Incannex Announces Appointment of Dr. Lou Barbato as Chief Medical Officer

October 24, 2024

NEW YORK and MELBOURNE, Australia, Oct. 24, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), (Incannex), a clinical-stage biopharmaceutical company developing innovative medicines for people with chronic diseases and significant unmet medical needs, today announced the appointment of Lou Barbato, M.D., as Chief Medical Officer (CMO) effective immediately. Dr. Barbato's drug development experience includes senior clinical development and operational roles at Jazz Pharmaceuticals, AbbVie, Biogen, Novartis, and Solvay. He joins Incannex as the company continues to advance its lead clinical-stage programs in obstructive sleep apnea, generalized anxiety disorder, and rheumatoid arthritis.

"We are delighted to welcome Dr. Barbato to Incannex as our Chief Medical Officer. With an established track record in directing drug development through late-stage clinical trials and multiple product launches, Lou is a valuable addition to the Incannex team," said Joel Latham, Incannex's President and Chief Executive Officer. "Lou's deep expertise in leading clinical development across CNS and neurodegenerative disorders, coupled with experience in the synthetic cannabinoid therapeutics will be instrumental in driving the success of our global development programs."

With more than 25 years of experience in clinical development, regulatory strategy, and global medical affairs, Dr. Barbato brings significant drug development expertise in psychiatric and neurological disorders, having contributed to the successful approval and launches of multiple therapeutics, including Marplan® (treatment-resistant depression), Luvox® CR (anxiety, OCD), Marinol® (synthetic cannabinoid appetite stimulant, chemotherapy-induced nausea and vomiting) and Gilenya® (multiple sclerosis). Dr. Barbato joins Incannex from Jazz Pharmaceuticals, where he served as Global Medical Lead for several clinical-stage therapeutic programs addressing neurological disorders. At Jazz, he led cross-functional teams, with responsibility for global medical strategies working with the FDA, EMA, and PMDA. Prior to joining Jazz, Dr. Barbato served as Global Senior Medical Director at AbbVie, and, prior to AbbVie, held leadership roles at Biogen Idec, Novartis, Stiefel Laboratories (GSK), Forest Research Institute, and Solvay Pharmaceuticals, where he contributed to successful U.S. and global product registration and approval of multiple psychiatric, neurologic, and oncologic therapeutics. Dr. Barbato served as Clinical Assistant Professor of Psychiatry and Behavioral Science at Emory University School of Medicine and has authored or co-authored more than 65 papers and presentations. Dr. Barbato earned his M.D. from St. George's University School of Medicine and B.S. in Biology at St. Peter's University.

"This is an exciting time to join Incannex with three clinical-stage therapeutics that have all demonstrated clinical proof-of-concept. We believe Incannex's science-driven development programs hold great therapeutic potential for chronic conditions with unmet patient needs, including obstructive sleep apnea, generalized anxiety disorder, and rheumatoid arthritis," said Dr. Barbato. "I look forward to leading our global clinical strategy for IHL-42X, PSX-001 and IHL-675A, and the opportunity to advance these important new therapeutics to patients and clinicians."

About IHL-42X

IHL-42X is Incannex's oral fixed dose combination of dronabinol and acetazolamide designed to act synergistically, targeting two different physiological pathways associated with the intermittent hypoxia (IH) and hypercapnia that characterize OSA. In an Australian Phase 2 clinical trial, IHL-42X was observed to reduce the apnea hypopnea index (AHI) and be well-tolerated in OSA patients. A global Phase 2/3 clinical trial investigating the safety and efficacy of IHL-42X is underway 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 top-line readout from the U.S. Phase 2 portion of the Phase 2/3 trial is anticipated in the first half of 2025. In addition, top-line results from an ongoing pharmacokinetic and safety study in Australia are expected in late 2024.

About PSX-001

PSX-001 is Incannex's oral synthetic psilocybin drug candidate, administered in combination with psychotherapy, for patients diagnosed with moderate-to-severe Generalized Anxiety Disorder (GAD). In the Australian Phase 2 "PsiGAD1" clinical trial, PSX-001 was observed to reduce anxiety scores and be well-tolerated in GAD patients. Forty-four percent of the subjects in the psilocybin group exhibited a clinically meaningful improvement of at least 50% in anxiety score from baseline; a ‘response rate' more than four times higher than that of the placebo group. Incannex anticipates reporting full data results from the PsiGAD1 trial in the first half of 2025. The "PsiGAD2" Phase 2 trial is expected to recruit 94 patients with GAD, including those currently treated with selective serotonin reuptake inhibitors (SSRIs), who meet the study inclusion and exclusion criteria in the United States and United Kingdom.

About IHL-675A

IHL-675A is an oral fixed dose combination of cannabidiol and hydroxychloroquine sulfate designed to target two different pathways, acting synergistically to alleviate inflammation. IHL-675A was observed to be well tolerated and bioavailable in an Australian Phase 1 clinical trial. IHL-675A was also observed to reduce inflammatory markers and disease scores across multiple animal inflammatory disease models and in vitro assays in preclinical evaluation. IHL-675A is in an Australian Phase 2 trial investigating the safety and efficacy in rheumatoid arthritis (RA) patients, enrolling 128 subjects with pain and reduced function regardless of current treatment regimen.

About Incannex Healthcare Inc.

Incannex is a clinical-stage biopharmaceutical company focused on developing innovative medicines for patients living with chronic diseases and significant unmet needs. The company is advancing oral synthetic cannabinoid and psilocybin drug candidates targeting sleep apnea, anxiety, and inflammatory diseases. Incannex's lead programs include IHL-42X, an oral fixed dose combination of dronabinol and acetazolamide, designed to act synergistically in the treatment of OSA, in a global Phase 2/3 study for the treatment of obstructive sleep apnea, PSX-001, an oral synthetic psilocybin treatment in combination with psychotherapy, for the treatment of generalized anxiety disorder, in a Phase 2 trial conducted in the United States and United Kingdom, and IHL-675A, an oral fixed dose combination of cannabidiol and hydroxychloroquine sulfate, acting synergistically to alleviate inflammation, in an Australian Phase 2 trial. 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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