

Incannex engages Procaps to develop and manufacture IHL-675A soft-gel capsules in preparation for clinical trials

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it has engaged Procaps S.A. ('Procaps') to develop the specific formulation for IHL-675A, IHL's anti-inflammatory multi-use drug product with Procaps' proprietary patented Unigel technology.

Procaps is equipped to provide an end-to-end service that includes formulation development, clinical trial supply and subsequent commercial manufacture. Development at Procaps is supported by its own robust intellectual property portfolio, providing access to a range of proprietary formulation and manufacturing technologies for the IHL-675A finished product, including but not limited to Procaps' proprietary patented Unigel technology which consists of an apparatus and process for encapsulating capsules or other solid dosage form within capsules.

Procaps has extensive scientific expertise, having developed over 500 formulations for both pharmaceutical and nutritional products reaching over 50 markets globally. It is the largest integrated contract development and manufacturing company in Latin America and are ranked within the top three companies globally for soft gel manufacturing capacity.

Procaps manufacturing plant has been inspected and approved for good manufacturing practices (GMP) by multiple regulatory agencies including FDA, TGA, Health Canada and MHRA. Procaps offers services to a diverse range of industry-leading customers, doing business with 12 out of the top 20 global multinational pharma companies, among many others.

CEO and Managing Director of Incannex Healthcare, Mr Joel Latham, said; "Procaps offers Incannex a complete supply chain solution for a sophisticated, GMP-grade product. Manufacturing at Procaps will support our clinical trial programs and can also quickly ramp up production for commercial supply upon successful clinical trial outcomes".

IHL-675A development activities

IHL-675A comprises a combination of hydroxychloroquine ('HCQ') and Cannabidiol ('CBD'). Incannex has demonstrated that IHL-675A components, HCQ and CBD act synergistically to inhibit production of key inflammatory cytokines both *in vitro* and *in vivo* and reduce disease severity in three established inflammatory disease animal models.

Following guidance received from FDA at a pre-investigational new drug application (pre-IND) meeting reported in April 2021, Incannex expanded its development program to assesses the potential of IHL-675A to become a multi-use pharmaceutical drug applicable to three indications: lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis, and inflammatory bowel disease.

Incannex is well-advanced in its planning and coordination of a phase 1 clinical trial to assess IHL-675A soft gel capsules in healthy volunteers. The aims of the study 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 (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.

Subject to clinical success, the results of the phase 1 clinical trial will form part of three FDA investigational new drug (IND) applications for each indication the Company is pursuing 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.

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.

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