Incannex Healthcare Inc. Provides Clinical Program Update on IHL-42X, an Oral Once-Daily Treatment for Obstructive Sleep Apnea (OSA)

May 14, 2025

- Patient dosing completed in Phase 2 portion of Phase 2/3 RePOSA study evaluating IHL-42X oral treatment for OSA.
- End-of-study follow-up assessments on track for completion by May 17, 2025.
- Topline results expected in July 2025.

NEW YORK and MELBOURNE, Australia, May 14, 2025 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), (Incannex), a clinical-stage biopharmaceutical company leading the way in developing oral combination medicines, today provided an update on its obstructive sleep apnea (OSA) clinical program and outlined key upcoming catalysts in the development of IHL-42X.

"We are pleased with the rapid completion of patient dosing in the Phase 2 study," said Joel Latham, President and CEO of Incannex. "The IHL-42X program continues its strong momentum as we prepare for data analysis and advance toward our end-of-Phase 2 meeting with the FDA. The third quarter of 2025 represents a pivotal period of progress for the company. With the successful completion of Phase 2 enrollment, encouraging pharmacokinetic and safety data, and expanded clinical advisory expertise, we are well-positioned to advance IHL-42X as a potential first-in-class oral treatment for millions of patients living with OSA."

"Obstructive sleep apnea affects millions globally and is closely linked to other serious conditions including obesity, cardiovascular disease, and metabolic dysfunction. Incannex believes that IHL-42X will offer a significant breakthrough in a therapeutic area long dominated by mechanical interventions like CPAP devices. We believe IHL-42X is uniquely positioned to address one of the most prevalent sleep disorders worldwide."

"We have also engaged in several promising commercial discussions regarding IHL-42X and look forward to continuing these as we work to deliver maximum value for our shareholders. The enthusiasm shown by U.S. clinical sites and trial participants has further reinforced our decision to conduct Phase 3 exclusively in the United States, ensuring a focused and efficient development pathway."

Clinical and Program Updates:

- Patient dosing in the Phase 2 portion of the Phase 2/3 study was completed on May 8, 2025. End-of-study follow-up assessments are expected to conclude by May 17, 2025 and topline data is anticipated in July 2025. Ahead of the data readout, Incannex is preparing for an end-of-Phase 2 meeting with the FDA to discuss results and next steps toward a 505(b)(2) NDA submission.
- RePOSA Phase 3 planning is underway and will be conducted exclusively at U.S. sites to improve operational efficiency. This decision was supported by U.S. clinical site and patient enthusiasm. The study will recruit 440 patients across sites including those rolled over from the Phase 2 trial portion.
- As the asset advances in clinical development, Incannex has started to engage in preliminary commercial discussions that reflect growing interest in the IHL-42X program and its position in the OSA treatment market.

Unlike weight loss therapies, IHL-42X is uniquely engineered to target two key physiological pathways, intermittent hypoxia (IH) and hypercapnia, that underlie the pathology of OSA. This differentiated mechanism positions IHL-42X as a potential treatment option for a broader OSA population, including the 67% of patients who are not obese, as reported in a recent publication examining the link between obesity and OSA[1].

In a previously completed Phase 2 clinical trial conducted in Australia, IHL-42X demonstrated clinically meaningful reductions in the Apnea-Hypopnea Index (AHI) across all dose levels, with the lowest dose reducing AHI by an average of 51% from baseline. A subsequent peer-reviewed publication analyzing this trial, further clarified IHL-42X's mechanism of action and the treatment was shown to improve OSA severity by lowering loop gain and enhancing upper airway stability [2].

Importantly, the analysis also found that IHL-42X significantly reduced hypoxic burden (HB)—a more comprehensive and clinically relevant measure of OSA severity than AHI alone, as it captures both the depth and duration of oxygen desaturation events[2]. Elevated HB has been strongly correlated with cardiovascular morbidity and all-cause mortality, reinforcing the therapeutic potential of IHL-42X as a once-daily, oral treatment capable of addressing a critical unmet need in sleep medicine.

For more information on the IHL-42X clinical program, please visit www.incannex.com.

About IHL-42X

IHL-42X is designed to treat OSA by targeting its underlying pathophysiology. An oral fixed-dose combination of dronabinol and acetazolamide, IHL-42X is currently advancing through the RePOSA Phase 2/3 clinical trial, which is expected to enroll more than 560 patients at sites worldwide.

