Date: 24th September 2020
ASX Announcement (ASX: IHL)

Ethics Approval Received for Phase 2b Clinical Trial for Obstructive Sleep Apnoea

Highlights:

- Ethics approval received for Phase 2b clinical trial to investigate IHL-42X oral pharmaceutical in subjects with Obstructive Sleep Apnoea ('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
- The trial will be performed at the Alfred Hospital in Melbourne under the supervision of experienced principal investigator Professor Terry O'Brien
- The primary endpoint in the trial will be reduction in Apnoea Hypopnea Index ('AHI'), compared to baseline, or pre-treatment, levels.

Clinical stage cannabinoid development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce it has received ethics approval for its Phase 2b clinical trial to investigate IHL-42X in subjects with OSA.

The randomised, double-blind, placebo-controlled dose ranging Phase 2b clinical trial will treat patients with OSA to assess the therapeutic benefit of IHL-42X at three different dose levels. The primary endpoint in the trial will be reduction in Apnoea Hypopnea Index ('AHI'), compared to baseline, or pre-treatment, levels. Participants will also be monitored for improvements in alertness, daytime sleepiness, mood, and quality of life. A positive result in the trial would be a major valuation inflection point for Incannex.

The study will be performed at the Alfred Hospital under the supervision of experienced principal investigator Professor Terry O'Brien with support from Novotech, an experienced contract research organisation.

Patient recruitment is expected to commence in the near future, at which point IHL intends to inform ASX. The clinical trial is also classified as a cross over study, which means that all participants will receive three different doses, plus a placebo. The study will be broken up into four one-week treatment periods, each at a different dose level. The treatment periods will be separated by one-week 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. This is 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.

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.

Major market opportunity with limited current treatment options

OSA is a major public health problem and represents a significant market opportunity for Incannex. It 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 CPAP device, however, patient compliance to CPAP devices 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 devices is over US$10B per annum and growing.

OSA is a highly prevalent disease affecting approximately 30M adults in the USA. It is calculated that the annual economic burden of undiagnosed sleep apnoea among U.S. adults is approximately $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 $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 receipt of ethics approval to commence our first in-human clinical trial is a significant milestone for Incannex.

A successful drug treatment would be a paradigm shift in obstructive sleep apnoea considering low patient compliance to the current standard of care, the CPAP device. It is an important step in the right direction for patients that, for various reasons, cannot tolerate the cumbersome, mechanical CPAP device.

Accomplishing this goal with highly credentialed partners, including the Alfred Hospital, speaks to scientific rigour of this project and the dedication of Incannex's research team as we continue to build upon our clinical and commercial potential".

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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References:

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

About Incannex Healthcare Limited (ASX: IHL)

Incannex Healthcare Limited (IHL.ASX) is developing unique medicinal cannabis products for the treatment of Obstructive Sleep Apnoea (OSA), Traumatic Brain Injury (TBI)/Concussion, Acute Respiratory Distress Syndrome (ARDS) and Temporomandibular Joint Disorder (TMD). FDA registration, where being sought, is subject to clinical success.

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

There is an established body of research validating the hypothesis for the cannabinoids being used in Incannex's chosen therapeutic areas and 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 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 IHL.

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