



Incannex Granted FDA Fast Track Designation for IHL-42X in Obstructive Sleep Apnea (OSA)

December 3, 2025

MELBOURNE, Australia and NEW YORK, Dec. 03, 2025 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), a clinical-stage biopharmaceutical company developing innovative combination therapies, announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for IHL-42X, the Company's oral fixed-dose combination product candidate for the treatment of obstructive sleep apnea (OSA).

The Fast Track designation was supported by promising safety, efficacy, and pharmacokinetic results from the three clinical trials completed to date within the IHL-42X development program. These include the Company's successful Phase 2 "RePOSA" study demonstrating statistically significant reductions in Apnea-Hypopnea Index (AHI), with individual reductions of up to 83%, outstanding patient-reported outcomes, and an excellent safety profile.

Fast Track designation is granted by the FDA to drug candidates that treat serious conditions and address unmet medical needs with the aim of making important new therapies available to patients sooner.

Under the Fast Track program, IHL-42X will now benefit from:

- More frequent, structured interactions between Incannex and the FDA to discuss clinical strategy, trial design, and data requirements
- Eligibility for rolling review, enabling the Company to submit completed sections of a future New Drug Application (NDA) ahead of the full submission
- Potential access to Accelerated Approval and Priority Review, should relevant criteria be met

Incannex expects to receive detailed written feedback from the FDA in response to its Phase 2 data package and clinical development strategy. The Company expects to provide further updates regarding the FDA's guidance, the agreed next steps, and the proposed path toward late-stage development once it has received and reviewed this feedback.

Comment from Mark Bleackley, Chief Scientific Officer

"We are delighted with the FDA's decision to grant Fast Track designation to IHL-42X for OSA. This supports the potential for IHL-42X to address the unmet need for an oral pharmacotherapy for OSA patients. OSA is a serious disease with impacts on both short- and long-term aspects of patient health and quality of life. We look forward to continuing to work with the FDA on the development of IHL-42X."

Comment from Joel Latham, President & CEO

"We believe Fast Track designation for IHL-42X is one of the most significant regulatory milestones in Incannex's history. OSA affects millions of people globally, yet there remains no approved oral pharmacotherapy, a gap we are determined to close. Following our exceptional Phase 2 results, this designation validates the strength of our data package and the potential for IHL-42X to transform the treatment landscape. We believe the designation also provides a clear, expedited regulatory pathway, allowing us to accelerate development and capitalise on the pillars we have built throughout the year, including our recent Nasdaq extension. We look forward to working closely with the FDA as we advance IHL-42X toward late-stage development and ultimately to patients who urgently need new options."

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 ability to execute on its objectives, prospects or plans; evaluations and judgments regarding Incannex's research and development efforts, clinical trial results, its ability to expedite to accelerate future development, future interactions with the FDA and potential future commercialization, including any implications that the results 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 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: Incannex's ability to comply with applicable listing standards; Incannex's ability to raise capital to fund continuing operations and to maintain or potentially further improve its capital structure; 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 product 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; 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, 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.

Investor & Media Contacts

CORE IR

(212) 655-0924

investors@incannex.com

media@incannex.com.au