

Incannex Expands Intellectual Property Position over IHL-42X

Sydney, Australia, December 06, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic medicine therapies for unmet medical needs, is pleased to announce the filing of a provisional patent application directed to the use of IHL-42X for the treatment of Obstructive Sleep Apnoea ('OSA').

With this latest provisional patent application, Incannex intends to pursue additional patent protection for its IHL-42X clinical program, consistent with the Company's ongoing commercial strategy to accrue a patent position across the development, manufacture, and use of the Company's drug candidates.

IHL-42X was designed to combine two drugs, tetrahydrocannabinol ('THC' or 'dronabinol') and acetazolamide, with therapeutic effects on OSA that act via different mechanisms. Acetazolamide induces metabolic acidosis, raises the drive to breathe and reduces the sensitivity of body system that controls breathing, which helps to reduce the incidence and severity of apnoeas and hypopnoeas. Dronabinol is believed to activate muscles in the upper airway during sleep, thereby reducing incidence of airway collapse. Incannex previously discovered that the two drugs act synergistically to reduce the Apnea Hypopnea Index (AHI) in patients with OSA.

Incannex engaged Dr Brad Edwards, Associate Professor of Physiology at Monash University, to further assess the polysomnography data from the Company's Phase 2 proof-of-concept clinical trial that investigated the effect of IHL-42X on OSA.

Dr Edwards is an expert on mechanisms of OSA, having contributed to the development of a method to characterise the underlying causes (or endotypes) of OSA. Working in collaboration with the Phase 2 trial's principal investigator, Dr Jen Walsh and her team at the University of Western Australia, Dr Edwards and his team have characterised the effects of IHL-42X on the different endotypes of OSA.

IHL-42X was shown to have a dose dependent effect on loop gain. Low dose IHL-42X showed a statistically significant improvement in airway collapsibility. This validates why low dose IHL-42X was observed to be more effective than the medium or high doses.

The efficacy of low dose IHL-42X in the phase 2 proof of concept trial has been an ideal outcome for the Company. Low dose IHL-42X encompasses low doses of THC and acetazolamide such that the side effect profile was observed to be similar to that of the placebo arm. IHL-42X did not have a significant effect on the arousal threshold (propensity to wake up from sleep) at any dose.

These findings shed important light on the mechanism of action of IHL-42X. In particular, the relationship between OSA endotypes and response to IHL-42X is useful in identifying patients who will best respond to IHL-42X, as set out in the new provisional patent application.

CEO and Managing Director of Incannex Healthcare, Mr Joel Latham said; “Incannex works closely with its patent attorneys to build upon its competitive position through the ongoing development of intellectual property assets. Our intention is to build patent families around our drug candidates as we learn more about them through our research and development programs undertaken by our dedicated scientific teams”.

Incannex has previously filed International Patent Application No. PCT/AU2021/050734 as part of the IHL-42X development program.

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

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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 published 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 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 sleep¹. 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 growing². 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 accidents³.



Date: December 06, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

References

- ¹ <https://www.mayoclinic.org/diseases-conditions/obstructive-sleep-apnea/symptoms-causes/syc-20352090>
- ² <https://www.fortunebusinessinsights.com/industry-reports/sleep-apnea-devices-market-100708>
- ³ <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.

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 19 granted patents and 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 of 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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