Incannex Commences Participant Screening in DReAMzz Phase 2 Study of IHL-42X for Obstructive Sleep Apnea

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- First clinical sites approved and actively screening potential participants
- Represents another major milestone in the advancement of IHL-42X towards Phase III development
- IHL-42X has received FDA Fast Track designation, highlighting its potential to address the significant unmet medical need in obstructive sleep apnea and supporting a potentially expedited regulatory pathway
- Study designed to optimize both objective sleep metrics and patient-reported outcomes to support regulatory approval and commercial differentiation
- Builds upon previously announced positive Phase 2 data demonstrating up to 83% reduction in AHI and significant improvements across multiple patient-reported outcome measures
- Obstructive sleep apnea affects an estimated one billion people globally, with no FDA-approved oral pharmaceutical therapies currently available

MELBOURNE, Australia and NEW YORK, July 23, 2026 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL) ("Incannex" or the "Company"), a clinical-stage biopharmaceutical company developing innovative therapies for high-impact indications, is pleased to announce that participant screening has commenced in the Company's DReAMzz Phase 2 dose confirmation study evaluating IHL-42X for the treatment of obstructive sleep apnea ("OSA"). IHL-42X has previously been granted Fast Track designation by the U.S. Food and Drug Administration ("FDA"), underscoring its potential to address the significant unmet medical need in OSA and providing opportunities for more frequent interactions with the FDA throughout the development process, supporting a potentially expedited pathway towards regulatory review.

The first tranche of clinical trial sites have now received approval to commence screening potential participants for the DReAMzz study, marking another important milestone in the advancement of Incannex's lead clinical program towards Phase III development. Additional clinical sites are expected to commence screening activities as they receive the necessary approvals.

Potential participants will be identified through site patient databases and public outreach initiatives before undergoing screening assessments against the study's predefined inclusion and exclusion criteria.

The commencement of screening represents the transition of the DReAMzz study into active clinical recruitment and follows significant operational progress made by the Company, including the appointment of a global CRO, completion of drug product manufacturing activities, finalization of import and export permits, and the establishment of clinical and drug distribution infrastructure required to support the study.

The DReAMzz study has been strategically designed to optimize the dosing profile of IHL-42X while further evaluating the relationship between objective sleep metrics and patient-reported outcomes. The additional data generated from the study is expected to strengthen both the regulatory package and commercial positioning of IHL-42X ahead of the Company's planned Phase III development program.

Importantly, patient-reported outcomes are becoming increasingly relevant in both regulatory review and commercialization strategies for therapies targeting chronic diseases such as OSA, particularly where improvements in quality of life, fatigue and overall patient wellbeing represent meaningful treatment objectives alongside objective clinical endpoints.

Joel Latham, President and Chief Executive Officer of Incannex Healthcare, commented:

"The commencement of participant screening is another major milestone for the IHL-42X development program and represents the culmination of significant work undertaken by our clinical, regulatory and manufacturing teams over recent months."

"We believe IHL-42X has the potential to fundamentally change the treatment paradigm for obstructive sleep apnea. While existing treatment options are often associated with poor patient compliance and there are currently no FDA-approved oral pharmaceutical therapies available for OSA, IHL-42X has already demonstrated compelling efficacy across both objective sleep metrics and patient-reported outcomes in our previous Phase 2 study."

“The FDA’s decision to grant Fast Track designation to IHL-42X provides further validation of both the significant unmet medical need in OSA and the potential of our program. Fast Track designation is reserved for therapies intended to treat serious conditions and that have the potential to address unmet medical needs, and we believe it further reinforces the significant opportunity that exists for IHL-42X as we advance towards Phase III development.”

“DReAMzz has been specifically designed to further optimize our dosing strategy ahead of Phase III development while generating additional data that will strengthen both our regulatory submission strategy and the commercial profile of IHL-42X. We remain highly encouraged by the potential opportunity ahead of us in a market affecting an estimated one billion people globally.”

About the DReAMzz Study

The DReAMzz study is a randomized, crossover Phase 2 dose confirmation study designed to further optimize the dosing profile of IHL-42X. The study is expected to generate important data evaluating dose optimization across objective sleep metrics and patient-reported outcomes that will inform the Company’s planned Phase III clinical development program.

The study builds upon previously announced positive Phase 2 results, which demonstrated statistically significant reductions in Apnea-Hypopnea Index (“AHI”) versus placebo, with reductions of up to 83% observed. IHL-42X also demonstrated statistically significant improvements across multiple patient-reported outcome measures, including fatigue and sleep related impairment, while maintaining a favorable safety profile.

About Incannex Healthcare Inc.

Incannex Healthcare Inc. is a clinical-stage biopharmaceutical company developing innovative combination therapies and next-generation medicines for conditions with significant unmet medical need. The Company’s lead programs include IHL-42X for obstructive sleep apnea, IHL-675A for rheumatoid arthritis and PSX-001 for generalized anxiety disorder. Incannex is committed to advancing therapies that address multiple biological pathways with the goal of improving patient outcomes and creating long-term shareholder value. For more information, please visit www.incannex.com.

Forward-Looking Statements

Certain statements in this press release may constitute “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, statements relating to management’s expectations regarding the development, regulatory progress and commercialization of the Company’s drug candidates, the potential value of the Company’s drug candidates and business, and potential shareholder value. When or if used in this communication, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” and similar expressions and their variants, as they relate to the Company, its operations or its management, may identify forward-looking statements. The forward-looking statements contained in this press release are based on management’s current expectations and projections about future events. Nevertheless, actual results or events could differ materially from the plans, intentions, and expectations disclosed in, or implied by, the forward-looking statements. These risks and uncertainties, many of which are beyond our control, include: the risk that the Company’s estimates and current projections regarding the sufficiency of its current cash on hand to fund the Company’s planned operations may be incorrect and the Company may use these resources faster than anticipated, risks associated with the clinical development of IHL-42X and PSX-001, and other risks described in the section entitled “Risk Factors” described in the Company’s 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, which can be obtained on the SEC website and are made available on the Company’s website upon their filing with the SEC. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management’s current estimates, projections, expectations and beliefs. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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