Incannex Healthcare Announces Positive Topline Results from Pharmacokinetics (PK) Study of IHL-42X, an Oral Combination Medicine for the Treatment of Obstructive Sleep Apnea

January 23, 2025

- Demonstrated bioavailability of IHL-42X, Incannex's proprietary combination formulation, confirming delivery of both dronabinol and acetazolamide
- Achieved similar PK and equivalent total drug exposure levels of IHL-42X and the reference listed drugs (RLD) for dronabinol and acetazolamide, building a scientific bridge to established safety and toxicology data with the potential to support a future FDA 505(b)(2) new drug application (NDA)
- Pharmacokinetic results for IHL-42X will inform analysis of anticipated Phase 2/3 data assessing IHL-42X in patients with obstructive sleep apnea
- Continued excellent safety and tolerability findings, with no serious adverse events reported

NEW YORK and MELBOURNE, Australia, Jan. 23, 2025 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (Nasdaq: IXHL), (Incannex), a clinical-stage biopharmaceutical company leading the way in developing combination medicines, today announced positive topline results from a completed pharmacokinetics (PK) and safety study of IHL-42X, a novel, oral fixed-dose combination of acetazolamide and dronabinol for the treatment of Obstructive Sleep Apnea (OSA).

"The topline IHL-42X PK findings we are reporting today provide data necessary to support a 505(b)(2) application in accordance with FDA guidance, assuming continued positive results from our Phase 2 and 3 clinical trials," said Mark Bleackley, Ph.D., Incannex's Chief Scientific Officer. "The trial results are consistent with our expectations and the objectives for IHL-42X, a novel, oral fixed-dose combination therapeutic."

The study confirmed bioavailability of IHL-42X, demonstrating delivery of both dronabinol and acetazolamide. The PK profile of IHL-42X was similar to those observed for the respective RLDs, including equivalent total exposure levels observed for the drug molecules. Furthermore, administration of IHL-42X with food, in contrast to fasted conditions, indicated no substantial food effect on overall exposure to acetazolamide. Consistent with what is known for the RLD, an increase in overall exposure to THC was observed when IHL-42X was administered with food compared to fasted state. No serious adverse events were reported during the study. All but one Treatment-Emergent Adverse Event (TEAE) was reported to be mild or moderate. The proportion of subjects reporting at least one TEAE on the IHL-42X fasted period (57.4%) was similar to the dronabinol fasted period (52.1%). Fewer subjects reported TEAEs during the acetazolamide fasted treatment period (37.8%). Food did not have a substantial effect on the number of subjects reporting TEAEs for IHL-42X, with 57.4% fasted vs 58.8% fed.

This data establishes a scientific bridge to the reference listed drugs (RLD), potentially enabling the Company to leverage existing safety and toxicology data in a FDA 505(b)2 new drug application for IHL-42X, and assist in the analysis of the global Phase 2/3 RePOSA trial.

The study was designed to assess the safety and pharmacokinetics of IHL-42X, a novel combination formulation, as compared to its respective FDA reference listed drugs. Conducted as a randomized, four-period crossover study in healthy volunteers at two sites in Australia, the trial involved 125 participants, 114 of whom completed all treatment periods. Each treatment period involved the administration of one of four regimens: IHL-42X (dronabinol 5 mg, acetazolamide 250 mg) in fasted or fed state, dronabinol (5 mg) in a fasted state, or acetazolamide (250 mg) in a fasted state. Subjects were assigned to one of four sequences, with each sequence following a distinct order.

About IHL-42X
IHL-42X, an oral fixed-dose combination of acetazolamide and dronabinol, is currently in Phase 2/3 clinical studies for the treatment of obstructive sleep apnea (OSA). Designed to act synergistically, IHL-42X targets two different physiological pathways associated with the intermittent hypoxia (IH) and hypercapnia that characterize OSA. In a prior Australian Phase 2 clinical trial, IHL-42X was shown to reduce the Apnea-Hypopnea Index (AHI) in all dosage strengths, with the lowest dose reducing AHI by an average of 51 percent relative to baseline. RePOSA, a global Phase 2/3 clinical trial is underway, evaluating IHL-42X in individuals with OSA who are either non-compliant, intolerant, or naïve to positive airway pressure devices, including CPAP, with the Phase 2 portion conducted in the United States. The expanded Phase 3 portion will include sites in the United Kingdom and European Union. A topline readout from the U.S. Phase 2 portion is anticipated in the first half of 2025.

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 novel oral fix-dosed treatments and therapeutic regimens based on evidence-based innovation. Incannex's lead Phase 2/3 and Phase 2 clinical programs include IHL-42X, an oral fixed-dose combination of dronabinol and acetazolamide, designed to act synergistically in the treatment of OSA for the treatment of obstructive sleep apnea; IHL-675A, an oral fixed-dose combination of cannabidiol and hydroxychloroquine sulfate, acting synergistically to alleviate inflammation, and PSX-001, an oral synthetic psilocybin treatment in combination with psychotherapy, for the treatment of generalized anxiety disorder. Incannex's programs target disorders that have limited, inadequate, or no approved pharmaceutical treatment options.

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. 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, or plans, the skills and experience of the newly appointed officer of Incannex and expectations with respect to his future contributions to the Company and statements, evaluations and judgments regarding Incannex's research and development efforts, including any implications that the results of earlier clinical trials will be representative or consistent with later clinical trials or final results; the expected timing of enrollment for these trials and the availability of data or results of these trials, and the potential benefits, safety or of Incannex's drug candidates. Forward-looking statements are statements other than historical facts and relate to future events or circumstances or Incannex's future performance, and they are based on management's current assumptions, expectations, and beliefs concerning future developments and their potential effect on Incannex's business. 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 and to complete capital raising transactions; 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; competition from other providers and products; that the market for its drug candidates may not grow at the rates anticipated or at all; Incannex's compliance 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 to 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.

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Source: Incannex Healthcare