Incannex Reports Positive Topline Results from RePOSA Phase 2 Trial of IHL-42X

July 30, 2025

Statistically and clinically significant improvements across key clinical endpoints; IHL-42X reduced AHI by up to 83% from baseline. IHL-42X demonstrates compelling clinical benefit and an outstanding safety profile that exceeded expectations.

NEW YORK and MELBOURNE, Australia, July 30, 2025 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL) ("Incannex" or the "Company") is excited to share positive topline results from its RePOSA Phase 2 clinical trial evaluating IHL-42X, a novel oral drug candidate for obstructive sleep apnoea (OSA). With over 900 million people affected globally and no approved oral pharmaceutical treatments currently available, IHL-42X's robust efficacy and exceptional safety profile position it as a potential transformative therapy for OSA patients worldwide. The results confirm statistically significant and clinically meaningful improvements across key endpoints assessed in the study, reinforcing IHL-42x's potential as a best-in-class therapy for patients with OSA.

Compelling Clinical Efficacy
The RePOSA Phase 2 trial demonstrated clear statistically and clinically significant improvements across multiple key endpoints for patients receiving IHL-42X compared to placebo, highlighting its potential to reduce OSA severity and enhance patient quality of life:

- **Apnoea-Hypopnoea Index (AHI):** The low-dose and high-dose IHL-42X groups achieved a statistically significant reduction in percent change in AHI from baseline compared to placebo ($p<0.05$), the primary measure of OSA severity. Maximum reductions in AHI were observed at up to 83% for the high-dose group and up to 79% for the low-dose group. Notably, 33.3% of patients in the low-dose group and 41.2% in the high-dose group achieved a greater than 30% reduction in AHI, while 13.9% (low-dose) and 14.7% (high-dose) experienced reductions exceeding 50%—demonstrating a strong therapeutic response in a substantial subset of the population.
- **Patient Global Impression of Change (PGI-C) Sleep related impairment**: The low-dose IHL-42X group showed statistically significant improvement ($p<0.05$), reflecting meaningful patient-perceived benefits.
- **PGI-C Fatigue**: Statistically significant improvement in the low-dose group, suggesting enhanced daytime alertness and reduced fatigue.
- **Oxygen Desaturation Index (ODI)**: Both low- and high-dose groups demonstrated statistically significant improvements, indicating better oxygenation during sleep.
- **Patient-Reported Outcomes**: IHL-42X led to clinically significant improvements in patient-reported outcome measures, including the Functional Outcomes of Sleep Questionnaire-10 (FOSQ-10), PROMIS Sleep-Related Impairment 8a (PROMIS-SRI 8a), PROMIS Fatigue 7a, and Epworth Sleepiness Scale (ESS) in both low- and high-dose groups, demonstrating enhanced sleep quality, reduced daytime fatigue, and improved daily functioning for patients with OSA.
- **Polysomnography (PSG) Metrics**: IHL-42X drastically improved objective sleep parameters as measured by PSG.
    - **Wake After Sleep Onset (WASO)**: Reduced by 29.8% in the high-dose arm, meaning patients spent less time awake during the night.
    - **AHI During Supine Sleep**: Decreased by 30.3% in the high-dose arm, a critical improvement given supine sleep exacerbates apneic events.

These results collectively demonstrate IHL-42X's ability to address both objective and subjective aspects of OSA, offering compelling clinical benefits to patients.

Outstanding Safety Profile
IHL-42X was well tolerated across both low- and high-dose cohorts. No serious adverse events were reported during the treatment period, and treatment-emergent adverse effects (TEAEs) were infrequent, with the majority being mild or moderate in severity. This excellent safety profile supports IHL-42X's potential for broad patient use.

Joel Latham, CEO and President of Incannex, commented: "We are extremely pleased with the RePOSA trial results. The combination of statistically significant improvements across multiple endpoints and an outstanding safety profile positions IHL-42X as one of the most compelling drug candidates in the global race to bring a pharmaceutical treatment for OSA to market. The depth of response seen in a defined subset of patients further reinforces our belief in its clinical and commercial potential. These

results are a clear signal of the strength of our development strategy and a critical step forward in building long-term shareholder value. We continue to facilitate commercial discussions and look forward to providing shareholders with an update in this regard soon."

Dr. Mark Bleackley, Chief Scientific Officer of Incannex, added:
"These findings highlight the statistically significant treatment effects observed across multiple measures of disease severity and patient experience. Combined with an excellent safety and tolerability profile, the results provide strong validation of IHL-42X's potential as an innovative and impactful therapy for obstructive sleep apnea."

Next Steps
With positive Phase 2 data in hand, Incannex is now focused on advancing IHL-42X toward commercial readiness. Preparations are in progress for the Company's End-of-Phase 2 meeting with the FDA, where discussions will focus on identifying the most efficient and effective path to registration. This engagement is expected to provide critical guidance for optimising the Phase 3 trial design and regulatory strategy.

In parallel, Incannex will continue to evaluate all clinical data and complete the full Clinical Study Report in the coming months. These strategic activities mark a new phase of execution for Incannex as it progresses toward late-stage development and possible future commercialisation.

RePOSA Phase 2 Trial Overview
The RePOSA Phase 2 trial was a randomized, double-blind, placebo-controlled clinical study designed to evaluate the safety, tolerability, and efficacy of IHL-42X, a novel oral drug candidate for the treatment of obstructive sleep apnoea (OSA). The study enrolled 121 adult participants with confirmed moderate to severe OSA, who were randomized to receive either a high dose, low dose, or placebo version of IHL-42X for a 28-day treatment period. Efficacy was assessed using both objective and patient-reported outcome measures aligned with FDA guidance, including the primary endpoint of change in Apnea-Hypopnoea Index (AHI) as measured by polysomnography (PSG). Key secondary endpoints included the Oxygen Desaturation Index (ODI), Patient Global Impression of Change (PGI-C), Epworth Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ-10), and PROMIS fatigue and sleep-related impairment scores. The study was designed to generate high-quality clinical data to support the advancement of IHL-42X into Phase 3 development and regulatory discussions.

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. Forward-looking statements are statements other than historical facts and relate to future events, future circumstances and Incannex's future performance. These statements are based on management's current assumptions, expectations, and beliefs. 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, commercial discussions or plans; evaluations and judgments regarding Incannex's research and development efforts and potential future commercialization, including any implications that the results of earlier clinical trials or interim or topline results (such as the topline results of the RePOSA Phase 2 Study) will be representative or consistent with a full Clinical Study Report, later clinical trials or their respective interim or final results; the potential benefits and safety of Incannex's drug candidates and the market opportunity for these candidates; and potential shareholder value. 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, to complete capital raising transactions and to maintain or potentially further improve its capital structure; Incannex's ability to maintain the listing of its shares of common stock on the Nasdaq Stock Market; 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 (including its ability to successfully complete the Phase 3 trial for IHL-42) and to obtain necessary regulatory approvals for commercialization of its product candidates, including IHL-42; the effects of competition from other providers and products as currently existing or that may be developed in the future; that the market for its drug candidates may not grow at the rates anticipated or at all or that estimates for these markets may ultimately be incorrect; that Incannex may be unable to successfully execute upon any commercial discussions; Incannex's ability to comply 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 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.

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