Date: 9th July 2020
ASX Announcement (ASX: IHL)

# Incannex Partners with The Alfred and Novotech on IHL-42X Clinical Program for Obstructive Sleep Apnoea

**Highlights:**

- Incannex has partnered with The Alfred Hospital in Melbourne from where the trial will be based
- Professor Terence O'Brien is named as Principal Investigator; a world-renowned clinician and highly experienced Principal Investigator of more than 100 clinical trials
- Professor O'Brien heads the Neuroscience Clinical Trials Unit at The Alfred Hospital and has an experienced team of study coordinators and research nurses
- The primary endpoint of the clinical trial is the improvement in AHI as measured by an overnight polysomnography ('PSG')
- Trial protocol to be submitted to the Alfred Health Ethics Committee, registration of the project will occur on or before 27th July 2020 with full submission by August 5th 2020
- IHL will endeavour to:
    - supply the IHL-42X product for sale in Australia under the Special Access Scheme
    - proceed to the second Phase 2 'Factorial' clinical trial as it compiles the necessary information for a 505(b)(2) new drug application for exclusive marketability
- Incannex partners with Novotech, who are internationally recognised as a leading full-service contract research organisation; engaged to ensure that the IHL-42X clinical trial meets the requirements of the FDA
- IHL-42X is targeting the OSA market with an addressable market of US$10B per annum for which there is no existing pharmacological (drug) treatment
- Animal study for the assessment of IHL-675A against Sepsis Associated ARDS has been completed, with the results expected from Eurofins Taiwan very soon.

Clinical stage cannabinoid development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to provide an update on material changes and improvements that have been made to the clinical trial protocol for its upcoming Phase 2b dose finding crossover trial investigating the effect of IHL-42X on the Apnoea Hypopnea Index ('AHI') in adults diagnosed with Obstructive Sleep Apnoea ('OSA').

***The Alfred Hospital and Professor Terence O'Brien***

Incannex has partnered with The Alfred Hospital in Melbourne, from where it will base the trial. The Alfred is one of Australia's busiest emergency and trauma centres, is Victoria's largest Intensive Care Unit and is home to multiple state-wide services. The Alfred Campus is the largest centre in Australia for Clinical Trials, with a particular focus on early stage clinical trials.

The principal investigator of the trial is Professor Terence O'Brien (MB, BS, MD, FRACP, FRCPE, FAHMS, FAES), who is The Van Cleef Roet Professor of Medicine (Neurology), Head, Departments of Neuroscience and Medicine, and Deputy Head of School, Central Clinical School, Monash University. He also heads the Neuroscience Clinical Trials Unit at The Alfred and has an experienced team of study coordinators and research nurses that are an integral part of the trials team.

Professor O'Brien is a specialist in neurology and clinical pharmacology, with expertise in epilepsy and related brain diseases, including traumatic brain injury, brain tumours and neurodegenerative diseases, neuropharmacology and in-vivo imaging in animal models and humans. Professor O'Brien was formerly The University of Melbourne's James Stewart Chair of Medicine and Head of the Department of Medicine at the Royal Melbourne Hospital (2008-17).

He has been the Principal Investigator of more than 100 commercially sponsored and investigator-initiated trials and is Chair of the Australian Epilepsy Clinical Trial Network. He has published more than 395 peer-reviewed papers in leading scientific and medical journals, which have been cited approx. 14,000 times.

***Clinical Trial Design and Endpoints***

Patients will be assessed at The Alfred Hospital sleep clinic. A baseline sleep clinic visit will confirm patient OSA diagnoses and establish baseline levels for AHI as measured by an overnight PSG. Thereafter, patients will receive treatment with IHL-42X followed by additional sleep clinic visits to assess improvement in AHI relative to baseline.

Secondary outcomes include the following:

- Reduction in oxygen desaturation index (ODI)
- Daytime somnolence measured by the Epworth Sleepiness Scale
- Improvement in mood as measured by the POMS (Profile of Moods State), and well-being as measured by the Short Form 36
- Safety of the IHL-42X combination will be established through adverse event monitoring.

