Incannex Receives IRB Approval for the RePOSA Phase 2/3 Clinical Trial Protocol to Assess IHL-42X Drug in Patients with Obstructive Sleep Apnea

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MELBOURNE, Australia and NEW YORK, Jan. 17, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), ('Incannex' or the 'Company'), a pharmaceutical company developing unique medicinal cannabinoid pharmacotherapies and psychedelic medicine therapies is pleased to announce that an independent Institutional Review Board (IRB) has approved the protocol for the Company's Phase 2/3 clinical trial to be conducted in the United States to assess safety and efficacy of proprietary combination drug candidate IHL-42X in patients with obstructive sleep apnea (OSA). IRB approval of the protocol is a key step in activation of clinical trial sites for the RePOSA study.

Under regulations of the Food & Drug Administration, IRB approval is required prior to commencing research in human subjects and serves to ensure that appropriate measures are in place to protect the rights and welfare of research participants. The approval process involves review of the research protocol, informed consent procedures, recruitment materials, and participant risk versus benefit analysis.

The RePOSA Clinical Trial

The RePOSA study is a Phase 2/3, randomised, double-blind clinical trial to determine the safety and efficacy of IHL-42X in subjects with OSA who are intolerant, non-compliant, or naïve to positive airway pressure (PAP), such as that administered via a continuous positive airway pressure (CPAP) machine.

The RePOSA study consists of two component studies. A four-week Phase 2 dose ranging trial that will determine the optimal dose of IHL-42X based on safety and efficacy in OSA patients, and a 52-week Phase 3 factorial trial that will compare the optimal dose of IHL-42X to the component APIs, dronabinol and acetazolamide, at equivalent doses, as well as placebo. The study is designed to facilitate a seamless transition between Phase 2 and Phase 3, reducing downtime and accelerating development timelines.

The endpoints, inclusion criteria and study procedures are the same across both component studies, which streamlines the transition process from Phase 2 to Phase 3. The target patient population is individuals aged 18 years or older with OSA who are intolerant, non-compliant or naïve to Positive Airway Pressure. At least 560 patients will be recruited, with a total of 355 patients receiving IHL-42X over the course of the study. RePOSA is registered on clinicaltrials.gov with identification code NCT06146101.

Start-up for the Phase 2/3 trial is in progress with 24 sites selected in the United States, 13 in Germany, 4 in Spain and 2 in Finland. IRB approval of the protocol allows the U.S.-based sites to proceed with site-specific approval, which is a critical step in site activation.

The RePOSA study follows a Phase 2 proof-of-concept study whereby IHL-42X reduced apnea hypopnea index (AHI), the main measure used to diagnose and monitor OSA, by greater than 50% at the optimal dose, which was the low dose in the study. At the low dose of IHL-42X patient changes in AHI relative to baseline revealed that, during the treatment period, 62.5% of patients experienced a reduction in AHI of greater than 50% and 25 % of patients experienced a reduction in AHI of greater than 80%. IHL-42X also improved participant oxygen desaturation index, sleep efficiency, and patient reported sleep quality. IHL-42X was well tolerated in the study.

About Obstructive Sleep Apnea (OSA)

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 Positive Airway Pressure (PAP) machine. However, patient compliance to PAP 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 PAP, the global annual market for OSA detection and treatment using PAP 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 Inc.

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabinoid 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 20 granted patents and over 30 pending patent applications.

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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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