Date: March 15, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Interim review of proprietary PsiGAD clinical trial data indicates no safety concerns and projects a statistically significant benefit for the psilocybin arm versus the placebo arm in those participants who have completed the treatment

Highlights:

- Interim analysis of study data to date indicates that there is a greater than 85% chance (>85%, alpha error probability 0.05) of the study showing a statistically significant benefit for the psilocybin treatment arm versus the placebo treatment arm at the conclusion of the study period.
- An independent Data Safety Monitoring Board (DSMB) has reviewed data from Incannex's ongoing Phase 2 "PsiGAD" clinical trial and recommends no changes to study design.
- The trial team and DSMB have identified no safety concerns to date.

Melbourne, Australia, March 15, 2023 - Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a pharmaceutical cannabinoid and psychedelic medicines company, is pleased to announce results of an interim review of the conduct, safety and data from its ongoing Phase 2 clinical trial assessing its proprietary psilocybin-assisted psychotherapy program for Generalised Anxiety Disorder ('GAD'), known as "PsiGAD".

IHL has reviewed the interim data from the first 29 participants to complete the treatment protocol and completed a conditional power analysis using the interim data to model and project total study data. Given the strong results to date, the company found that there is a high probability (greater than 85% - alpha error 0.05 or 95% confidence level) that the total study will show a statistically significant benefit for the psilocybin treatment arm over the placebo treatment arm. This projection is made by assuming the effect size observed in the interim analysis for 29 participants is representative of the effect size through the remaining 43 participants. The end point used in this modelling was a reduction in Hamilton Anxiety Rating Scale (HAM-A) score at 11 weeks relative to baseline, which is the primary endpoint in the trial. This modelling is completed internally by the company and does not get verified by the DMSB.

A review was also conducted by an independent DSMB, which reviewed the available data from the first 37 out of 72 participants. The DSMB recommended no adjustments to the original study design or sample size.

IHL announced the original study on December 8, 2020, under the heading: **Incannex partners with Monash University to conduct a world-first clinical trial: Psilocybin-assisted psychotherapy in the treatment of**

Generalised Anxiety Disorder. The study design is based on the hypothesis that psilocybin-assisted psychotherapy will show a large treatment effect, as measured by a reduction in HAM-A scores compared to the control condition (active-placebo-assisted psychotherapy).

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, and the DSMB has recommended that the trial continues without changes.

The trial employs a team of experienced and qualified clinicians and researchers who undergo specialist training before they deliver and assess the treatment. To date, over 45 participants have been enrolled in the study, with 29 participants having now completed the treatment protocol and main outcome assessment following treatment. Treatment of all 72 trial participants is anticipated to be completed in the fourth quarter of 2023.

CEO and Managing Director of Incannex, Mr Joel Latham, said: "The results from the interim analysis of Incannex's Phase 2 clinical trial provide us with encouragement that our PsiGAD psilocybin-assisted psychotherapy treatment protocol has the potential to transform the lives of people suffering from anxiety, I believe IHL is leading the way in research on novel treatments for this debilitating indication. Even though the results must remain blinded until the conclusion of the trial, the confidential review has given us the confidence to commence manufacture of our own psilocybin drug product with the appointment of Catalent, progress planning of our pivotal trials and commence drafting our FDA IND application for the PsiGAD treatment program. The Clinical Psychedelic Lab at Monash University has overseen training of 14 psychotherapists to work on the phase 2 trial, demonstrating that this transformational treatment is scalable to many therapists and patients throughout the world."

Generalised Anxiety Disorder

GAD affects millions of people across the globe each year. GAD is characterised by excessive anxiety and worry that occurs more days than not for at least 6 months, and is not restricted to any particular environmental circumstances. Symptoms include feelings of persistent and excessive worry, nervousness, restlessness, difficulty concentrating, and a range of somatic manifestations.

People with GAD find it difficult to control their worry, which may cause significant distress and impairment in social, occupational, or other areas of functioning. As with other mood disorders, current treatments of GAD remains inadequate, with less than half of patients achieving remission following evidence-based treatment, alongside high relapse rates, and substantial treatment side-effects or cost.

About PsiGAD Psilocybin-assisted Psychotherapy for Generalised Anxiety Disorder

Psilocybin-assisted psychotherapy uses psilocybin to improve the effectiveness of psychotherapy for Generalised Anxiety Disorder. The treatment involves two administrations of psilocybin in conjunction with psychotherapy in a controlled clinical setting as part of a 10-week course of specialised treatment.

Led by Dr Paul Liknaitzky, Head of Clinical Psychedelic Research at Monash University, the trial is well-controlled (triple-blind, active placebo), and includes a range of treatment innovations alongside the development of a specialised therapist training program. The study is being conducted at Monash University's BrainPark facility, alongside co-investigators Professor Suresh Sundram (Head of the Dept of Psychiatry, Monash) and Professor Murat Yücel (Director of BrainPark).

Hamilton Anxiety Rating Scale (HAM-A)

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe. The HAM-A ratings scale used for assessing GAD in the IHL PsiGAD trial and has been used to demonstrate the efficacy of other FDA-approved medications for GAD including, but not limited to, Lexapro[1], Paxil[2], and Effexor XR[3].

This announcement has been approved for release to ASX by the Incannex Board of Directors.

ENDS

[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021323s047lbl.pdf
[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020031s077lbl.pdf
[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020699s107lbl.pdf

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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