Incannex Strengthens Clinical Development Pathway for IHL-42X Following Positive Phase 2 Outcomes

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Enhanced Phase 2 dose-optimization study designed to accelerate development and support a streamlined Phase 3 program

MELBOURNE, Australia and NEW YORK, March 12, 2026 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), a clinical-stage biopharmaceutical company developing innovative combination therapies, today announced an enhanced clinical development strategy for IHL-42X, its lead oral drug candidate for the treatment of obstructive sleep apnea (OSA), following statistically significant outcomes across key endpoints in its completed Phase 2 program.

Importantly, IHL-42X has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA), enabling more frequent interaction with the FDA as the program advances.

The updated development strategy includes a Phase 2 crossover dose-optimization study (DReAMzz), followed by a streamlined Phase 3 clinical program. This strategy is designed to optimize efficacy, strengthen the clinical data package, and potentially accelerate the pathway toward registration while maintaining strong capital efficiency.

“Following the strong, statistically significant outcomes from our Phase 2 RePOSA trial, we believe IHL-42X is emerging as one of the most promising oral therapies in development for obstructive sleep apnea,” said Joel Latham, President and Chief Executive Officer of Incannex Healthcare. “The optimization study we are initiating is designed to further refine the drug’s efficacy while strengthening the clinical package ahead of Phase 3. We believe the optimized study design provides a pathway that could accelerate development timelines, potentially shorten time to registration if successful, and allow us to progress efficiently through the end of Phase 3 development.”

Phase 2 Results Demonstrate Broad Clinical Benefit
Data from the completed RePOSA Phase 2 trial demonstrated that IHL-42X achieved statistically significant and clinically meaningful improvements across both objective physiological measures and patient-reported outcomes, reinforcing the therapeutic potential of the drug in OSA.

RePOSA demonstrated:

- 33.3% of patients in low-dose group and 41.2% in high-dose group achieved greater than 30% reduction in apnea-hypopnea index (AHI), while 13.9% (low-dose) and 14.7% (high-dose) experienced reductions exceeding 50%
- Maximum of 83% and 79% reduction in AHI for high and low dose IHL-42X respectively
- Preservation of REM sleep, differentiating from existing sleep medications
- 58% of participants reported their OSA condition improved. Among those, ~90% described the benefit as meaningful to daily life (better rest, reduced fatigue, improved function)
- No serious adverse events (SAEs)

The study demonstrated efficacy across both dose strengths, with differentiated performance observed between objective and subjective endpoints. This outcome highlights the robustness of the underlying drug combination and presents a clear opportunity to further optimize dosing to maximize benefit across all clinically relevant measures.

Data-Driven Optimization Strategy
Following a comprehensive review of the RePOSA data and discussions with the FDA, Incannex elected to conduct a Phase 2 crossover study evaluating alternative ratios of the two active pharmaceutical ingredients in IHL-42X, dronabinol and acetazolamide.

FDA feedback emphasized the importance of demonstrating benefits across both physiological endpoints and patient-reported outcomes, particularly in chronic diseases such as OSA. Given the statistically significant improvements already observed in both domains in RePOSA, Incannex believes the program is well positioned to advance into this next optimization phase with a strong clinical foundation.

DReAMzz Phase 2 Study Designed to Maximize Phase 3 Success
The DReAMzz Phase 2 crossover study will evaluate multiple ratios of dronabinol and acetazolamide to identify the optimal formulation that delivers consistent improvements across objective sleep and respiratory endpoints while maintaining meaningful

patient-reported benefits and the favorable safety profile observed to date.

The study design has been developed with input from Incannex's Obstructive Sleep Apnea Clinical Advisory Board, comprising world-leading experts in sleep medicine and respiratory disease, and has been reviewed by the FDA with agency feedback incorporated into the final protocol.

Importantly, Incannex has already appointed a leading contract research organization (CRO), and expects to begin dosing patients in the coming months.

Streamlined Phase 3 Program Supports Efficiency and Value Creation
Results from the DReAMzz study are expected to enable Incannex to advance into a highly efficient Phase 3 development program, potentially conducted under a single master protocol comprising parallel studies.

This optimized development design has several potential advantages, including accelerating the clinical development timeline, potentially shortening time to registration if successful, reducing overall development costs, and maximizing the probability of regulatory success.

By refining the optimal dose prior to Phase 3, Incannex believes this approach provides a capital-efficient pathway to completing late-stage development while maximizing the probability of clinical and regulatory success.

Unlocking the Full Potential of IHL-42X
Incannex believes the enhanced development strategy builds directly on the clinical outcomes already generated in RePOSA and represents the most effective pathway to advancing IHL-42X toward potential registration and commercialization.

With Fast Track designation, statistically significant Phase 2 results and a clearly defined regulatory pathway, Incannex believes IHL-42X is well positioned to continue advancing as a potential first-in-class oral therapy for obstructive sleep apnea.

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 drug 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: the objectives considered in the design of Incannex's clinical trials; evaluations and judgments regarding Incannex's research and development efforts and potential future commercialization, including any implications that the results (including qualitative patient-reported outcomes) of earlier clinical trials or interim or topline results will be representative or consistent with later clinical trials or their respective interim or final results; the potential benefits (including qualitative patient-reported outcomes) and safety of Incannex's drug candidates and the market opportunity for these candidates; Incannex's ability to execute on its strategies objectives, prospects, commercial discussions or plans; any statements regarding Incannex's beliefs with respect to or objectives in seeking or potential to obtain regulatory approvals or regulatory success, including any implication that communications with regulators affect the likelihood of obtaining any regulatory approvals in a timely and cost efficient manner or at all. 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: that Incannex may fail to maintain the listing of the Company's common stock on Nasdaq and to comply with applicable listing requirements; the closing price of the common stock may fall below $0.10 for ten consecutive trading days and be subject to Nasdaq's low bid price rules and subject to delisting or denial of compliance periods; the continued availability of financing; Incannex's ability to raise capital to fund continuing operations; 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 and to obtain necessary regulatory approvals for commercialization of its drug candidates; 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; 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, 2025, filed with the SEC on September 29, 2025, 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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