Date: 08th December 2020
ASX Announcement (ASX: IHL)

Incannex partners with Monash University to conduct a world-first clinical trial: Psilocybin-assisted psychotherapy in the treatment of Generalised Anxiety Disorder

Highlights

- IHL executes partnership agreement with Monash University to conduct psilocybin-assisted psychotherapy trial to treat Generalised Anxiety Disorder, led by Dr Paul Liknaitzky
- The trial will recruit at least 72 patients to make it the largest psychedelic R&D project in Australia and is anticipated to have a substantial impact on the field globally
- The treatment will be delivered within BrainPark, a state-of-the-art research platform at Monash University's Turner Institute for Brain and Mental Health
- Treatment will include psilocybin dosing sessions alongside a program of specialised psychotherapy
- The clinical trial is planned to be US Food and Drug Administration ('FDA') compliant, with the Company calling a Pre-IND meeting as soon as practicable to discuss the clinical trial protocol
- Currently, two psilocybin research programs for depression have received Breakthrough Designation from the FDA
- Generalised Anxiety Disorder is a relatively common disorder with about 6-9% lifetime prevalence, and about 3% 12-month prevalence in countries like Australia and the United States.

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it has executed a partnership agreement with Monash University ('Monash' or 'Monash University') to conduct a Phase 2 randomised double-blind active-placebo-controlled trial to assess the safety and efficacy of psilocybin-assisted psychotherapy in the treatment of Generalised Anxiety Disorder ('GAD').

This world-first clinical trial will be led by Dr Paul Liknaitzky, with support from leading researchers and clinicians at Monash, across Australia, and internationally. The trial will recruit at least 72 patients and will include a number of major innovations in treatment approach and study design. The project has been established as an investigator-initiated trial, prioritising scientific independence, rigour, and patient outcomes. IHL will fund the clinical trial, and retain all developed intellectual property created by the trial. However, a strong partnership has been formed between Monash and the Company, and the two will share data towards the advancement of research and development, wherever reasonably feasible, within this promising treatment approach.

In addition, the trial will include the development of a substantive specialist training program to equip trial therapists in the safe and effective use of psilocybin-assisted psychotherapy to treat GAD. Central to this treatment approach is the combination of psilocybin and psychotherapy, with participants receiving specialised forms of psychotherapeutic support before, during and after each psilocybin session.

Monash University

Monash will sponsor the trial, ensuring rigorous scientific independence and the highest standards in ethical and safe research. Monash is one of Australia's leading universities and ranks among the world's top 100. The treatment will be delivered within BrainPark (photos presented in Appendix 1), a state-of-the-art research platform at Monash's Turner Institute for Brain and Mental Health and Biomedical Imaging Facility, that provides a highly conducive environment for this treatment approach in a research context. Both the School of Psychological Sciences within the Turner Institute for Brain and Mental Health, and the Department of Psychiatry within the School of Clinical Sciences, will combine forces to conduct this innovative trial, and the team will be comprised of leading researchers and clinicians in relevant fields of psychiatry, psychotherapy, and mental health treatment development.

Chief Principal Investigator - Dr Paul Liknaitzky

Dr Paul Liknaitzky works as a Research Fellow at Monash University, and has Adjunct or Honorary appointments at St Vincent's Hospital, Macquarie University, Deakin University, and the University of Melbourne. He earned an Honours in Neuroscience and a PhD in Psychology from the University of Melbourne. His work examines mechanisms of mental illness and treatment development, primarily within mood disorders and addiction research. Dr Liknaitzky is Principal Investigator across a number of Australia's first clinical psychedelic trials. He is currently establishing a rigorous program of research in psychedelic medicine at Monash University that seeks to evaluate therapeutic effects, innovate on treatment design, mitigate known risks, explore potential drawbacks, and understand therapeutic mechanisms.

The Trial Treatment

With support from leading psychedelic research groups internationally, this planned FDA-compliant clinical trial will be a world-first using psilocybin in the treatment of GAD. Research indicates that psilocybin's therapeutic efficacy and safety may depend in part on patient screening and preparation, psychotherapeutic support, and a conducive physical and interpersonal setting[i]. Accordingly, the treatment will include psilocybin dosing sessions alongside a program of specialised psychotherapy. The treatment will be facilitated by experienced and qualified clinicians who have undergone substantive training in psilocybin-assisted psychotherapy, and channels to procure cGMP psilocybin have been established. Treatment will take place within BrainPark at Monash University, a state-of-the-art research platform that is unparalleled in its ability to support this unique form of treatment. A number of major innovations in treatment design will be developed.

