Date: 22nd April 2021
ASX Announcement (ASX: IHL)

Positive pre-IND meeting with US FDA; Incannex to compile and submit three INDs for IHL-675A for lung inflammation, IBD and rheumatoid arthritis, significantly expanding IHL-675A's addressable market

Highlights:

- IHL to expand its development program to assesses the potential for IHL-675A to become a multi-use pharmaceutical drug applicable to the treatment of patients with lung inflammation, irritable bowel disease (IBD) and rheumatoid arthritis
- FDA agreed that marketing applications for IHL-675A should be 505(b)(2) applications; an accelerated and less-costly route to registration and marketing approval than the traditional 505(b)(1) pathway
- Following the FDA meeting, IHL will combine its ARDS/SAARDS and pulmonary neutrophilia (COPD, asthma, and bronchitis) development activities into a common project and IND; expanding the program's scope and economic potential
- Incannex to conduct a phase 1 clinical trial designed to form part of three distinct development programs and FDA INDs for lung inflammation, IBD and rheumatoid arthritis.

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it held its Pre-Investigational New Drug Application meeting ('PIND') with the US Food and Drug Administration ('FDA') to discuss the regulatory pathway for the development IHL-675A in the United States.

Following guidance from FDA, Incannex is delighted to report that it will expand its development program to assesses the potential for IHL-675A to become a multi-use pharmaceutical drug. IHL has received positive pre-clinical results from five distinct *in vivo* assessments of IHL-675A applicable to various disorders caused by excessive inflammation. The indications prioritised for clinical assessment are:

- Acute respiratory distress syndrome (ARDS) and sepsis associated ARDS (SAARDS)
- pulmonary neutrophilia (the primary underlying cause of COPD, asthma, and bronchitis)
- inflammatory bowel disease, and
- rheumatoid arthritis.

Incannex has commenced the process of designing a phase 1 clinical trial necessary to assess these conditions in-human with the purpose to form part of three distinct investigational new drug applications ('INDs') and their associated studies required for registration and marketing authority. The Company will update ASX when the development outline is finalised.

Following the meeting with FDA, Incannex will combine its ARDS/SAARDS and pulmonary neutrophilia (COPD, asthma, and bronchitis) development activities into a common project and IND, which Incannex will refer to as its lung inflammation program herein.

The expanded lung inflammation development program contrasts with the former plan to pursue an Emergency Use Authorisation ('EUA') IND for only ARDS patients with COVID-19. Combining the programs into a single IND submission markedly increases the patient cohort to include those with bronchitis, asthma, COPD, SAARDS, ARDS and COVID-19 ARDS; increasing the scope and economic potential of the program.

Whilst Incannex could submit an EUA IND, EUAs are conditional on the continuance of the state of emergency, and subject to revocation by FDA when the emergency subsides. The rapid roll out of more that 210M doses of COVID-19 vaccines domestically (USA), has significantly improved the COVID-19 outlook in the USA in 2021. The Company does not wish to limit its development program to COVID-19 ARDS patients as the success of the vaccines as a preventative measure has shortened the expected time in which therapies with EUA approval will persist without having to achieve full product registration. An EUA application for COVID-19 ARDS remains accessible to IHL as a development option during the lung inflammation development program, should the COVID-19 pandemic outlook worsen.

FDA also agreed that marketing applications for IHL-675A should be 505(b)(2) applications. A 505(b)(2) New Drug Application ('NDA') contains full safety and effectiveness reports but allows some of the information required for NDA approval, such as safety and efficacy information on the active ingredients, to originate from historical studies not conducted by Incannex. This will result in an accelerated and less-costly route to approval, compared with a traditional development path [505(b)(1)], whilst creating new and differentiated commercial products, subject to clinical success. Additionally, the FDA panel provided valuable guidance on the design of clinical trials, including opinions on the selection of clinical trial endpoints.

Incannex CEO and Managing Director, Mr Joel Latham, said; "the directors of Incannex are delighted with the positive feedback and encouragement from the FDA at the PIND meeting and will now move forward with conviction on our clinical programs to develop IHL-675A as a multi-use pharmaceutical.

The combined annual global market size of the indications being targeted by Incannex with IHL-675A is over US$125B[1,2,3,4] so we consider the economic potential, as well as the benefit to patients over incumbent treatments, to be enormous".

ENDS

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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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References:

[1]https://www.alliedmarketresearch.com/rheumatoid-arthritis-RA-drugs-market#:~:text=The%20global%20rheumatoid%20arthritis%20drugs,pain%20and%20inflammation%20in%20joints
[2]https://www.grandviewresearch.com/industry-analysis/inflammatory-bowel-disease-ibd-treatment-market
[3]https://www.alliedmarketresearch.com/asthma-COPD-drug-market
[4]https://www.ihealthcareanalyst.com/global-acute-respiratory-distress-syndrome-devices-market

About Incannex Healthcare Limited (ASX: IHL)

Incannex Healthcare Limited (IHL.ASX) is a clinical stage pharmaceutical development company 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 and Acute Respiratory Distress Syndrome (ARDS). FDA registration, subject to ongoing clinical success, is being pursued for each product and therapy under development.

Each indication represents major global markets that currently have no, or limited, existing registered pharmacotherapy (drug) treatments available to the public, raising the possibility of patients receiving Government subsidies for products 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 advisory board.

Further to its clinical programs, Incannex has its Australian license to import, export and distribute medicinal cannabis products and has launched a line of cannabinoid oil products. The cannabis-based oils are sold under Incannex's product supply and distribution agreement with Cannvalate Pty Ltd, which is the largest network of cannabis medicine prescribers in Australia and a major shareholder of Incannex.

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