

## **Review of IND Application for IHL-42X by US FDA has been completed; Clinical Trial for Patients with Obstructive Sleep Apnoea May Proceed**

Melbourne, Australia, August 22, 2023 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic assisted psychotherapies for unmet needs, is pleased to announce that it has received approval from the US Food and Drug Administration ('FDA') to conduct the Company's Investigational New Drug ('IND') opening pivotal IHL-42X Phase 2/3 clinical trial in the United States as planned.

Incannex submitted the IND application on 20 July 2023 and the FDA completed their review of the substantial application package during the allocated 30-day period. Incannex received communication that the FDA review was completed, and the IND-opening clinical trial is deemed safe to proceed following assessment of the trial protocol, lead trial investigators, and a risk benefit analysis of the trial and prospective product. The IND opening trial will assess the effect of IHL-42X in obstructive sleep apnoea patients who are non-compliant, intolerant, or naive to positive airway pressure treatment, such as that administered by CPAP devices.

Incannex will continue the start-up process for the Phase 2/3 clinical trial. This will include finalisation of institutional review board (IRB) applications and submissions for the lead clinical trial sites. Site selection, approvals and IRB submission for additional study sites will continue in parallel.

In the IND opening Phase 2/3 clinical trial, participants will receive one dose of IHL-42X, dronabinol, acetazolamide or placebo for the entirety of the trial. All participants will complete daily surveys on their sleep quality, attend monthly clinic visits to assess functional outcomes of sleep, cognitive function and other measures of safety and efficacy. Every three (3) months, overnight polysomnography will be conducted to determine the effect of treatment on the patients' Apnea Hypopnea Index (AHI) along with a range of other sleep parameters. All drug treatments will be compared to placebo.

**This announcement has been approved for release to ASX by the Incannex Board of Directors.**

**END**

### **About IHL-42X**

IHL-42X is a synergistic composition of dronabinol, a synthetic form of tetrahydrocannabinol (THC), and acetazolamide, a carbonic anhydrase inhibitor. Results from a Phase 2 proof of concept clinical trial undertaken by Incannex were released in 2022. Incannex observed that IHL-42X reduced average

apnoea-hypopnoea index ('AHI') by an average of 50.7% versus baseline assessments and 25% of participants experienced greater than an 80% reduction in the AHI. No serious treatment emergent adverse events were reported during the clinical trial. Furthermore, THC concentrations in blood were below the limits for impaired driving the morning after nocturnal dose administration of IHL-42X.

### **About Obstructive Sleep Apnoea ('OSA')**

OSA is the most common sleep-related breathing disorder. It involves the narrowing of the upper airway during sleep, interfering with a person's breathing, decreasing oxygen uptake, resulting in poor-quality sleep<sup>1</sup>. Untreated OSA leads to serious long-term adverse health outcomes including hypertension, cardiovascular disease, heart attack, cognitive impairments, anxiety and depression, irritability and daytime fatigue increasing the risk of accidents. There are no pharmacotherapy (drug) treatments available to those afflicted.

The current 'standard of care' is the Continuous Positive Airway Pressure ('CPAP') machine. However, patient compliance to CPAP is low due to various factors related to patient discomfort. Incannex anticipates greatly improved treatment compliance and outcomes from a pharmaceutical product, such as IHL-42X, subject to further clinical assessment and approval from regulators.

Regardless of the discomfort caused by CPAP, the global annual market for OSA detection and treatment using CPAP and other breathing aides is approximately US\$10 billion per annum and growing<sup>2</sup>. OSA is highly prevalent, affecting approximately 30 million adults in the United States alone. It is estimated that the annual economic burden of undiagnosed sleep apnoea among U.S. adults is approximately US\$149.6 billion per annum. These costs include US\$86.9 billion in lost productivity, US\$26.2 billion in motor vehicle accidents and US\$6.5 billion in workplace accidents<sup>3</sup>.

#### **References**

<sup>1</sup><https://www.mayoclinic.org/diseases-conditions/obstructive-sleep-apnea/symptoms-causes/syc-20352090>

<sup>2</sup><https://www.fortunebusinessinsights.com/industry-reports/sleep-apnea-devices-market-100708>

<sup>3</sup><https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf>

### **About Incannex Healthcare Limited**

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of obstructive sleep apnoea (OSA), traumatic brain injury (TBI) and concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis, inflammatory bowel disease, anxiety disorders, addiction disorders, and pain, among other indications.

U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication under investigation currently has no, or limited, existing registered pharmacotherapy (drug) treatments available to the public and represent major global economic opportunities to Incannex and its shareholders.



Date: August 22, 2023  
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex has a strong patent filing strategy in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners. The Company holds 20 granted patents and over 30 pending patent applications. Incannex is listed on the Australian Stock Exchange (ASX) with stock code "IHL" and has American Depository Shares listed on NASDAQ under code "IXHL".

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#### Forward-looking statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are made as of the date they were first issued and were based on current expectations and estimates, as well as the beliefs and assumptions of management. The forward-looking statements included in this press release represent Incannex's views as of the date of this press release. Incannex anticipates that subsequent events and developments may cause its views to change. Incannex undertakes no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Incannex's views as of any date after the date of this press release.

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