Date: 22nd July 2021
ASX Announcement (ASX: IHL)

Incannex files international patent application over IHL-42X and receives ethic's approval to commence open label extension study

Clinical stage cannabinoid development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it has filed an International Patent Application entitled "Methods for the treatment of obstructive sleep apnoea" as part of the IHL-42X development program.

The application was filed pursuant to the Patent Cooperation Treaty (PCT), thus providing IHL with an opportunity to pursue patent protection in foreign jurisdictions, including the key markets of North America, the European Union, Japan and Australia, among others. Specifically, the patent application makes claim that the IHL-42X formulation of acetazolamide, a registered off-patent pharmaceutical, combined with tetrahydrocannabinol (THC) is a method for the treatment of obstructive sleep apnoea ('OSA').

Importantly, the filing of the patent application secures the filing date of the application and the claims within it. An interim analysis of the data from IHL's ongoing phase 2b double blind randomised placebo-controlled clinical trial was performed and these results have been included in the patent application to support the claims.

Patient dosing is continuing at the University of Western Australia Centre for Sleep Science so whilst interim clinical trial analysis was made available to file the patent application, that data remains confidential and not yet available for publishing to ensure that the trial remains blinded. Final results of the trial will be available once all subjects have completed treatment and the Clinical Study Report is finalised, which is anticipated to be in Q4 of 2021.

IHL-42X open label extension studies

Incannex is also pleased to announce that it has received ethic's approval to commence an open label extension to the phase 2b clinical trial. The open label extension study will recruit people who have experienced a benefit from IHL-42X in the phase 2b trial and will assess the therapeutic benefit and tolerability of IHL-42X in those patients over an extended timeframe.

The open label extension study will consist of 6 months of treatment with IHL-42X. The primary endpoint will be reduction in Apnoea Hypopnea Index ('AHI') compared to the patient's original, pre-treatment baseline measurement. AHI will be assessed during three overnight sleep studies at day 28, 64 and 168. The main goal of this study is to determine whether the reduction in AHI that was observed for these subjects in the phase 2b study is maintained over an extended period. Participants will also be monitored for improvements in alertness, daytime sleepiness, mood, and quality of life every 28 days. The safety of the IHL-42X will be

assessed through monitoring of vital signs, serum liver enzymes, blood cell counts and electrolyte levels at each clinic visit.

CEO and Managing Director of Incannex Healthcare, Mr Joel Latham said; "We are delighted to have received ethic's approval to proceed with our open label extension study. Patients who have finished their dosing regimens in the phase 2b trial are now eligible to use IHL-42X every day for an extended period and the data we gather from this program will be invaluable to our ongoing FDA development plan".

Obstructive sleep apnoea - major market opportunity with limited current treatment options

OSA is a major public health problem and represents a significant market opportunity for Incannex. OSA is characterised by a narrowing (obstruction) of the upper airway in sleep, interfering with breathing and interrupting sleep. This relatively common and chronic disorder is underdiagnosed and inadequately treated and is understood to contribute to a wide range of serious long-term outcomes, including cardiovascular disease, cognitive impairments such as memory loss, poor concentration and judgment, depression and death or injury due to traffic accidents resulting from excessive daytime sleepiness. The costs associated with OSA are substantial, relating to lost productivity, workplace, and motor vehicle accidents.

A 2019 article published by the Lancet premised on literature-based analysis of 17 studies across 16 countries, estimated that OSA affects some 936 million adults worldwide[1]. This alarming statistic is also thought to be increasing due to growing prevalence of obesity and an ageing global population. Many people with OSA develop high blood pressure (hypertension), which can increase the risk of cardiovascular disease. The more severe the OSA, the greater the risk of coronary artery disease, heart attack, heart failure and stroke.

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[2]. Even in Australia, Deloitte Access Economics has estimated that the direct economic costs due to OSA were more than $21B per annum[3]. 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 are no registered pharmacological solutions (drugs) for OSA. The standard treatment option is the mechanical continuous positive air pressure ('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. Despite these discomforts, the global annual market for OSA detection and treatment using CPAP devices is over US$10 billion and growing.

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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 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, raising the possibility of patients receiving Government subsidies for drugs that demonstrate suitable safety and efficacy profiles in clinical trials. IHL has a strong patent filing strategy as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners.

Website: www.incannex.com.au

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References:

[1]https://pubmed.ncbi.nlm.nih.gov/31300334/
[2]https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf
[3]https://www2.deloitte.com/au/en/pages/economics/articles/cost-effectiveness-continuous-positive-airway-pressure-sleep-apnoea.html