Date: October 13, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Completes Dosing in Phase 1 Clinical Trial to Assess Multi-Use, Anti-Inflammatory Drug IHL-675A; Proceeds to Phase 2 Clinical Trials

Highlights:

- Patient dosing has been completed in the Phase 1 clinical trial measuring the safety, tolerability, and pharmacokinetic profiles of IHL-675A
- IHL-675A has been well tolerated, with no adverse events of concern reported to date
- Incannex is arranging Phase 2 studies for patients with rheumatoid arthritis and planning Phase 2 studies for patients with Inflammatory bowel disease and lung inflammation
- Incannex is preparing for a pre-IND meeting with FDA on the development of IHL-675A specifically for the treatment of patients with arthritis
- the Company intends to open an IND in parallel with the Australian Phase 2 study
- HCQ is widely used for treatment of rheumatoid arthritis in the form of hydroxychloroquine sulphate; marketed as Plaquenil. An improvement to patient wellbeing achieved by IHL-675A would potentially open a major economic opportunity for Incannex in the treatment of arthritis.

Melbourne, Australia, October 13, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has completed dosing of trial participants in the phase 1 clinical trial undertaken to assess pharmacokinetics and safety of the anti-inflammatory drug IHL-675A.

IHL-675A is a combination cannabinoid drug comprising cannabidiol ('CBD') and hydroxychloroquine ('HCQ') in a fixed dose combination. IHL-675A was observed to outperform either CBD and HCQ in various pre-clinical models of inflammation, including *in vivo* models of rheumatoid arthritis, inflammatory bowel disease and lung inflammation. Synergistic anti-inflammatory activity of CBD and HCQ was observed in these distinct pre-clinical studies and was evidence to support the Company's international patent application over the drug.

The Phase 1 trial measured the safety, tolerability, and pharmacokinetic profiles of IHL-675A compared to the reference listed drugs, Epidiolex (CBD) and Plaquenil (HCQ). Three cohorts of 12 participants (n = 36) received either IHL-675A, CBD or HCQ and the clinical assessments were identical across the three arms of the trial. The trial was conducted by CMAX Clinical Research in Adelaide, South Australia and managed by Avance Clinical.

IHL-675A has been well tolerated, with no adverse events of concern reported to date. No serious adverse events have been reported. Participants will continue to be monitored until the end of October, after which blood samples collected during the study will be assessed for levels of CBD, HCQ and major metabolites to characterise the pharmacokinetics of each active pharmaceutical ingredient. The full clinical study report will be available to Incannex in Q1 2023 following complete analysis by the contract research organisation, however, the absence of adverse events of concern reasonably permits Incannex to plan and arrange Phase 2 studies, initially in patients with rheumatoid arthritis.

Incannex Chief Scientific Officer, Dr Mark Bleackley said: "It is an exciting milestone for us to complete dosing in our Phase 1 study on IHL-675A because it has so many potential therapeutic uses. At this stage, there have been no unexpected adverse events and the drug appears to be well tolerated. This gives our team the confidence to take the next steps necessary to commence Phase 2 clinical trials, initially in patients with arthritis, then in patients with lung inflammation and inflammatory bowel disease".

Next Steps – Phase 2 Trial Planning and Arrangement for IHL-675A

Initial reports of drug tolerability afford Incannex the opportunity to proceed with the next stage of development for IHL-675A. As HCQ is already approved for treatment of rheumatoid arthritis, arthritis is the first indication for which IHL-675A will be assessed in a Phase 2 clinical trial of more than 100 trial participants. Incannex is arranging a clinical trial to assess IHL-675A in arthritis patients in Australia and will update the ASX and Nasdaq once this study has formally commenced. Planning of Phase 2 studies in patients with inflammatory bowel disease and lung inflammation is underway. The treatment of these three indications has a combined global annual market size exceeding US$125B per annum[1].

Additionally, Incannex is preparing for a pre-IND meeting with FDA on the development of IHL-675A specifically for the treatment of patients with arthritis. Following the pre-IND meeting, the Company intends to open an IND in parallel with the Australian Phase 2 study, allowing for the conduct of trials in the US if the Australian study continues to support the therapeutic potential of IHL-675A in patients with arthritis.

In March of 2021, Incannex announced results from an *in vivo* model of rheumatoid arthritis whereby IHL-675A was observed to benefit the treatment of rheumatoid arthritis in mice greater than that of CBD or HCQ alone. In fact, low dose IHL-675A was 1.06x to 3.52x more effective at reducing arthritis across multiple disease assessments including clinical score, paw volume, pannus score, total histology score and serum cytokine levels as the standard dose of HCQ. HCQ is widely used for treatment of rheumatoid arthritis in the form of hydroxychloroquine sulphate; marketed as Plaquenil. An improvement to patient wellbeing achieved by IHL-675A would potentially open a major economic opportunity for Incannex in the treatment of arthritis.

Incannex CEO and Managing Director, Mr Joel Latham said: "Many people throughout the world are using unapproved CBD or cannabinoids for inflammation-based disorders. By undertaking pivotal clinical studies over IHL-675A, and subject to ongoing clinical success, we intend to both disrupt the market for CBD and to open our product to the purview of medical professionals who are eminently more comfortable prescribing FDA approved, pharmaceutical grade products to their patients".

This announcement has been approved for release to ASX by the Incannex Board of Directors.

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About Incannex Healthcare Limited

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis 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 19 granted patents and 29 pending patents. Incannex is listed on the Australian Stock Exchange (ASX) with stock code "IHL" and also has American Depository Shares listed on NASDAQ under code "IXHL".

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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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