Next Steps

IHL will conduct a Pre-Investigational New Drug (Pre-IND) meeting with the US Food and Drug Administration ('FDA') as soon as practicable. The Pre-IND meeting will provide Incannex with the ability to seek advice from the FDA on the proposed clinical trial protocol. Following FDA feedback, the protocol will be adjusted as required so that the trial may become one of the pivotal trials necessary for marketing approval. Once the protocol has been updated, trial investigators will apply for Human Research Ethics Committee approval in Australia to commence patient recruitment, with psilocybin available for use within approved clinical research trials.

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[ii].
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)[iii]. 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.

Psilocybin-assisted psychotherapy research

Evidence is accumulating that psychotherapy assisted by psilocybin can provide significant and lasting benefit across a range of mental health and addiction disorders[iv]. Psilocybin is a psychoactive molecule that occurs naturally in several genera of mushrooms, primarily acts on the serotonin receptor system, and can modulate states of consciousness, cognition, perception, and mood[v]. When combined with specialised forms of psychotherapeutic support, psilocybin can be both a safe and highly effective mental health treatment[vi]. Through the 1950s and 1960s, tens of thousands of individuals participated in psychedelic research[vii]. While methodologically limited by modern standards, the findings from many of these studies showed substantial improvements in anxiety, depression, alcohol use disorder, and quality of life[viii]. Following a few decades of socio-political obstruction to psychedelic treatments, an increasing number of clinical psychedelic trials are now being conducted at highly esteemed institutions around the world. Recent research indicates that psilocybin-assisted psychotherapy may be an effective treatment for major depressive disorder, depression and anxiety associated with terminal illness, alcohol use disorder, smoking addiction, and other conditions[ix]. Currently, two psilocybin research programs for depression have received Breakthrough Designation from the US Food and Drug Administration[x], and along with the trial reported herein, a small number of other psilocybin treatment development programs are underway globally[xi]. Should the results from any of these trials be positive, registration of psilocybin-assisted psychotherapy as a prescription treatment could occur within the next five years.

Dr Paul Liknaitzky, Chief Principal Investigator of the trial, said: *"This trial, and the associated partnership between IHL and Monash University, represents a major leap forward for psychedelic research and development in Australia, and will have a substantial impact on the field globally. I'm heartened by the support of IHL, and their ethical approach to supporting scientifically independent and patient-focused treatment development. I'm inspired by our esteemed and brilliant research and clinical team at Monash, and the strong support from the University. And I'm confident that we will conduct a highly rigorous, patient-focused, world-class trial to assess the safety and efficacy of this treatment approach for people dealing with severe anxiety. Given the early yet highly promising results from other psilocybin trials for different conditions, this treatment – alongside innovations we will develop – may deliver a substantial step forward in the treatment of anxiety disorders."*

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 developing unique medicinal cannabis products for the treatment of Obstructive Sleep Apnoea (OSA), Traumatic Brain Injury (TBI)/Concussion, Acute Respiratory Distress Syndrome (ARDS) and Temporomandibular Joint Disorder (TMD). FDA registration, where being sought, is subject to clinical success.

Each indication represents major global markets and currently have no existing registered pharmacotherapy (drug) treatment, raising the possibility of patients receiving Government subsidies for products that demonstrate suitable safety and efficacy profiles in clinical trials.

IHL has a strong intellectual property strategy (e.g., 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) and it develops its products in conjunction with its Medical Advisory Board.

Further to its clinical programs, Incannex has its Australian license to import, export and distribute medicinal cannabis products and has launched a line of cannabinoid oil products. The cannabis-based oils are sold under Incannex's product supply and distribution agreement with Cannvalate Pty Ltd, which is the largest network of cannabis medicine prescribers in Australia and a major shareholder of IHL.

Website: www.incannex.com.au

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[x] https://www.businesswire.com/news/home/20191122005452/en/FDA-grants-Breakthrough-Therapy-Designation-Usona-Institutes
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Appendix 1