Date: July 21, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex Receives Ethics Approval to Commence Phase 1 Clinical Trial of Multi-Use Anti-Inflammatory Drug IHL-675A

Highlights:

- Bellberry human research ethics committee approved the phase 1 clinical trial investigating safety and pharmacokinetics of IHL-675A on July 20, 2022
- The trial will be performed at CMAX Clinical Research, a dedicated and experienced clinical trial centre in Australia, and managed by Avance Clinical
- The trial will assess the pharmacokinetics, safety, and tolerability of combination cannabinoid drug IHL-675A
- Trial data will be applicable to regulatory submissions for all three IHL-675A development programs, rheumatoid arthritis, inflammatory bowel disease and lung inflammation
- Formulation and manufacturing of IHL-675A soft gel capsules for the clinical trial has been completed; long term stability studies are ongoing
- Patient recruitment is scheduled to commence in August 2022.

Melbourne, Australia, July 21, 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 received approval from the Bellberry Human Research Ethics Committee ('HREC') for a phase 1 clinical trial investigating its proprietary multi-use, 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.

CEO and Managing Director, Mr Joel Latham said; "Approval to begin our Australian phase 1 trial is a significant milestone for Incannex and clinicians treating patients with disorders for which inflammation is the underlying cause. There's a growing trend whereby patients are using CBD to treat, or supplement their existing treatments, for inflammation disorders. We have observed in established models of inflammation that IHL-675A is a stronger anti-inflammatory cannabinoid-based drug than CBD administered alone, hence we are delighted and excited to take IHL-675A to the clinic for the first time".

The trial will measure 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) will receive either IHL-675A, CBD or HCQ and the assessments will be identical across the three arms of the trial.

Chief Scientific Officer of Incannex Healthcare, Dr Mark Bleackley said; “The aims of the trial are to demonstrate that there are no, or minimal, additional side effects associated with the combination of CBD and HCQ compared to each drug alone and that the uptake and metabolism, otherwise known as pharmacokinetics, of the two drugs do not materially interfere with one another”.

Subject to clinical success, the results of the phase 1 clinical trial will form part of three U.S. Food and Drug Administration (‘FDA’) investigational new drug (‘IND’) applications for each of the initial three indications the Company is pursuing for IHL-675A. These indications are rheumatoid arthritis, inflammatory bowel disease and lung inflammation, representing major markets for Incannex to pursue with IHL-675A. Once the IND applications are evaluated and approved, the Company intends to conduct clinical trials partly or wholly in the United States.

The trial will be conducted at CMAX Clinical Research in Adelaide, South Australia, and managed by Avance Clinical. Patient recruitment is anticipated to commence in August 2022.

IHL-675A Formulation and Manufacturing of Clinical Trial Supply Completed

Incannex is also pleased to announce that formulation development of IHL-675A has been completed and the first batch of product has been manufactured.

The formulation development process included multiple experiments conducted to determine the ideal excipients to use in formulation of IHL-675A. Other assessments included the characterization of the dissolution of both active pharmaceutical ingredients (CBD and HCQ) from the IHL-675A gel capsule and ensuring that the dissolution profile was consistent with the reference listed drugs.

Data from the characterization of the IHL-675A gel capsules, the quality assessment and early timepoints in the stability analysis were a critical component of the HREC submission package. These results, along with data from the ongoing stability studies are essential to support future regulatory submissions, including IND and new drug applications with the FDA and corresponding applications with other regulatory agencies. Stability studies to establish the shelf life of the IHL-675A gel capsule product are also underway.

The manufacturing facilities at Incannex’s formulation partner have been inspected and approved for good manufacturing practices (GMP) by multiple regulatory agencies including FDA, TGA, Health Canada and MHRA. Production of IHL-675A soft gel capsules can quickly ramp up to commercial quantities when required.

About IHL-675A

IHL-675A comprises a combination of HCQ and CBD. HCQ is a disease modifying anti-rheumatic drug that regulates the activity of the immune system, which may be overactive in some conditions. HCQ can modify the underlying disease process, rather than simply treating the symptoms. Incannex has demonstrated that IHL-675A components, CBD and HCQ, act synergistically to inhibit production of key

inflammatory cytokines in an *in vitro* study of human cells and in four distinct successful *in vivo* experiments using established models of inflammation.

Incannex has evaluated the results of these experiments and believe IHL-675A to be a multi-use drug candidate suitable for the prevention and treatment of inflammation, with an initial focus on inflammatory lung conditions (acute respiratory distress syndrome, COPD, asthma, and bronchitis), rheumatoid arthritis, and inflammatory bowel disease.

The treatment of these indications has a combined global annual market size of exceeding US$125B per annum[1]. IHL has completed a pre-IND meeting with the FDA to discuss the regulatory pathway for the development of IHL-675A in the United States and plan to open INDs for each of the three indications. FDA agreed that marketing applications for IHL-675A should be 505(b)(2) applications due to the existence of certain safety and efficacy information on the active ingredients of IHL-675A originating from historical studies that we are entitled to use in a new drug application.

This announcement has been approved for release to ASX by the Incannex board of directors.

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[1] https://www.alliedmarketresearch.com/asthma-COPD-drug-market
https://www.alliedmarketresearch.com/rheumatoid-arthritis-RA-drugs-market#:~:text=The%20global%20rheumatoid%20arthritis%20drugs,pain%20and%20inflammation%20in%20joints
https://www.grandviewresearch.com/industry-analysis/inflammatory-bowel-disease-ibd-treatment-market#:~:text=The%20global%20inflammatory%20bowel%20disease,market%20over%20the%20forecast%20period

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 anxiety disorders, obstructive sleep apnoea (OSA), traumatic brain injury (TBI)/concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis and inflammatory bowel disease. U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication represents major global markets and currently have no, or limited, existing registered pharmacotherapy (drug) treatments available to the public.

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. 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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