Date: 20th October 2021
ASX Announcement (ASX: IHL)

# Incannex engages Procaps to manufacture IHL-42X soft-gel capsules in preparation for pivotal clinical trials

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it has engaged Procaps S.A. ('Procaps') to develop and manufacture IHL-42X soft gel capsules, the Company's proprietary combination cannabinoid drug under development for the treatment of obstructive sleep apnoea ('OSA').

The soft gel capsules will be pharmaceutical-grade and used in pivotal phase 2, phase 3 and open label clinical trials. Procaps is also equipped to provide subsequent commercial manufacture at scale.

Development at Procaps is supported by its own robust intellectual property portfolio, providing access to a range of proprietary formulation and manufacturing technologies for the IHL-42X finished product, including but not limited to Procaps´ proprietary patented Unigel technology which consists of an apparatus and process for encapsulating capsules or other solid dosage form within capsules.

Procaps has extensive scientific expertise, having developed over 500 formulations for both pharmaceutical and nutritional products reaching over 50 markets globally. It is the largest integrated contract development and manufacturing company in Latin America and is ranked within the top three companies globally for soft gel manufacturing capacity.

Procaps' manufacturing plant has been inspected and approved for good manufacturing practices (GMP) by multiple regulatory agencies including FDA, TGA, Health Canada and MHRA. Procaps offers services to a diverse range of industry-leading customers, doing business with 12 out of the top 20 global multinational pharma companies, among many others.

The agreement between IHL and Procaps is effective immediately and will remain in place for as long as supply of IHL-42X soft gel capsules are required for clinical trial purposes. Twelve-month non-binding forecasts with four-month firm orders will be required for Procaps´ planning purposes. The expense associated with the development and manufacture of the IHL-42X supply is anticipated to be immaterial.

**CEO and Managing Director of Incannex Healthcare, Mr Joel Latham, said;** "Procaps is a sophisticated pharmaceutical company with extensive capabilities. Partnering with Procaps will help us formulate the best possible product for IHL-42X. Procaps will supply our clinical trial programs but can also quickly ramp up production for commercial supply upon successful clinical trial outcomes".

## IHL-42X development activities

Incannex is currently undertaking a proof-of-concept Phase 2 clinical trial to assess IHL-42X, which comprises a combination of dronabinol and acetazolamide. The primary endpoint of the trial is the reduction in the Apnea Hypopnea Index (AHI). Secondary endpoints include the reduction in Oxygen Desaturation Index

(ODI), reduction in daytime somnolence measured by the Epworth Sleepiness Scale (ESS) and improvement in mood as measured by Profile of Mood States (POMS) rating scale.

Patient dosing is expected to be completed in the December quarter of 2021 with results due in first quarter of 2022. These results will be used to support an investigational new drug (IND) application with the FDA and to inform the design of subsequent clinical trials. In July 2021, confidential interim analysis of the data from the clinical trial was performed and these results were used to support a patent application regarding the methods for the treatment of OSA.

Incannex has also commenced an open label extension to the phase 2 clinical trial. The open label extension study has recruited people who have experienced a benefit from IHL-42X in the phase 2 trial and will assess the therapeutic benefit and tolerability of IHL-42X in those patients over an extended timeframe of 6 months.

**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, inadequately treated, and is understood to contribute to a wide range of serious long-term outcomes. These outcomes include 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.

**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 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 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