Date: 28th October 2021
ASX Announcement (ASX: IHL)

Positive pre-IND meeting with US FDA and ethics approval to commence Phase 2a Psi-GAD clinical trial: psilocybin-assisted psychotherapy for Generalised Anxiety Disorder

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce:

1. that the Phase 2a Psi-GAD clinical trial, led by Dr Paul Liknaitzky at Monash University, has received approval to proceed from the Monash University Human Research Ethics Committee (MUHREC); and

2. the completion of its pre-Investigational New Drug Application ('pre-IND') meeting with the US Food and Drug Administration ('FDA') regarding the Company's clinical development program comprising psilocybin-assisted psychotherapy for Generalised Anxiety Disorder ('GAD').

Ethics Committee approves Phase 2a Psi-GAD clinical trial

Led by Dr Paul Liknaitzky, Head of Clinical Psychedelic Research at Monash University, the trial is the first in the world to examine the safety and efficacy of psilocybin for any primary anxiety disorder. With 72 participants, this investigator-initiated trial is the largest psychedelic trial in Australia to date. 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.

"This is an exciting step for Incannex, the team at Monash, and for the emerging field of psychedelic medicine", says Dr Liknaitzky. "Most importantly, this is a solid step in the development of what we hope will be a highly effective treatment for people suffering under the weight of severe anxiety."

In another world-first, the study has been approved to investigate the option for trial therapists to experience psilocybin under supportive conditions as part of therapist training. Dr Liknaitzky said: "Research suggests there may be substantial benefit for psychedelic therapists to undergo well-supported psychedelic administration as part of their training. For the first time ever, we're able to provide supported psilocybin sessions to research trial therapists to better equip them to accompany our clinical participants through profoundly unfamiliar terrain, potentially improving treatment outcomes."

Having now received approval from the Monash University Human Research Ethics Committee, the study team will commence the drug importation process, complete the training of trial therapists that is currently underway, and finalise site infrastructure. Participant recruitment is expected to commence early in 2022.

Positive pre-IND meeting with FDA

The pre-IND meeting package was prepared with assistance from regulatory consultants Camargo Pharmaceutical Services. Included in the meeting package was an overview of the Psi-GAD program, and specific questions Incannex had on the regulatory requirements for opening an investigational new drug ('IND') folder required to conduct human trials in pursuit of FDA marketing approval in the USA.

Both the written responses and the responses provided in the teleconference held recently were positive, constructive, and supportive. The FDA confirmed that the therapeutic strategy for the development of a psilocybin-assisted therapy for GAD is appropriate and conveyed interest in its development. FDA also provided guidance on IHL's proposed long-term development strategy with regards to what will be required for a successful NDA (FDA approval) and marketing authorisation. Specific feedback from the FDA on IHL's proposed clinical trial designs will shape a pivotal Phase 2b clinical trial, which will be the IND opening study following either interim or full results from the Phase 2a trial.

About Generalised Anxiety Disorder

Generalised Anxiety Disorder (GAD) is characterised by diffuse, excessive, uncontrollable anxiety that is not restricted to any specific environmental circumstances and occurs more days than not for at least 6 months (American Psychiatric Association, 2013). About 3% of the adult population in the USA and Australia are estimated to have GAD in any 12-month period. This equates to an estimated 9M people in the US (7m moderate-to-severe) having GAD and approximately 1M people in Australia.

Patients experience intense, persistent, and often debilitating anxiety. First line treatment options for GAD include Cognitive Behavioural Therapy, anti-depressants (SSRIs, SNRIs) and pregabalin, with benzodiazepines (e.g., Diazepam) as a second-line, short-term option. Existing treatments show limited efficacy, with less than 50% of patients achieving remission, alongside high relapse rates. These treatment limitations highlight significant unmet need in this patient group.

GAD tends to be more frequent and severe than within other anxiety disorders (Olatunji et al., 2010), having a chronic, unremitting course. It is associated with a high public burden, and significant distress and impairment in quality of life, relationships, work, or other areas of functioning (Comer et al., 2011; Revicki et al., 2012).

ENDS

The release of this announcement has been approved for issue by IHL's Board of Directors. For further details on the announcement, interested parties should contact:

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About Incannex Healthcare Limited (ASX: IHL)

Incannex Healthcare Limited (IHL.ASX) is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of generalised anxiety disorder (GAD), obstructive sleep apnoea (OSA), traumatic brain injury (TBI)/concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis and inflammatory bowel disease. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development.

Each indication represents major global markets and currently have no, or limited, existing registered pharmacotherapy (drug) treatments available to the public.

IHL 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.

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