

Incannex partners with the UWA Centre for Sleep Science to uprate the IHL-42X clinical trial to a multi-site study

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is delighted to announce that the University of Western Australia Centre for Sleep Science ('UWA', 'Centre for Sleep Science' or 'CSS') has been engaged as an additional site for the ongoing phase 2b dose-finding crossover trial investigating the effect of IHL-42X on the Apnoea Hypopnea Index ('AHI') in adults diagnosed with Obstructive Sleep Apnoea ('OSA').

Patient recruitment at UWA will run in parallel with The Alfred Hospital in Melbourne where the trial is currently underway with initial results from trial participants collected but not yet available for assessment due to blinding. The trial is now considered a multi-site study with additional medical, and scientific staff contributing to the conduct of the trial.

CEO and Managing Director of Incannex Healthcare, Mr Joel Latham, said; "We have been impressed with the academic credentials of the team at UWA CSS and their enthusiasm for the potential of IHL-42X as a treatment for OSA. UWA CSS are also the only academic institution in Australia that has experience in conducting research on cannabinoids and sleep disorders.

Our partnership with UWA, also puts us in good stead for the next steps in the IHL-42X development program because pivotal studies necessary for FDA registration will require multi-site patient examinations".

Centre for Sleep Science, the UWA and Dr Jen Walsh

Four in 10 Australian adults experience regular poor sleep, the consequences of which can have significant impacts on health, performance, and society. The Centre for Sleep Science at the University of Western Australia is a world-class facility at the forefront of sleep research and sleep education. The Centre for Sleep Science boasts five bedrooms dedicated to research and teaching, all of which are equipped with state-of-the-art sleep recording and analysis systems. Research conducted at the Centre for Sleep Science broadly aims to identify the causes of, and investigate novel therapies for, both respiratory and non-respiratory sleep disorders. The results of this research are regularly published in international medical journals and the multidisciplinary research team often present their work at national and international meetings. In affiliation with the University of Western Australia, the Centre for Sleep Science also offer online training courses aimed at introducing people to the field of sleep science or further educating professionals already working in relevant fields. This combined focus on clinical research and education ensures that the Centre for Sleep Science works towards its vision of providing evidence-based education and conducting quality, clinically relevant research which will ultimately improve sleep health in the community.

Dr Jen Walsh is the Director of the Centre for Sleep Science at the UWA and also leads the sleep physiology research team at the West Australian Sleep Disorders Research Institute ('WASDRI') at Sir Charles Gairdner Hospital. She is Principal Investigator on over 10 projects currently running at CSS and WASDRI. Dr Walsh and the CSS team collaborate with many colleagues including engineers, anaesthetists, physiologists, and psychologists who are nationally and internationally recognised leaders in their field. Dr Walsh and the team also collaborate with many industry partners to investigate the effects of novel devices and pharmaceuticals for the treatment of obstructive sleep apnoea and/or insomnia.

Dr Jen Walsh said; "Given the number of people with OSA and the proportion unable to tolerate existing therapies, it is exciting to be working with Incannex on this trial of an alternate treatment option. Even patients who can tolerate existing therapies for their OSA would sometimes like the option to take a medication rather than sleep with a device"

Clinical Trial Design and Endpoints

IHL received ethics approval for its Phase 2b clinical trial to investigate IHL-42X in subjects with OSA in September 2020. The randomised, double-blind, placebo-controlled dose ranging Phase 2b clinical trial is underway treating patients with OSA to assess the therapeutic benefit of IHL-42X at three different dose levels. The primary endpoint in the trial is the reduction in AHI, compared to baseline, or pre-treatment, levels. Participants are also monitored for improvements in alertness, daytime sleepiness, mood, and quality of life.

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 nose and/or 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 condition 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 accidents¹.

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 people with 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.

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:

Mr Joel Latham, Managing Director and Chief Executive Officer

P: +61 409 840 786

E: joel@incannex.com.au

References:

¹ <https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf>



Date: 11th May 2021
ASX Announcement (ASX: IHL)

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

Investors: investors@incannex.com.au