Date: 10th August 2021
ASX Announcement (ASX: IHL)

Incannex submits HREC proposal and FDA pre-IND meeting request for Psi-GAD psilocybin therapy for Generalised Anxiety Disorder

Highlights:

- IHL, in partnership with Monash University, submits research proposal to HREC for a phase 2a Psi-GAD clinical trial
- IHL submits pre-IND meeting request to US FDA for guidance on a phase 2b pivotal trial
- The phase 2a trial is planned to commence in 2021 and the phase 2b trial in 2022
- Phase 2a trial will be conducted at BrainPark, a state-of-the-art neuroscience research platform at Monash University, Melbourne Australia
- An estimated 7M people in the US alone have moderate to severe generalised anxiety disorder, experiencing intense, persistent, and often debilitating symptoms of anxiety.

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company') is pleased to announce that, in partnership with Monash University, it has completed a Human Research Ethics Committee ('HREC') submission for its phase 2a Psi-GAD study that combines the administration of psilocybin with specialised therapy to patients with Generalised Anxiety Disorder ('GAD').

The Company has simultaneously submitted a comprehensive information package to the US Food and drug administration ('FDA') for the purpose of requesting a pre-IND meeting. The information package and meeting request was prepared in conjunction with regulatory specialists Camargo Pharmaceuticals. The submission includes questions to FDA intended to seek regulatory clarity on the Company's follow-up phase 2b Psi-GAD pivotal clinical trial.

These two submissions follow an extensive and collaborative trial design process led by Principal Investigator Dr Paul Liknaitzky (Head, the Clinical Psychedelic Research Lab, Monash University), along with Co-Investigators Professor Suresh Sundram (Head, Dept of Psychiatry, Monash University) and Professor Murat Yucel (Director, BrainPark, Monash University). The wider research team includes national and international experts in psychedelic-assisted therapies, psychometric evaluation, qualitative research, and therapist training. The phase 2a trial is planned to commence in 2021 and the phase 2b trial in 2022.

Phase 2a clinical trial

The phase 2a study is a randomised triple-blind, active-placebo-controlled trial that will include 72 participants that experience two psilocybin or active-placebo dosing sessions and up to 11 non-drug, specialist psychotherapy sessions over a period of 10 weeks.

The trial will be conducted at BrainPark, a state-of-the-art neuroscience research platform at Monash University's Turner Institute for Brain and Mental Health. Both the Monash University School of Psychological

Sciences and the Department of Psychiatry will combine forces to conduct this innovative trial. Monash University is one of Australia's leading universities and consistently ranks among the world's top 100; ranking number 55 out of 1604 university institutions in the 2021 QS World University Rankings.

Primary outcomes from the trial are safety, efficacy and tolerability, and secondary outcomes are quality of life, functional impairment, and comorbidities. A preliminary analysis of patient data will be conducted by an independent data safety monitoring board after 30 patients have completed primary endpoint assessment. This preliminary analysis will allow the trial investigators to inform the second part of the trial (n=42) and/or the follow-up phase 2b clinical trial that Incannex is actively planning.

Phase 2b clinical trial

Preparations for this larger, pivotal, multi-site phase 2b clinical trial are continuing. Guidance from FDA at the pre-IND meeting, as well as data and learnings from the initial phase 2a trial being conducted in Australia, will be leveraged to make an investigational new drug application (IND) application with the FDA in 2022.

Dr Paul Liknaitzky, Chief Principal Investigator of the trial, said: *"Over the past few months, the Clinical Psychedelic Research Lab at Monash has made substantial progress on the Psi-GAD program, developing trial protocols, treatment protocols, a therapist training program, site infrastructure, risk mitigation planning, recruiting therapists, and a suite of scientific innovations – all part of a solid foundation for rigorous, innovative, and patient-focused research. This world-first and ambitious clinical research program is rapidly developing, supported by a strong partnership between Monash and IHL."*

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, raising the possibility of patients receiving Government subsidies for drugs that demonstrate suitable safety and efficacy profiles in clinical trials.

IHL has a strong patent filing strategy (as announced "IHL files cannabinoid patent over IHL-216A for TBI" 04th October 2019 and "IHL Files Patent over IHL-42X for OSA" 06th of December 2019) as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners.

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