Date: 21st December 2020
ASX Announcement (ASX: IHL)

First patients recruited into IHL-42X phase 2 obstructive sleep apnoea clinical trial

Highlights:

- Incannex has recruited first patients to its phase 2b clinical trial to assess the safety and efficacy of IHL-42X in the treatment of obstructive sleep apnoea ('OSA')
- Patient recruitment follows the receipt of Human Research and Ethic Committee ('HREC') approval to commence the trial
- The primary endpoint is the reduction in Apnoea Hypopnea Index ('AHI'), compared to baseline, or pre-treatment, levels
- The trial is being performed at the Alfred Hospital under the supervision of experienced principal investigator Professor Terry O'Brien
- There is no existing registered pharmacotherapy (drug) treatment option for sufferers of OSA
- OSA is a highly prevalent condition with limited tolerable treatment options: affecting approximately 30M people and having a total economic burden of US$149.6 billion per annum in the USA alone.

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce the recruitment of the first patients to its IHL-42X phase 2b OSA clinical trial. Patient recruitment follows the receipt of HREC approval from the Alfred Health Ethics Committee who assessed and approved the ethical design of the trial.

The randomised, double-blind, placebo-controlled dose-ranging phase 2b clinical trial will assess the therapeutic benefit of IHL-42X at three different dose levels. The primary endpoint is the reduction in Apnoea Hypopnea Index ('AHI'), compared to baseline, or pre-treatment, levels. Participants will also be monitored for improvements in secondary endpoints, including a reduction in the oxygen desaturation index, daytime somnolence, mood, and quality of life.

OSA and epilepsy – secondary endpoint investigation

OSA is more prevalent in patients with epilepsy than the general population and poor sleep quality has been linked to higher seizure frequency. Professor O'Brien is an expert in epilepsy and has an active research interest in sleep disordered breathing in patients with epilepsy. His access to patients with comorbid epilepsy and OSA that may be enrolled in this trial will allow IHL to assess whether the improvement in AHI from IHL-42X also reduces seizure frequency in this cohort.

The trial is being performed at the Alfred Hospital under the supervision of experienced principal investigator Professor Terry O'Brien. It is classified as a cross over study, which means that all participants will receive three doses, plus a placebo. The study will be broken up into four treatment periods, each at a different dose level. The treatment periods will be separated by washout periods to allow the drugs to clear from the system.

On the final night of each treatment period, subjects will visit the sleep clinic at the Alfred Hospital to have their sleep assessed using overnight polysomnography, where AHI will be determined. During these clinic visits, surveys will be completed to monitor secondary endpoints (and blood samples collected to monitor the safety of IHL-42X).

Major market opportunity – obstructive sleep apnoea

Incannex considers that a positive result in the trial would be a major valuation inflection point for the Company. OSA is a lethal disease that increases the risk of numerous health complications, not least an increased risk of cardiovascular morbidity. 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 attack, heart failure and stroke.

The main current treatment option is the mechanical Continuous Positive Airway Pressure device ('CPAP'), however, patient compliance to CPAP is low due to discomfort and claustrophobia resulting from pressurised air being pumped into the patient's mouth during sleep. Regardless of this intrusive and uncomfortable mechanical treatment option, the global annual market for OSA detection and treatment using CPAP is over US$10B per annum and growing.

OSA is a highly prevalent disease affecting approximately 30M adults in the USA alone. It is calculated that the annual economic burden of undiagnosed sleep apnoea among U.S. adults is approximately US$149.6 billion per annum. The estimated costs include $86.9 billion in lost productivity, $26.2 billion in motor vehicle accidents and $6.5 billion in workplace accidents[1]. Even in Australia, Deloitte Access Economics has estimated that the direct economic costs due to OSA were more than A$21B per annum. This estimation was made by assessing loss of workdays and morbidity caused by OSA through cardiovascular problems, depression, motor vehicle accidents, workplace accidents and type 2 diabetes.

There is no existing registered pharmacotherapy (drug) treatment option for sufferers of OSA. Incannex anticipates greatly improved patient treatment compliance and outcomes from a pharmaceutical product, which could be IHL-42X should it prove successful under clinical assessment.

CEO and Managing Director of Incannex Healthcare, Mr Joel Latham said; "the entire team at Incannex is excited to have commenced screening for, and formally recruited its first patients to its first ever in-human trial. Sleep apnoea is a dangerous condition, which has wide-ranging effects on sufferers, and current treatment options are impractical for many. A successful pharmaceutical solution to would be revolutionary to patients with this condition and we look forward to providing updates on the clinical program as we undertake patient dosing of our unique IHL-42X formulation".

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

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References:

[1]https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf