Incannex Announces First Patient Dosed in DReAMzz Phase 2 Study of IHL-42X

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First patient dosing represents another major clinical milestone for IHL-42X, building on positive Phase 2 RePOSA results demonstrating reductions in AHI of up to 83% and FDA Fast Track designation

NEW YORK and MELBOURNE, Australia, Aug. 25, 2026 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL) ("Incannex" or the "Company"), a clinical-stage biopharmaceutical company developing innovative combination therapies for high-impact indications, today announced that the first patient has been dosed in the DReAMzz Phase 2 dose-optimization study of IHL-42X, the Company's oral fixed-dose combination drug candidate for the treatment of obstructive sleep apnea ("OSA"). The milestone builds on the positive results from the Phase 2 RePOSA study, in which IHL-42X demonstrated statistically significant reductions in apnea-hypopnea index ("AHI") compared with placebo, with individual reductions in AHI of up to 83% observed and exceptional safety profile.

First patient dosing represents another significant milestone in the continued advancement of IHL-42X and follows a period of substantial clinical and regulatory progress for the program. Over the past year, Incannex has reported positive Phase 2 RePOSA results, received Fast Track designation from the U.S. Food and Drug Administration ("FDA"), and advanced its regulatory strategy following engagement with the FDA. The company's current focus, the DReAMzz dose-optimization study, recently commenced patient screening and has now progressed to active patient dosing. All 14 DReAMzz sites now have approval from the Institutional Review Board to conduct the study.

The DReAMzz study is designed to further optimize dose selection for IHL-42X and strengthen the clinical and regulatory foundation for the Company's planned Phase 3 development program.

Joel Latham, President and Chief Executive Officer of Incannex, said:

"Dosing the first patient in DReAMzz is another important milestone for IHL-42X and continues a period of significant clinical and regulatory progress for the program.

"The momentum behind IHL-42X has continued to build over the past year. We delivered positive RePOSA results, including statistically significant reductions in AHI and individual reductions of up to 83%, secured FDA Fast Track designation, advanced our regulatory strategy and have now commenced patient dosing in DReAMzz.

"We believe IHL-42X has the potential to reshape the treatment landscape for obstructive sleep apnea. OSA affects hundreds of millions of people globally, yet there remains a significant need for an effective oral pharmaceutical treatment. The clinical results generated to date give us increasing confidence in the potential of IHL-42X to address that need.

"Our focus now is execution. DReAMzz is designed to optimize the treatment regimen and provide the data required to advance IHL-42X toward Phase 3 development. With strong clinical data, FDA Fast Track designation and DReAMzz now actively dosing patients, we believe IHL-42X is exceptionally well positioned as we enter this next stage of development."

FDA Fast Track Designation Supports Continued Development

The clinical progress of IHL-42X was further reinforced by the FDA granting Fast Track designation to the program.

Fast Track designation is designed to facilitate the development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs. The designation provides opportunities for more frequent interactions with the FDA during development and, subject to applicable requirements, may provide access to mechanisms intended to accelerate regulatory review.

The designation was supported by the safety, efficacy and pharmacokinetic data generated across the IHL-42X clinical development program, including the positive results from the Phase 2 RePOSA study.

Incannex believes Fast Track designation, together with the clinical evidence generated to date, provides important regulatory support as the Company advances IHL-42X through dose optimization and toward Phase 3 development.

DReAMzz Phase 2 Dose-Optimization Study

DReAMzz is a Phase 2 crossover dose-optimization study designed to further characterize the dose-response profile of IHL-42X and inform dose selection for subsequent late-stage clinical development.

The study will evaluate objective sleep-related measures alongside patient-reported outcomes, providing additional data intended to refine the IHL-42X treatment regimen and strengthen the design of the Company's planned Phase 3 program.

Incannex has established a network of 14 clinical trial sites across the United States to support execution of DReAMzz. Drug product has been manufactured, regulatory and operational preparations have been completed, clinical sites have commenced patient screening and the first patient has now been dosed.

About IHL-42X

IHL-42X is Incannex's proprietary oral fixed-dose combination of dronabinol and acetazolamide being developed for the treatment of obstructive sleep apnea.

The combination is designed to target complementary physiological mechanisms implicated in OSA through a single oral pharmaceutical therapy.

IHL-42X has received Fast Track designation from the U.S. Food and Drug Administration.

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 at www.sec.gov 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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