Date: October 11, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Completes Positive Pre-IND Meeting with US FDA on IHL-216A for Treatment of Concussion and Traumatic Brain Injury

Melbourne, Australia, October 11, 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 has completed a constructive pre-Investigational New Drug Application ('pre-IND') meeting with the U.S. Food and Drug Administration ('FDA') for its proprietary drug product IHL-216A for treatment of traumatic brain injury and concussion ('TBI').

IHL-216A is Incannex's proprietary combination of cannabidiol ('CBD') and isoflurane ('ISO') that is being developed for treatment of TBI. Incannex submitted a pre-IND meeting package to the FDA in August 2022. The meeting package included a description of the unique formulation developed by Incannex, an overview of the proposed clinical development plan and specific questions Incannex submitted on the regulatory requirements for opening an Investigational New Drug application ('IND'). Opening an IND is required to conduct trials in the United States and ensures that trials are designed to meet the data requirements necessary for FDA marketing approval.

In written correspondence, FDA provided valuable, multidisciplinary feedback on the proposed clinical development of IHL-216A and acknowledged that treatment of TBI is a significant unmet medical need that requires innovative treatment solutions. The FDA also confirmed that the FDA505(b)2 application was the appropriate regulatory pathway for IHL-216A, whereby some of the information required for marketing approval may derive from studies already completed on the drug components of IHL-216A and in the public domain.

FDA provided critical guidance on the data requirements for opening an IND for IHL-216A, particularly related to the intricacies of developing an inhaled drug product and conducting clinical trials that involve an anaesthetic. Incannex is drafting a follow-up request for additional information on the FDA's recommendations and will provide an update to ASX and Nasdaq investor platforms when it has been received.

Chief Scientific Officer of Incannex, Dr. Mark Bleackley, said; "Feedback from the FDA in the pre-IND meeting indicated that the agency is highly interested in the development of IHL-216A for treatment of traumatic brain injury. Their responses covered all aspects of the proposed development and engaged a range of disciplinary experts that provided useful insight on all aspects of our development plan. The FDA has provided essential advice on inhaled drug development that will guide the most efficient development of IHL-216A."

IHL-216A has demonstrated neuroprotective activity in two separate animal models of traumatic brain injury, one representing moderate to severe injury and the other representing mild injury, or concussion. In both models, treatment with IHL-216A improved the effects of injury to a greater extent that either CBD or ISO monotherapy.

In May of 2022, Incannex released the results of an extensive animal study that compared IHL-216A to its component drugs, CBD and ISO, in a model developed in collaboration with the U.S. National Football League (NFL). In that experiment, IHL-216A was observed to restore spatial memory after twenty-four hours in injured rodents whilst injured rodents that only received the vehicle as treatment did not display restored spatial memory.

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 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 29 pending patents. 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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