Incannex to Prepare FDA IND Application for Psilocybin-assisted Psychedelic Psychotherapy Program, Known as Psi-GAD

Melbourne, Australia, August 24, 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 its subsidiary Psychennex Pty Ltd has commenced preparations of an investigational new drug ('IND') application to the U.S. Food and Drug Administration ('FDA') for the Company's psilocybin assisted psychotherapy development program ('Psi-GAD').

Opening an IND with the FDA is the key regulatory approval required by the Company to undertake clinical trials in the United States. The Company has commenced the process of drafting the IND application in preparation for the receipt of final clinical trial results from the Psi-GAD clinical trial expected in Q4 2023 or Q1 2024.

The IND submission will include detailed modules on the safety and efficacy of psilocybin assisted psychotherapy across a range of mental health indications. It will include comprehensive data on the development, quality and stability of Incannex's psilocybin drug product and the design of the proposed IND opening study, which will be designed in a manner suitable for use in a new drug application (NDA).

The modules of the IND are:

- Module 1 – Administrative Information and Prescribing Information
- Module 2 – Nonclinical/Clinical Overviews and Summaries
- Module 3 – Quality data
- Module 4 – Nonclinical Study Reports and Key Literature References
- Module 5 – Clinical Study Reports, Clinical Protocol and Investigator Information

The FDA review process for an IND application involves evaluation of the modules to ensure that the drug product and proposed clinical trial meet regulatory requirements.

The Company announced on 15 March 2023 interim analysis for the Phase 2 Psi-GAD clinical trial being conducted at Brain Park, Monash University. Interim statistical analysis predicted that there was a greater than 85% chance of the trial showing statically significant benefit for the psilocybin treatment arm versus the placebo arm at the conclusion of the trial period. An independent Data Safety Monitoring Board ('DSMB') was tasked with confidentially reviewing the data for the first 37 out of 72 trial participants for the ongoing Phase 2 clinical trial and recommended no adjustments to the original study design or sample size. The trial team and DSMB identified no safety concerns at that time and permitted the trial to continue as originally designed.

CEO and Managing Director of Incannex, Mr Joel Latham said, “Commencing IND preparation demonstrates our confidence in the utility of the Psi-GAD therapy. The interim analysis and the progress made by Dr Liknaitsky and his team at Monash University has empowered us to fast-track various strategic business decisions to hasten the development of the therapy. Our organisation is consistently fortifying its position as a frontrunner within the psychedelic research sector, and we eagerly anticipate the results from our Phase 2 trial upon its completion.”

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 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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