Date: May 17, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Positive Pre-IND Meeting with US FDA for IHL-42X for Obstructive Sleep Apnoea

Melbourne, Australia, May 17, 2022 – 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 it completed a highly constructive Pre-Investigational New Drug Application ('pre-IND') meeting with the US Food and Drug Administration ('FDA') to discuss the development IHL-42X.

IHL-42X is a fixed dose combination of dronabinol and acetazolamide that is being developed as a treatment for obstructive sleep apnoea ('OSA') in adults. Incannex submitted a pre-IND meeting package and meeting request to the FDA in February 2022. The meeting package included an overview of the development program, and specific questions Incannex had on the regulatory requirements for opening an investigational new drug ('IND') application. Opening an IND is required to conduct clinical trials in the USA and ensures that trials are designed so that they meet the data requirements necessary for FDA marketing approval.

The written responses, and the responses provided in a teleconference with FDA representatives, were constructive and supportive, with interest in the project underpinned by the significant cohort of people diagnosed with OSA and the absence of pharmacological treatment solutions.

FDA provided guidance on Incannex's proposed long-term development strategy, including specific parameters to demonstrate safety and efficacy in phase 2 and 3 pivotal studies. Guidance provided by the FDA to the Company will inform adjustments to the clinical trial protocols to ensure that they generate the data required for a 505(b)(2) new drug application (NDA).

In a decision that will save Incannex time and cost, FDA agreed that Incannex does not need to conduct studies in animals. In particular, the agency confirmed that animal toxicology and animal pharmacokinetic (PK) studies are not required for opening an IND for IHL-42X. Therefore, the next step for the development of IHL-42X will be the adjustment of clinical trial designs and arrangement of operational imperatives necessary to open an IND with FDA.

Chief Scientific Officer for Incannex, Dr Mark Bleackley, said: "The FDA's interest in IHL-42X as a potential therapy for OSA was extremely encouraging. The feedback they provided on the overall proposed development program was positive. The agency's responses to the specific questions we posed allow us to revise our clinical trial protocols, to ensure that we are running highly efficient studies that generate the type and amount of data the FDA will require in a future marketing application. The results from the pre-IND meeting will shape the IHL-42X development program over the coming months."

Incannex completed a phase 2 proof of concept clinical trial in 2021 to assess IHL-42X in patients with OSA. Preliminary results from the trial have been published, showing that 60% of trial participants experienced a reduction in apnea-hypopnea index ('AHI') of greater than 55% during at least one treatment compared to

baseline. 20% of trial participants experienced a reduction in AHI of greater than 80%. The complete clinical study report is anticipated to be released in June 2022.

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

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About Incannex Healthcare Limited
Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabinoid 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.

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. Incannex is listed on the Australian Stock Exchange (ASX) with stock code “IHL” and also 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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