Designed to act synergistically, IHL-42X uniquely targets two physiological pathways associated with the intermittent hypoxia (IH) and hypercapnia that characterize OSA. In a prior Australian Phase 2 clinical trial, IHL-42X was shown to reduce the Apnea-Hypopnea Index (AHI) in all dosage strengths, with the lowest dose reducing AHI by an average of 51 percent relative to baseline. RePOSA, a global Phase 2/3 clinical trial is underway, evaluating IHL-42X in individuals with OSA who are either non-compliant, intolerant, or naïve to positive airway pressure devices, including CPAP, with the Phase 2 portion conducted in the United States. A topline readout from the U.S. Phase 2 portion is anticipated in July 2025.

About Incannex Healthcare Inc.
Incannex is leading the way in developing combination medicines that target the underlying biological pathways associated with chronic conditions, including obstructive sleep apnea, rheumatoid arthritis and generalized anxiety disorder. The company is advancing three clinical-stage product candidates based on evidence-based innovation, and supported by streamlined operations. Incannex's lead clinical program, IHL-42X, is an oral fixed-dose combination of dronabinol and acetazolamide designed to target underlying mechanisms and act synergistically in the treatment of obstructive sleep apnea. In a Phase 2 development program, IHL-675A is an oral fixed-dose combination of cannabidiol and hydroxychloroquine sulfate designed to act synergistically to alleviate inflammatory conditions, such as rheumatoid arthritis. Approved for Phase 2 clinical development, PSX-001 is an oral synthetic psilocybin treatment for the treatment of generalized anxiety disorder. Incannex's programs target disorders that have limited, inadequate, or no approved pharmaceutical treatment options. For additional information on Incannex, please visit our website at www.incannex.com.

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. Examples of forward-looking statements in this press release include statements about, among other things: Incannex's business strategy, future operations; Incannex's ability to execute on its objectives, prospects, or plans, the skills and experience of the newly appointed officer of Incannex and expectations with respect to his future contributions to the Company and statements, evaluations and judgments regarding Incannex's research and development efforts, including any implications that the results of earlier clinical trials will be representative or consistent with later clinical trials or final results; the expected timing of enrollment for these trials and the availability of data or results of these trials, and the potential benefits, safety or of Incannex's drug candidates. Forward-looking statements are statements other than historical facts and relate to future events or circumstances or Incannex's future performance, and they are based on management's current assumptions, expectations, and beliefs concerning future developments and their potential effect on Incannex's business. These forward-looking statements are subject to a number of risks and uncertainties, which may cause the forward-looking events and circumstances described in this press release to not occur, and actual results to differ materially and adversely from those described in or implied by the forward-looking statements. These risks and uncertainties include, among others: the continued availability of financing; Incannex's ability to raise capital to fund continuing operations and to complete capital raising transactions; the impact of any infringement actions or other litigation brought against Incannex; the success of Incannex's development efforts, including Incannex's ability to progress its drug candidates through clinical trials on the timelines expected; competition from other providers and products; that the market for its drug candidates may not grow at the rates anticipated or at all; Incannex's compliance with the various evolving and complex laws and regulations applicable to its business and its industry; and Incannex's ability to protect its proprietary technology and intellectual property; and other factors relating to Incannex's industry, its operations and results of operations. The forward-looking statements made in this press release speak only as of the date of this press release, and Incannex assumes no obligation to update publicly any such forward-looking statements to reflect actual results or to changes in expectations, except as otherwise required by law. Incannex's reports filed with the U.S. Securities and Exchange Commission (SEC) including its annual report on Form 10-K for the fiscal year ended June 30, 2024, filed with the SEC on September 30, 2024, and the other reports it files from time to time, including subsequently filed annual, quarterly and current reports, are made available on Incannex's website upon their filing with the SEC. These reports contain more information about Incannex, its business and the risks affecting its business, as well as its results of operations for the periods covered by the financial results included in this press release. For additional information on Incannex, please visit our website at www.incannex.com.

Contact Information
Jennifer Drew-Bear
Edison Group for Incannex
Jdrew-bear@edisongroup.com

[1] https://doi.org/10.1016/j.eclinm.2025.103221

[2] https://doi.org/10.1016/j.sleep.2025.106542