FDA Review of PsiGAD2 IND complete; clinical trial for Psilocybin Assisted Psychotherapy in Patients with Generalised Anxiety Disorder to Proceed

August 5, 2024

- Approval from FDA to proceed with 94 patient Phase 2 clinical trial received following review of IND dossier containing information on the clinical trial, as well as safety and quality of the investigational drug product.
- PsiGAD2, short for Psilocybin for Generalised Anxiety Disorder trial two, follows the PsiGAD1 proof of concept trial, which demonstrated a 12.8 point reduction in the Hamilton Anxiety Rating Sacle (HAM-A) score from baseline in the psilocybin treatment group.

NEW YORK and MELBOURNE, Australia, Aug. 05, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), ('Incannex' or the 'Company'), a clinical-stage pharmaceutical company developing proprietary medicinal cannabinoid products and psychedelic assisted psychotherapies is pleased to announce that it has received approval from the US Food and Drug Administration ('FDA') to conduct the Company's Investigational New Drug ('IND') opening Phase 2 clinical trial. The trial will investigate Incannex's psilocybin pharmaceutical formulation, known as PSX-001, in conjunction with psychotherapy in patients with generalised anxiety disorder in the United States and the United Kingdom.

Incannex submitted the IND application on 26 June 2024 and the FDA completed their review of the application package during the allocated 30-day period. Incannex received communication that the FDA review was completed, and the IND-opening clinical trial, PsiGAD2, is deemed safe to proceed following assessment of the trial protocol, lead trial investigator, and a risk benefit analysis of the trial and prospective drug product.

PsiGAD2 will recruit approximately 94 patients with generalised anxiety disorder, including those currently being treated with selective serotonin reuptake inhibitors, who meet the study inclusion and exclusion criteria. Patients will receive one of two dose strengths of PSX-001 under double blind conditions. There will be two dosing sessions for all patients as well as preparatory and integration sessions to facilitate psychotherapy.

The primary endpoint for the study will be change in HAM-A score, a widely used and validated measure of anxiety, two weeks after completion of the second dosing session. HAM-A scores will be collected at predefined intervals for 23 weeks after completion of the dosing sessions and the change from baseline assessed as secondary study endpoints. Additional endpoints in the study will include measures of quality of life, healthcare utilisation, electroencephalography (EEG), as well as assessment of safety and tolerability through adverse event monitoring.

The PsiGAD2 trial builds on the positive results of PsiGAD1, a phase 2 proof of concept clinical trial conducted at world renown Monash University. That trial reported a 12.8 point reduction in HAM-A score in the psilocybin treatment group, which was 9.2 points greater than observed for the placebo group ($p<0.0001$). In PsiGAD1, 44% of patients in the psilocybin group had a greater than 50% reduction in HAM-A score and 27% of patients achieved disease remission.

PsiGAD2 is also currently under review by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK) to permit the Company to conduct the trial also at sites in the United Kingdom. Incannex will continue start up activities for the PsiGAD2 trial in the UK in parallel with start up in the US.

About Generalised Anxiety Disorder

Generalised Anxiety Disorder (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 are variable, including 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. GAD is a relatively common disorder (about 6-9% lifetime prevalence, and about 3% 12-month prevalence in countries like Australia and the United States). As with other mood disorders, successful treatment 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 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. Incannex is listed and publicly traded on Nasdaq (NAS: IXHL), providing investors an opportunity to participate in the Company's growth.

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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