Incannex Commences Dosing in Phase 2 Clinical Trial Assessing IHL-675A in Patients with Rheumatoid Arthritis

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MELBOURNE, Australia and NEW YORK, Jan. 24, 2024 (GLOBE NEWSWIRE) -- Incannex Healthcare Inc. (NASDAQ:IXHL), ('Incannex' or the 'Company'), a pharmaceutical company developing novel medicinal cannabinoid pharmacotherapies and psychedelic medicine therapies for unmet medical needs, is pleased to announce that patient dosing has commenced in the Phase 2 clinical trial assessing IHL-675A in patients with rheumatoid arthritis (RA).

IHL-675A is the Company's proprietary combination drug candidate composed of Hydroxychloroquine Sulphate (HCQ) and cannabidiol (CBD), both of which have well characterized anti-inflammatory activity when administered individually (1, 2). The primary endpoint of the double-blind, Phase 2 clinical trial is pain and function relative to baseline determined via the score on the RAPID-3 assessment at 24 weeks. The trial will enroll 128 participants across 10 study sites in Australia with participants receiving either IHL-675A, CBD, HCQ or placebo. Participants will record their pain and function outcomes daily, by completing questionnaires on pain, fatigue, joint stiffness, and quality of life, using an electronic Patient Reported Outcomes device.

Chief Scientific Officer of Incannex, Dr. Mark Bleackley, said; "Commencing dosing in the Phase 2 clinical trial in patients with RA is an exciting milestone for the development of IHL-675A. Millions of people are affected by pain associated with rheumatoid arthritis despite the available treatment options. IHL-675A has the potential to address this unmet need. We look forward to generating data on the safety and efficacy of IHL-675A and sharing this data with FDA and other regulatory agencies."

Participants in the Phase 2 trial will attend monthly visits at the clinical trial site, where blood tests, and physical examinations will monitor additional safety and efficacy outcomes including inflammatory biomarkers. The trial will also include a sub-study examining joint inflammation and damage via Magnetic Resonance Imaging (MRI). The results of this trial will be a critical component of future regulatory applications, including contributing to the combination rule assessment in the FDA505(b)2 new drug application (NDA) dossier.

Background

IHL-675A is a combination drug candidate comprised of hydroxychloroquine sulfate (HCQ) and cannabidiol (CBD). HCQ is listed as an essential medicine by the World Health Organisation and was developed as an anti-malarial drug, but its anti-inflammatory activity has led to use in treatment of RA and lupus erythematosus. CBD is approved for use in seizure disorders but is also commonly used for RA as an unregistered therapy. The established use of the component active pharmaceutical ingredients to treat RA makes IHL-675A a strong candidate for treatment of RA. IHL-675A is also a potential treatment for other inflammatory conditions such as inflammatory bowel disease, COPD and asthma.

HCQ acts by interfering with antigen presentation and lysosomal acidification (2) whereas CBD modulates the activity inflammatory signalling receptors (1). Anti-inflammatory synergy between the two drugs was demonstrated across a range of preclinical studies and have provided the foundation for a robust intellectual property (IP) position over the IHL-675A drug candidate.

A video presentation of IHL-675A for treatment of rheumatoid arthritis can be found at https://www.incannex.com/clinical-trail/ihl-675a-rheumatoid-arthritis/.

Chronic inflammatory conditions affect tens of millions of people globally. Rheumatoid arthritis (RA) is estimated to have a global prevalence of 0.46% (3), which equates to approximately 36.8 million people with RA. Inflammatory bowel disease (IBD) has a global prevalence of 6.8 million (4). Estimated global prevalence of chronic obstructive pulmonary disease and asthma (COPD) are 391.9 million and 357.4 million respectively (5, 6).

Overview of Results from Phase 1 Clinical Trial Assessing Tolerability, Safety, and Pharmacokinetics of IHL-675A in Healthy Volunteers

In 2022 and 2023, Incannex undertook a Phase 1 clinical trial to assess the safety, tolerability, and pharmacokinetics of IHL-675A. The key endpoints of the trial were adverse events and the plasma levels of the active pharmaceutical ingredients (APIs), CBD and HCQ, and their major metabolites over a 28-day period. IHL-675A was compared to the reference listed drugs for CBD and HCQ, called Epidiolex and Plaquenil respectively, across all endpoints. The trial included three cohorts of twelve participants each (total n = 36), with equal evaluations applied across all three groups. Participants were monitored and had blood samples collected for pharmacokinetic analysis over a 28-day period. IHL-675A was well tolerated, with no adverse events of concern and no serious adverse events reported. The same number of treatment related treatment emergent adverse events (TEAEs) were reported for IHL-675A as for Epidiolex.

Trends in pharma profiles indicate that the uptake of CBD may be more rapid for IHL-675A than Epidiolex and uptake of HCQ may be slower for IHL-675A than Plaquenil. This could be advantageous for IHL-675A as a drug product. CBD would theoretically provide accelerated relief for inflammation and pain whereas HCQ is a slower acting molecule and may provide extended relief.

About Incannex Healthcare Inc.

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for the treatment of obstructive sleep apnoea (OSA), traumatic brain injury (TBI) and concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis, inflammatory bowel disease, anxiety disorders, addiction disorders, and pain, among other indications.

U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication under investigation currently has no, or limited, existing registered pharmacotherapy (drug) treatments available to the public and represent major global economic opportunities to Incannex and its shareholders.

Incannex has a strong patent filing strategy in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners. The Company holds 20 granted patents and over 30 pending patent applications.

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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. These forward-looking statements are made as of the date they were first issued and were based on current expectations and estimates, as well as the beliefs and assumptions of management. The forward-looking statements included in this press release represent Incannex's views as of the date of this press release. Incannex anticipates that subsequent events and developments may cause its views to change. Incannex undertakes no intention or obligation to update or revise any forward-looking statements, whether as of a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Incannex's views as of any date after the date of this press release.

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