Patient dosing commenced in RePOSA Phase 2/3 Clinical Trial Protocol to Assess IHL-42X Drug in Patients with Obstructive Sleep Apnea

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NEW YORK and MELBOURNE, Australia, May 30, 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 patient dosing has commenced in the Company's Phase 2/3 clinical trial to assess safety and efficacy of IHL-42X in patients with obstructive sleep apnea ('OSA').

IHL-42X is the Company's proprietary fixed dose combination drug for treatment of obstructive sleep apnea. Commencement of patient dosing in the United States represents a significant milestone in its development. Initiating dosing in the trial follows the opening of an Investigational New Drug (IND) application with the FDA and a Phase 2A study completed in 2022 whereby Incannex observed IHL-42X to reduce the apnea hypopnea index (AHI), the standard measure of OSA, by an average of greater than 50% at the low dose in the study. Furthermore, 25% of patients experienced a reduction in AHI of greater than 80%, representing a sub clinical AHI score for some trial participants.

Dr Mark Bleackley, Incannex Chief Scientific Officer said, "Patient dosing in the RePOSA study represents a critical step forward in the development of IHL-42X for treatment of obstructive sleep apnea. There are currently no registered pharmacotherapies available to patients and poor compliance to positive air way pressure devices means that many patients with sleep apnea are left untreated or chronically under-treated. IHL-42X has the potential to address this unmet need, improving the direct effects of sleep apnea, as well as the associated long-term health, and quality of life, impacts on this patient population. We look forward to working with trial sites and investigators to continue to recruit and dose patients in the RePOSA trial"

Joel Latham, Incannex CEO and President said, "We are thrilled to announce this significant milestone for our company, being first patient dosing in a major clinical trial assessing our IHL-42X candidate. This achievement marks a pivotal step forward in addressing a significant unmet medical need, as there are no orally administered pharmaceutical products registered with FDA for patients with sleep apnea. Therefore, the potential market for IHL-42X is immense, and its success could revolutionize the treatment landscape for this serious medical condition. We believe that, if successful, our drug will not only unlock tremendous commercial value but also significantly enhance shareholder value".

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 trial is designed to facilitate a seamless transition between Phase 2 and Phase 3, intended to reduce downtime, accelerating time to commercial product development.

The endpoints, inclusion criteria and study procedures are the same across both component studies, streamlining the transition 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. Phase 2 of the RePOSA study will be conducted at 25 sites in the United States. Phase 3 will extend the study to 30 additional sites across the EU and UK.

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. Incannex is listed and publicly traded on Nasdaq (NAS: IXHL), providing investors an opportunity to participate in the Company's growth.

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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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