

Incannex Completes Dosing Patients in Phase 2 Proof-of-Concept Trial of IHL-42X for the Treatment of Obstructive Sleep Apnoea

Commences Preparation for FDA Pre-IND meeting

Melbourne, Australia, December 20, 2021 – **Incannex Healthcare Limited (ASX:IHL)**, (“Incannex” or the ‘Company’) a clinical stage pharmaceutical company developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for unmet medical needs, today announced that it has completed dosing of participants in the phase 2, proof-of-concept clinical trial investigating novel cannabinoid combination product, IHL-42X, for the treatment of obstructive sleep apnoea (“OSA”). The Company also announced that it has commenced preparation of a pre-Investigational New Drug (IND) meeting package and is targeting a pre-IND meeting with the U.S. Food and Drug Administration (FDA) in Q1 2022.

The clinical trial assessed three doses of IHL-42X at reducing the apnoea hypopnoea index (“AHI”), the main diagnostic criteria for OSA, compared to placebo in patients who suffered from the disease. The study was conducted at the University of Western Australia Centre for Sleep Science and The Alfred Hospital. Trial participants received each of the three doses of IHL-42X and placebo across four seven-day treatment periods, separated by one week washout periods. At the end of each treatment period, they attended the clinic for an overnight sleep study where AHI was determined, along with other measures of sleep quality, quality of life and drug safety.

All participants in the phase 2 trial have now completed the treatment periods and the data is being analyzed by Novotech, the contract research organization engaged by Incannex to manage the study and resulting data. Delivery of the final clinical study report is anticipated in Q1 2022.

“Dosing of the last patient in our phase 2 trial of IHL-42X as a potential treatment for OSA marks an important inflection point for Incannex as we continue to advance our pipeline of cannabinoid pharmaceutical product through the clinic,” stated Joel Latham, Managing Director and Chief Executive Officer of Incannex. “OSA remains a significantly unmet medical need and can lead to a variety of cardiovascular complications, with no FDA approved pharmacotherapies. We believe that novel cannabinoid combination IHL-42X can potentially offer meaningful benefit to this large patient population.”

Mr. Latham continued, “Based on the results of a confidential interim analysis of the data from this trial performed in July, we submitted a patent application regarding the methods for the treatments of OSA. The key claims in the application were deemed novel and inventive by the International Search Report and Opinion, thus strengthening our intellectual property around IHL-42X.”

"Our preparation for a pre-IND meeting with the FDA demonstrates our commitment to advancing IHL-42X into a larger, pivotal phase 2 clinical trial under an IND application. We expect the pre-IND meeting to occur in the first quarter of 2022," concluded Mr. Latham.

About Obstructive Sleep Apnoea

OSA is the most common sleep-related breathing disorder, and it causes people to repeatedly stop and start breathing for elongated intervals during sleep. It is a major public health problem and IHL-42X represents a significant commercial opportunity for Incannex as there are no approved pharmacotherapy treatments at the present time.

OSA is a serious medical condition that increases the risk of numerous health complications¹. Drops in blood oxygen levels that occur during OSA increase blood pressure and strain the cardiovascular system. Many people with OSA develop high blood pressure (hypertension), which can increase the risk of heart disease. The more severe the OSA, the greater the risk of coronary artery disease, heart attacks, heart failure and strokes.

People with OSA often have severe daytime drowsiness, fatigue, and irritability due to lack of restorative sleep at night, which are observed causes of workplace accidents. Those diagnosed with OSA are also at higher risk of memory problems, headaches, mood swings and depression.

The current standard of care is a continuous positive airway pressure (CPAP) machine, however, patient compliance to CPAP is low due to discomfort and claustrophobia resulting from pressurized air being pumped into the mouth during sleep. Incannex anticipates greatly improved treatment compliance and outcomes from a pharmaceutical product, which could be IHL-42X should it prove successful in ongoing clinical assessments. Regardless of the discomfort caused by CPAP, the global annual market for OSA detection and treatment using CPAP and other breathing aids is approximately USD 10 billion per annum and growing².

OSA is highly prevalent, affecting approximately 30 million adults in the United States alone. It is estimated that the annual economic burden of undiagnosed sleep apnoea among U.S. adults is approximately USD 149.6 billion per annum. These costs include USD 86.9 billion in lost productivity, USD 26.2 billion in motor vehicle accidents and USD 6.5 billion in workplace accidents³.

¹<https://www.mayoclinic.org/diseases-conditions/obstructive-sleep-apnea/symptoms-causes/syc-20352090>

²<https://www.fortunebusinessinsights.com/industry-reports/sleep-apnea-devices-market-100708>

³<https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf>

ENDS



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ASX Announcement (ASX: IHL)

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 company that is 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, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis and inflammatory bowel disease. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug 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.

IHL has a strong patent filing strategy in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners. For more information visit www.incannex.com.au.

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