Incannex Completes Dosing and Therapy in Phase 2 "PsiGAD" Clinical Trial Assessing Psilocybin-assisted Psychotherapy for Generalized Anxiety Disorder; Data Analysis Commences

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Highlights:

- 72 patients treated at purpose-built facilities within Monash University, Melbourne, Australia.
- Topline results from the trial anticipated within current Q1 2024.
- FDA IND application is well-advanced after commencing preparations in August, 2023.
- Independent documentary covering Monash Clinical Psychedelic Lab and PsiGAD research program to be released by SBS television network following 2 years of filming and production.

MELBOURNE, Australia and NEW YORK, Jan. 18, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), ('Incannex' or the 'Company'), a pharmaceutical company developing unique medicinal cannabinoid pharmacotherapies and psychedelic medicine therapies is pleased to announce that it has completed dosing and treatment protocols for all 72 participants in the PsiGAD-1 clinical trial, the Company's Phase 2 study evaluating its own psilocybin treatment program for patients with generalized anxiety disorder (GAD).

PsiGAD-1 is a randomised triple-blind active-placebo-controlled Phase 2 trial. The primary objective of the study is to determine whether a 7-week program of psilocybin-assisted psychotherapy for GAD is superior to active placebo-assisted psychotherapy in decreasing symptoms of GAD, as measured by the change in the Hamilton Anxiety Rating Scale (HAM-A) from baseline to week 11. Safety and tolerability were assessed, as well as other secondary objectives of efficacy and quality of life.

"We're delighted to have completed all PsiGAD-1 treatments for our trial participants as we work towards finalising an FDA IND application to advance the development of this important treatment modality," said Joel Latham, Chief Executive Officer and Director of Incannex. "Generalised anxiety disorder is characterised by persistent, debilitating and excessive worry, affects millions of people globally, and has inadequate existing treatment options. We're thankful to our research partners at Monash University who conducted a thorough and extensive clinical trial, screening 975 people and undertaking 174 psychedelic dosing sessions in one of the largest clinical trials of its kind."

FDA IND Application Preparations for PsiGAD

Incannex commenced the process of drafting an FDA IND application in August 2023 in preparation of the receipt of topline results from the PsiGAD-1 clinical trial, and submission soon thereafter.

In March of 2023, Incannex announced the interim analysis for the Phase 2 PsiGAD-1 clinical trial, which predicted a greater than 85% chance that the trial would show 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. At that time, the DSMB recommended no adjustments to the original study design or sample size and acknowledged no safety concerns in the operation of the trial.

Documentary on the Monash Clinical Psychedelic Lab to be released in Late February 2024

Commissioned by the Australian Special Broadcasting Service (SBS), a film production company has tracked the activities of the Monash Clinical Psychedelic Lab for over 2 years, producing a documentary that focuses on the PsiGAD research program. *Psychedelics: Stepping into the Unknown* is a feature documentary on the first psychedelic lab in Australia and key partner in Incannex's psychedelic research program. The documentary is currently scheduled for release on the SBS streaming service in late February 2024, and aims to contribute to the awareness of mental health, psychedelic therapies, and the expertise required for safe delivery.

About Incannex Healthcare Inc.

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabinoid 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 20 granted patents and over 30 pending patent applications.

Website: **www.incannex.com**

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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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