Independent data review commences for Phase 2 trial of psilocybin-assisted psychotherapy for anxiety

Melbourne, Australia, January 18, 2023 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company'), a pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that the PsiGAD1 clinical trial, designed to assess Incannex's psilocybin-assisted psychotherapy for the treatment of generalised anxiety disorder ("GAD"), has achieved its interim milestone of 29 patients completing primary endpoint assessments. Independent analysis of the interim study data has commenced.

Treatment of GAD with currently accepted medications and therapies remains inadequate, with less than half of patients achieving remission. Psilocybin-assisted psychotherapy has shown promise in the treatment of several mental health conditions. PsiGAD1 was developed in collaboration with Dr Paul Liknaitzky, Head of the Clinical Psychedelic Lab at Monash University and a member of the Incannex scientific advisory board. The trial is designed to assess the safety and efficacy of the Company's unique psilocybin program in an active placebo-controlled study. The 10-week treatment program includes two dosing sessions with either psilocybin or active placebo. Safety, efficacy, quality of life, and other aspects of mental and physical health are assessed.

The study is being conducted at Monash University's BrainPark under the leadership of Dr Liknaitzky, alongside co-investigators Professor Suresh Sundram (Head of the Dept of Psychiatry, Monash) and Professor Murat Yücel (Director of BrainPark). Dr Liknaitzky has recruited a team of experienced and qualified clinicians and researchers to undergo specialist training, and deliver and assess the treatment.

To date, 45 participants have been enrolled in the study, with 29 participants having now completed the treatment protocol and main outcome assessment following treatment. The interim analysis of the study data to date, conducted by an independent Data Safety Monitoring Board ('DSMB') comprising experts who are not part of the trial, has commenced.

The independence of the DSMB is critical to maintain a blinded study and consequent integrity of the final data readout and analysis. Recommendations from the DSMB will be provided in March 2023, at which time the Company will provide another public announcement. The trial continues to progress well and on time, with retention of all participants who have been enrolled. The trial team have identified no safety concerns to date.

The interim analysis will allow Incannex to make key decisions on regulatory strategy and, in parallel, planning of pivotal studies, while continuing to collect data from the PsiGAD1 trial. Patient recruitment is ongoing towards fulfilling the complete study cohort of 72 patients.

"The PsiGAD1 trial is supported by a fantastic team of researchers and clinicians and has been an intensive and gratifying project to lead", said Dr Paul Liknaitzky, Principal Investigator on the trial. "I

look forward to the recommendations of the Data Safety Monitoring Board, and to continuing to progress this trial to completion."

Incannex Chief Scientific Officer, Dr Mark Bleackley, said: "Monash University is a major globally recognised and highly innovative university. Dr Liknaitzky and his team are at the forefront of psychedelic research and development. Incannex continues to benefit from the academic rigour that Monash University and Dr Liknaitzky bring to the development of this therapy, which should assist our ambitions to be amongst the first companies in the world to provide a proprietary psychedelic therapy to the public. We look forward to providing a further update to our stakeholders following the recommendations from the DSMB."

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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