***Alfred Health Ethics Committee Submission***

The responsibility for the ethical design, review and conduct of human research is exercised principally by researchers and the Alfred Health Ethics Committee. Meetings of the Ethics Committee occur periodically and IHL will register its trial for review by the next registration deadline, which is the 27th of July 2020.

***Formulated IHL-42X***

IHL will endeavour to supply IHL-42X for sale in Australia under the Special Access Scheme for unregistered medicinal cannabis products, alongside its existing range of cannabinoid oils and CBD Inhaler.

IHL will also proceed to the second Phase 2 'Factorial' clinical trial as it compiles the necessary information for a 505(b)(2) new drug application for exclusive marketability; details of which were released in the

announcement on the 25th of March 2020 and entitled, "IHL-42X (OSA) accelerated FDA approval pathway".

***Partnership with Novotech***

Incannex has contracted the services of Novotech, the Asia-Pacific CRO, established in 1996 and has grown into a full-service Contract Research Organisation (CRO), with offices in 11 locations across the Asia Pacific region. In 2018, Novotech acquired Clinical Network Services (CNS), an integrated service group focused on product development headquartered in Australia with offices in New Zealand, the UK and the USA. Novotech has been instrumental in the success of over 1000 Phase I - IV clinical trials for biotechnology companies.

Novotech provides clinical development services across all clinical trial phases and therapeutic areas including: feasibility assessments; ethics committee and regulatory submissions, data management, statistical analysis, medical monitoring, safety services, central lab services, report write-up to ICH requirements, project and vendor management.

The partnership with Novotech will ensure the integrity of the IHL-42X program, further ensuring that the IHL-42X clinical trial meets the requirements of the FDA in relation to site management, data collection, analysis, and safety monitoring.

**Managing Director and CEO of Incannex Healthcare, Mr Joel Latham said**, "Whilst we have been modestly delayed by limitations experienced by COVID-19 measures, we're delighted to have partnered with The Alfred and it's credentialed team.

Professor O'Brien is a highly experienced medical clinician and clinical trial investigator. He lends strong credibility to our study, which is important due to our goal of making a new drug application with the FDA for drug registration, subject to ongoing clinical success".

The onset of COVID-19 and the ensuing lockdown that occurred in March of 2020 threw doubt over the ability of hospitals to be involved in any clinical trial activities. As a result, the Board of Incannex was determined to push forward with its trial and initially designed the trial around participants using portable measuring devices that, once fitted under the instruction of a sleep specialist, could be worn at home and feed data back to a central hub.

However, as restrictions began to ease and appropriate trial management protocols were put in place, the participation of hospitals in clinical trial activity became clearer, and the Company identified The Alfred as being the ideal partner in the IHL-42X trial.

After the recent protocol changes, each patient will have their own room for the sleep study, adhering to social distancing rules. The Company has also been advised by its regulatory consultants that its newly designed trial in partnership with The Alfred will provide a more robust and comprehensive trial, which will be important in its pursuit of registration under the FDA 505b(2) pathway.

***About Obstructive Sleep Apnoea***

OSA is a lethal disease that increases the risk of numerous health complications, affecting approximately 40M adults in the USA alone. Untreated OSA is associated with an increased risk of cardiovascular morbidity. The main current treatment option is the mechanical CPAP device. Patient compliance to CPAP devices is low due to discomfort and claustrophobia.

The current direct global annual market size for OSA detection and treatment using CPAP devices is over US$10B per annum and growing. There is no existing registered pharmacotherapy (drug) treatment option for sufferers of OSA and IHL anticipates greatly improved patient treatment compliance from a once-nightly oral pharmaceutical product, such as IHL-42X, should it prove successful under clinical assessment.

**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:

Mr Joel Latham, Managing Director and Chief Executive Officer
P: +61 409 840 786
E: joel@incannex.com.au

**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.

There is an established body of research validating the hypothesis for the cannabinoids being used in Incannex's chosen therapeutic areas and 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 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.

**Investors:** investors@incannex.com.au