Date: 27th July 2021
ASX Announcement (ASX: IHL)

Incannex commences phase 1 clinical trial for multi-use drug candidate IHL-675A; International patent application labelled "novel and inventive"

Highlights:

- Incannex commences phase 1 in-human clinical trial to assess the safety of IHL-675A soft gel capsules
- The trial will be conducted at CMAX Clinical Research in South Australia and managed by Avance Clinical
- Pre-clinical studies suggest that IHL-675A has the potential to be a multi-use drug candidate for the prevention and treatment of inflammatory lung conditions, rheumatoid arthritis, and inflammatory bowel disease
- The treatment options associated with these indications has a combined global annual market size exceeding US$125B per annum[1,2,3]
- Following receipt of FDA pre-IND meeting guidance, results from the trial will form part of three FDA investigational new drug (IND) applications for each of the three indications Incannex is pursuing for IHL-675A
- An International Patent Application entitled "Methods and compositions for treating or preventing an inflammatory condition" was recently filed as part of the IHL-675A development program
- The International Search Report and Opinion of the International Searching Authority has also been received on the recently filed International Patent Application, with the International Examiner indicating that claims directed to IHL-675A and methods for the treatment of inflammatory conditions using IHL-675A are novel and inventive and meet the requirements for industrial applicability.

Clinical stage cannabinoid and psychedelic medicine development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company') is pleased to announce that it has commenced a phase 1 clinical trial to assess IHL-675A soft gel capsules in healthy volunteers. The study will be conducted at CMAX Clinical Research ('CMAX') in South Australia and managed by Australian CRO Avance Clinical ('Avance').

The aims of the study are to demonstrate that there are no, or minimal, additional side effects associated with the combination of Cannabidiol ('CBD') and Hydroxychloroquine ('HCQ') compared to each drug alone and that the uptake and metabolism (pharmacokinetics) of the two drugs do not materially interfere with one another. A total of 36 subjects will participate in the trial, evenly divided across three arms. The three arms of 12 subjects each will receive one of IHL-675A, CBD, or HCQ. The safety and pharmacokinetic assessments will be identical across the three arms of the trial.

IHL anticipates that the first participants will be recruited in Q4 2021. Subject to clinical success, the results of this clinical trial will form part of three FDA investigational new drug (IND) applications for each of the three indications the Company is pursuing with IHL-675A. Those indications are lung inflammation, rheumatoid arthritis, and inflammatory bowel disease, representing major markets for IHL to pursue with IHL-675A. Once the IND applications are evaluated and approved, the Company intends to conduct phase 2 and 3 clinical trials partly or wholly in the United States.

On the 16th of July 2021, Incannex announced that it engaged Procaps S.A. ('Procaps') to manufacture soft gel capsules for the Company's clinical trial programs. Procaps manufacturing plant has 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 for sale as either an unregistered or registered product in various markets upon the achievement of successful clinical trial outcomes.

CMAX Clinical Research

CMAX Clinical Research is an independent clinical research facility, based in Adelaide, Australia. CMAX has been established as a Phase I-II unit since December 1993, making it the longest-running in Australia which has consistently maintained world class standards with a commitment to providing excellence and quality in all areas of clinical service. CMAX has conducted more than 600 studies since the unit was established and was most recently US FDA audited in 2019 with no findings.

CMAX is one of Australia's most modern Phase I-II clinical facilities, adjacent to Adelaide's Biomed City. The facility offers 66-bed capacity for in-house stays, three sample processing laboratories (including one PC2), secure investigational product storage room and 24-bed cardiac telemetry system. Features of the modern environment include isolation zones, recreation spaces for participants, purpose-built monitoring room, secure-swipe access to the facility, and more.

Avance Clinical

Avance Clinical is the largest full-service Australian CRO specializing in delivering quality clinical trials, with globally accepted data, in Australia and New Zealand. Avance Clinical, a Frost & Sullivan Asia-Pacific CRO Market Leadership Award recipient, has been providing CRO services in the region for the past 24 years. The company's clients are biotech companies in their early phases of drug development that need fast, agile, and adaptive solution-oriented clinical research services. Avance Clinical offers pre-clinical services with their experienced clinic ready team right through to Phases 1 and 2 leveraging significant Government incentive rebates of up to 43.5% and rapid start-up regulatory processes.

With experience across more than 105 indications the CRO can deliver world-class results and high-quality internationally accepted data for FDA and EMA review. Avance Clinical delivers customised solutions designed around specific client needs rather than a one size fits all approach.

As a company, Avance Clinical has focused on state-of-the-art technology and systems across all functional areas to provide clients with the most effective processes. Medidata, Oracle, and Medrio are just some of Avance Clinical's trusted technology partners.

Intellectual Property Considerations

An International Patent Application entitled "Methods and compositions for treating or preventing an inflammatory condition" was recently filed as part of the IHL-675A development program. This application was filed pursuant to the Patent Cooperation Treaty (PCT), thus providing IHL with an opportunity to pursue patent protection in foreign jurisdictions, including key markets (North America, the EU, Japan, Australia, Israel, among others) with established and developing medicinal cannabis industries.

The PCT Application process includes the conduct of preliminary searches by the International Searching Authority to identify prior art that may be relevant to the novelty and inventive step of the claims as filed. The results of such preliminary searches are published in the form of an International Search Report and Opinion, which is followed by the International Preliminary Report on Patentability.

The International Search Report and Opinion of the International Searching Authority have now been received by IHL. Pleasingly, the International Examiner considers that claims directed to IHL-675A and methods for the treatment of inflammatory conditions using IHL-675A are novel and inventive and meet the requirements for industrial applicability. Based on the International Search Report and Opinion, IHL is currently considering options to expedite the filing and examination of patent applications in key jurisdictions as part of IHL's intellectual property (IP) strategy.

About IHL-675A

IHL-675A comprises a combination of HCQ, a registered pharmaceutical, 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, cannabidiol and hydroxychloroquine, 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 for the prevention and treatment of:

- Inflammatory lung conditions (ARDS, COPD, asthma, and bronchitis),
- rheumatoid arthritis, and
- inflammatory bowel diseases.

The treatment of these indications has a combined global annual market size of exceeding US$125B per annum[1,2,3]. 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.

ENDS

The release of this announcement has been approved for issue by IHL's Board of Directors. For further details on the announcement, interested parties should contact:

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About Incannex Healthcare Limited (ASX: IHL)

Incannex Healthcare Limited (IHL.ASX) is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of generalised anxiety disorder (GAD), obstructive sleep apnoea (OSA), traumatic brain injury (TBI)/concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis and inflammatory bowel disease. 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, raising the possibility of patients receiving Government subsidies for drugs that demonstrate suitable safety and efficacy profiles in clinical trials.

IHL has a strong patent filing strategy (as announced "IHL files cannabinoid patent over IHL-216A for TBI" 04th October 2019 and "IHL Files Patent over IHL-42X for OSA" 06th of December 2019) as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners.

Website: www.incannex.com.au

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References:

[1] https://www.alliedmarketresearch.com/asthma-COPD-drug-market

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[3] https://www.grandviewresearch.com/industry-analysis/inflammatory-bowel-disease-ibd-treatment-market#:~:text=The%20global%20inflammatory%20bowel%20disease,market%20over%20the%20forecast%20period