distribution agreement with Cannvalate Pty Ltd, which is the largest network of cannabis medicine prescribers in Australia and a major shareholder of Incannex.

**Website:** [www.incannex.com.au](http://www.incannex.com.au)

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### **References:**

<sup>1</sup><https://www.vectura.com/about-vectura/track-record/>