Date: March 10, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex observes substantial reduction in AHI in preliminary results of clinical trial assessing IHL-42X in patients with OSA; proceeds to pivotal studies

Highlights:

- 20% of trial participants experienced a reduction in AHI of greater than 80% (range: 82.7% to 91.5%) during at least one treatment compared to baseline
- 60% of trial participants experienced a reduction in AHI of greater than 50% (range: 55.0% to 91.5%) during at least one treatment compared to baseline
- Average of low, mid and high-dose IHL-42X reduced AHI in trial participants by 44.4%, compared to baseline
- IHL-42X was observed to be well tolerated in the clinical trial
- IHL-42X has the potential to reduce disease severity, resulting in improved sleep quality, multiple major health benefits and increased quality of life
- The Company has been granted a pre-IND meeting with FDA on May 11, 2022 (U.S. EST)
- Planning commences for pivotal clinical trials to commence after opening an IND with FDA.

Melbourne, Australia, March 10, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for unmet medical needs, today announced the completion of a preliminary analysis of data from its phase 2, proof-of-concept clinical trial investigating novel cannabinoid combination product, IHL-42X, for the treatment of obstructive sleep apnoea ('OSA').

The clinical trial assessed three doses of IHL-42X at reducing the apnoea hypopnoea index ('AHI'), the main diagnostic and monitoring criteria for OSA, compared to placebo in patients who suffered from the disease. Trial participants received each of the three doses of IHL-42X and placebo across four seven-day treatment periods, separated by one week washout periods. At the end of each treatment period, they attended the clinic for an overnight sleep study where AHI was determined, along with other measures of sleep quality, quality of life and drug safety. The study was conducted at the University of Western Australia Centre for Sleep Science and The Alfred Hospital.

A total of eleven participants were recruited to the study and ten participants completed treatment periods. The crossover design of the study permitted Incannex to generate high quality data with a reduced participant number compared to a conventional parallel arm study. Each participant serves as their own internal control and inter-participant variation is eliminated. The study included ten placebo treatment periods and twenty-six IHL-42X treatment periods totalling thirty-six AHI data points that were compared to baseline.

Incannex has undertaken preliminary analysis of the study data comparing the AHI during treatment with IHL-42X across all three dose levels or placebo to baseline. At baseline, the average AHI was 42.84. For all IHL-42X treatment periods (using low, mid, and high doses), the average AHI was 23.81, a 44.4 % reduction (p-value 0.0067) compared to baseline AHI. During placebo treatment periods, the average AHI was 40.08, a 6.4 % reduction (p-value 0.75) compared to baseline. 60% of participants experienced a reduction in AHI of greater than 50% (range: 55.0% to 91.5%) and a resulting AHI of less than 20 during at least one treatment period of one dose strength of IHL-42X. 20% of participants experienced a reduction in AHI of greater than 80% (range: 82.7% to 91.5%) relative to baseline during at least one treatment period of one dose strength of IHL-42X.

Specific data from the study, including which IHL-42X doses were received by which patient and when, remain blinded. Patient response to specific IHL-42X doses (low, mid, and high) and the secondary endpoints continue to be analysed by contract research organisation, Novotech, and will only be released to Incannex upon the completion of the analysis as per usual clinical trial processes. This will include a comparison between IHL-42X doses for each patient, which increases the power of the analysis, and provides a more robust differentiation of dose strengths. The full clinical study report is anticipated in Q2 2022.

Preliminary analysis also revealed that IHL-42X was observed to be well tolerated in the clinical trial. All treatment associated adverse events were consistent with what has been reported for constituent components of IHL-42X in historic studies.

Chief Scientific Officer of Incannex Healthcare, Dr. Mark Bleackley, said; "We are delighted that IHL-42X has demonstrated efficacy and good safety characteristics in our preliminary assessment of data from the proof-of-concept trial. The average reduction in AHI calculated across low, mid, and high-dose IHL-42X has met our expectations for what would constitute a valuable product for the treatment of obstructive sleep apnoea. IHL-42X has the potential to reduce disease severity, resulting in improved sleep quality, multiple major health benefits and increased quality of life. We look forward to the further analysis of the study data by Novotech, which will include identification of which dose strength performed best."

As announced on December 20, 2021, Incannex is preparing for a pre-IND meeting with the U.S. Food and Drug Administration ('FDA') on the future development plan for IHL-42X. The Company and its medical and scientific advisors have been granted a meeting via teleconference on May 11, 2022 (U.S. EST). This meeting will provide guidance on what data is required to open an Investigational New Drug (IND) application with FDA for IHL-42X for treatment of OSA and the design of a larger pivotal phase 2 clinical trial with trial sites in the United States.

Bonus Entitlement Offer

The Board of Directors has progressed its initiative to offer a bonus option entitlement to both reward shareholders and provide additional funding for the Company in the future. The terms of this entitlement offer will be finalised imminently and announced to ASX.

About Obstructive Sleep Apnoea

OSA is the most common sleep-related breathing disorder, and it causes people to repeatedly stop and start breathing for elongated intervals during sleep. It is a major public health problem and IHL-42X represents a significant commercial opportunity for Incannex as there are no approved pharmacotherapy treatments available to patients at the present time.

OSA is a serious medical condition that increases the risk of numerous health complications[1]. Drops in blood oxygen levels that occur during OSA increase blood pressure and strain the cardiovascular system. 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 attacks, heart failure and strokes.

People with OSA often have severe daytime drowsiness, fatigue, and irritability due to lack of restorative sleep at night, which are observed causes of workplace accidents. Those diagnosed with OSA are also at higher risk of memory problems, headaches, mood swings and depression.

The current standard of care is a continuous positive airway pressure ('CPAP') machine, however, patient compliance to CPAP is low due to discomfort and claustrophobia resulting from pressurized air being pumped into the mouth during sleep. Incannex anticipates greatly improved treatment compliance and outcomes from a pharmaceutical product, which could be 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 aids is approximately US$10 billion per annum and growing[2].

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[3].

[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

This announcement has been approved for release to ASX by the Incannex board of directors.

END

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 anxiety disorders, obstructive sleep apnoea (OSA), traumatic brain injury (TBI)/concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis and inflammatory bowel disease. U.S. 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 in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners.
Website: **www.incannex.com.au**
Investors: **investors@incannex.com.au**

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.

Contact Information

Incannex Healthcare Limited
Mr Joel Latham
Managing Director and Chief Executive Officer
+61 409 840 786
joel@incannex.com.au

US IR Contact
Rx Communications Group
Michael Miller
+1-917-633-6086
mmiller@rxir.com