Incannex engages Fortrea to Manage its FDA IND Opening Phase 2/3 Clinical Trial Investigating IHL-42X for Treatment of Obstructive Sleep Apnoea

Highlights:

- Incannex has engaged Fortrea as the contract research organisation ('CRO') to manage the IND opening Phase 2/3 clinical trial investigating IHL-42X for treatment of OSA.
- The Phase 2/3 clinical trial will assess the safety and efficacy of IHL-42X in people with OSA who are intolerant, non-compliant, or naïve to continuous positive airway pressure ('CPAP').
- The extensive trial will be conducted across 45 sites, including many in the United States.
- Fortrea will implement its technology enabled clinical trial solutions designed to increase drug development efficiency, reduce timelines, and improve compliance.
- There are no registered pharmacotherapy (drug) treatments available to people with OSA, representing a major economic opportunity to Incannex with IHL-42X, should the study achieve its endpoints as in the proof of concept trial.

Melbourne, Australia, July 18, 2023 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has engaged Fortrea (Nasdaq: FTRE) as the contract research organisation ('CRO') for management of the IND opening Phase 2/3 clinical trial investigating IHL-42X for treatment of OSA.

The Phase 2/3 clinical trial will assess the safety and efficacy of IHL-42X at the best performing two doses from the proof-of-concept clinical trial, in patients with OSA who are intolerant, non-compliant, or naïve to positive airway pressure, over a 52-week treatment period. Participants will receive one of IHL-42X, dronabinol, acetazolamide or placebo for the entirety of the study. All participants will complete daily surveys on their sleep quality, attend monthly clinic visits to assess functional outcomes of sleep, cognitive function and other measures of safety and efficacy. Every three (3) months, overnight polysomnography will be conducted to determine the effect of treatment on the patients' Apopnea Hypopnea Index score ('AHI'). All drug treatments will be compared to placebo.

Fortrea, formerly Labcorp Drug Development's Clinical Development and Commercialization Services, was previously engaged to conduct a 12-week operational feasibility study where the trial design was provided to potential investigators along with a survey to gauge interest in conducting the study and identify any region-specific regulatory hurdles. This study involved contacting 195 potential trial sites

across 14 countries in North America, Europe, South America, and Australasia. Sixty-three sites expressed interest in participating in the IHL-42X study. Incannex is targeting 45 clinical trial sites to be included in the study and recently appointed two highly experienced lead principal investigators to the study.

Fortrea will use its high-value data sets, combined with its technology enabled clinical trial solutions to improve study recruitment, reduce study risk, safeguard data quality, and gain operational insights as the trial progresses.

CEO and Managing Director of Incannex, Mr Joel Latham said, "The initial Phase 2 proof of concept clinical trial over IHL-42X demonstrated an average reduction in our primary end point, AHI of 50.7%, with 25% of subjects having a reduced AHI of >80%. Importantly, we also observed a reduction in average patient oxygen desaturation index of 59.7%, markedly improved sleep quality and a reduction in cardiovascular stress. These results were truly remarkable and now allows for this Phase 2/3 trial to be a genuine long-term safety and efficacy trial. If we again observe such remarkable drug efficacy, safely administered over the 52 weeks, Incannex is confident that our product will be marketable."

"Fortrea has been a valuable partner to Incannex for a long time over multiple projects and we have full confidence that its team will successfully manage this very important trial. Fortrea's familiarity with the study and established relationships with potential trial sites will expedite the study start up and site engagement activities."

This announcement has been approved for release to ASX by the Incannex Board of Directors.

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About IHL-42X

IHL-42X is a synergistic composition of dronabinol, a synthetic form of Tetrahydrocannabinol (THC), and acetazolamide, a Carbonic anhydrase inhibitor. Results from a Phase 2 proof of concept clinical trial undertaken by Incannex were published in 2022. Incannex observed that IHL-42X reduced average apnoea-hypopnoea index ('AHI') by an average of 50.7% versus baseline assessments and 25% of participants experienced greater than an 80% reduction in the AHI. No serious treatment emergent adverse events were reported during the clinical trial. Furthermore, THC concentrations in blood were below the limits for impaired driving the morning after nocturnal dose administration of IHL-42X.

About Obstructive Sleep Apnoea

OSA is the most common sleep-related breathing disorder. It involves the narrowing of the upper airway during sleep, interfering with a person's breathing, decreasing oxygen uptake, resulting in poor-quality sleep[1]. Untreated OSA leads to serious long-term adverse health outcomes including hypertension,

cardiovascular disease, heart attack, cognitive impairments, anxiety and depression, irritability and daytime fatigue increasing the risk of accidents. There are no pharmacotherapy (drug) treatments available to those afflicted.

The current 'standard of care' is the Continuous Positive Airway Pressure ('CPAP') machine. However, patient compliance to CPAP is low due to various factors related to patient discomfort. Incannex anticipates greatly improved treatment compliance and outcomes from a pharmaceutical product, such as IHL-42X, subject to further clinical assessment and approval from regulators.

Regardless of the discomfort caused by CPAP, the global annual market for OSA detection and treatment using CPAP and other breathing aides is approximately US$10 billion per annum and growing[2]. OSA is highly prevalent, affecting approximately 30 million adults in the United States alone. It is estimated that the annual economic burden of undiagnosed sleep apnoea among U.S. adults is approximately US$149.6 billion per annum. These costs include US$86.9 billion in lost productivity, US$26.2 billion in motor vehicle accidents and US$6.5 billion in workplace accidents[3].

References

[1]https://www.mayoclinic.org/diseases-conditions/obstructive-sleep-apnea/symptoms-causes/syc-20352090
[2]https://www.fortunebusinessinsights.com/industry-reports/sleep-apnea-devices-market-100708
[3]https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf

About Incannex Healthcare Limited

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis 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 19 granted patents and 30 pending patent applications. Incannex is listed on the Australian Stock Exchange (ASX) with stock code "IHL" and has American Depository Shares listed on NASDAQ under code "IXHL".

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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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