Date: July 06, 2023
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Receives Ethics Approval for Bioequivalence/Bioavailability Clinical Trial for IHL-42X, the Company's Proprietary Drug for Treatment of Obstructive Sleep Apnoea ('OSA')

Highlights:

- Incannex has received approval from Bellberry Human Research Ethics Committee ('HREC') to commence the bioavailability/bioequivalence ('BA/BE') clinical trial to assess the pharmacokinetics and tolerability of IHL-42X
- The trial will include 116 participants at CMAX Clinical Research in South Australia and will be managed by Novotech
- Data from the clinical trial will be a critical component of future marketing submissions for IHL-42X for treatment of OSA
- The trial will be conducted in parallel to the IND opening and pivotal Phase 2/3 clinical trial
- OSA is highly prevalent, affecting approximately 30 million adults in the United States alone and there are no registered prescription drugs available to patients for the treatment of OSA
- The design of the BA/BE trial is consistent with FDA recommendations as part of the required research required to undertake a new drug application.

Melbourne, Australia, July 06, 2023 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that Incannex has received approval from Bellberry Human Research Ethics Committee to commence a bioavailability/bioequivalence ('BA/BE') clinical trial on IHL-42X, the Company's proprietary drug product for treatment of obstructive sleep apnoea.

The BA/BE clinical trial will assess the pharmacokinetics and tolerability of the two active pharmaceutical ingredients ('APIs') in IHL-42X, dronabinol ('THC') and acetazolamide, compared to the respective FDA reference listed drugs, as well as the effect of food on pharmacokinetics of the two APIs.

The study will include 116 participants who will each complete four (4) single dose treatment periods, being dosed with IHL-42X, dronabinol and acetazolamide under fasted conditions as well as IHL-42X under fed conditions. Blood samples will be collected over 48 hours and the concentrations of the APIs and their major metabolites in the samples will be analysed.

The clinical trial will be conducted at CMAX Clinical Research in Adelaide, South Australia and managed by Novotech. The design of the BA/BE trial is consistent with US Food and Drug Administration ('FDA')

recommendations and specific advice received by Incannex in its pre-IND with the FDA regarding the development of IHL-42X for treatment of OSA.

The results of the BA/BE trial will form a critical component of a future new drug application ('NDA'), providing the necessary bridge to the reference listed drugs, thereby facilitating the use of historic safety data via the FDA505(b)2 regulatory pathway. Importantly, the BA/BE study will run in parallel to the pivotal Phase 2/3 trial that will commence after the Company opens an IND with the FDA.

Incannex Chief Scientific Officer Dr Mark Bleackley said: "The BA/BE trial is a very important component of the IHL-42X pipeline. Being able to bridge to historic safety data on the reference listed drugs for dronabinol and acetazolamide accelerates the development of the drug product and reduces cost and timelines. Approval of the study by Bellberry HREC for the BA/BE study allows us to move towards patient recruitment and data collection with CMAX and Novotech."

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 sleep[1]. 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[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].

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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