Date: 25th March 2021
ASX Announcement (ASX: IHL)

Pre-IND meeting granted with the US FDA regarding IHL-675A for use in preventing ARDS and SAARDS

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it has been granted a Pre-IND meeting with the US Food and Drug Administration ('FDA'). The meeting follows the submission of a comprehensive information package, which details IHL-675A and its proposed use in preventing Acute Respiratory Distress Syndrome ('ARDS', caused by trauma) and Sepsis Associated Acute Respiratory Distress Syndrome ('SAARDS', caused by infection).

FDA has indicated a goal date for providing comment on Incannex's development proposal by 21st of April 2021; after which time IHL will formalise its clinical development plans. FDA members from multiple divisions within the agency, including representatives from the medical, pharmacology, and CMC divisions will provide feedback on the entire development program.

The purpose of the meeting is to obtain regulatory guidance and agreement on the most efficient clinical development plan to be included in an investigational new drug ('IND') application for IHL-675A in the prevention of ARDS and SAARDS in the United States.

Approximately 10 to 15 percent of patients admitted to intensive care have ARDS. ARDS is a life-threatening injury characterised by fluid leakage into the lungs. ARDS results from lung injury due to trauma and SAARDS is a leading cause of mortality associated with lung, urinary tract, stomach, skin infections and SARS-CoV-2 viral infections.

Patients diagnosed with ARDS currently have poor treatment outcomes and the standard treatment continues to be the use of oxygen ventilators to treat symptoms, but not the underlying inflammation "feedback loop" that causes the fluid leakage. IHL-675A is designed to directly target lung inflammation.

Additional US FDA Development Programs

Since June 2020, IHL has announced positive results on the anti-inflammatory potency of IHL-675A from seven separate preclinical studies covering multiple models of inflammation applicable to various medical conditions. In close consultation with FDA, Incannex intends to expand the development of IHL-675A in clinical settings to the following conditions:

- pulmonary neutrophilia (the primary underlying cause of COPD, asthma, and bronchitis),
- inflammatory bowel disease, and
- rheumatoid arthritis.

The additional development programs align with IHL's strategy to harness increasing regulatory enthusiasm for promising medicinal cannabinoid and psychedelic therapies. IHL plans to seek FDA approval for its programs to fulfill unmet medical needs for patients.

CEO and Managing Director of Incannex Healthcare, Mr Joel Latham said;

"The United States is the largest pharmaceutical market in the world, so being granted a Pre-IND meeting review with FDA represents an important milestone for our company and a strong foundation for the clinical development of IHL-675A.

Our preclinical studies have demonstrated that IHL-675A has the potential to be a platform drug applicable to the treatment of multiple indications. We anticipate that the work completed on the FDA information package for IHL-675A for ARDS and SAARDS will assist us with hastening submissions to FDA for the other indications being pursued".

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 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 and 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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