Date: 02nd June 2020
ASX Announcement (ASX: IHL)

Impression Commences Animal Study for the Assessment of IHL-675A against Sepsis Associated ARDS; the leading cause of COVID-19 mortality

Highlights:

- Impression has commenced its first clinical trial, being the animal study for its sepsis associated acute respiratory distress syndrome ('SAARDS') program
- SAARDS is the leading cause of mortality associated with COVID-19 coronavirus infection and other lung, kidney, stomach, and skin infections
- IHL-675A is hypothesised to limit the progression of infections to sepsis hyperinflammation caused by the "cytokine storm" feedback loop
- The animal study will investigate IHL-675A mechanisms of inflammation dampening by assaying cytokine levels following the induction of sepsis
- There is significant unmet need in the treatment of SAARDS and there are no registered pharmacotherapy (drug) treatments available for the condition.

Clinical stage cannabinoid development company, Impression Healthcare Limited (ASX: IHL, 'Impression' or the 'Company'), is pleased to announce the commencement of its first clinical trial, being the animal study for its sepsis associated acute respiratory distress syndrome ('SAARDS') program. IHL previously announced that it filed a provisional patent over IHL-675A for SAARDS , a combination drug comprising Cannabidiol ('CBD') and Hydroxychloroquine ('HCQ'), on the on the 15th of April 2020.

The trial is two pronged, with an initial 17-arm dose escalation study to assess dose response of the individual components of IHL-675A in rodents with induced sepsis ('septic shock' or 'septicaemia'). The second stage of the study will involve the investigation of specific combinations of CBD and HCQ, using the learnings of stage one, to investigate the optimal inflammation dampening response of the IHL-675A combination drug.

Specifically, the induced-sepsis animal model being undertaken will investigate IHL-675A on the mechanisms of inflammation in septic shock by assaying cytokine levels from blood collected across the cohorts of rodents over the two stages of the study. Stage one results are expected to be available in approximately in 4-6 weeks. During that time, preparations will be made for the combination studies.

Sepsis occurs when the immune system overreacts to an infection, producing excessive levels of cytokines, which are signalling molecules that attract immune cells[1]. Elevated levels of those cells secrete more cytokines, and this "cytokine storm" recruits even more immune cells, fuelling a cascading cycle that eventually damages host tissues and organs[2].

When the lungs are damaged by the cytokine storm hyperinflammatory response, SAARDS is said to be occurring. SAARDS is characterized by widespread inflammation of the lungs, often referred to as 'wet lung' or pneumonia, inhibiting the patient's ability to oxygenate blood[3]. SAARDS is the leading cause of mortality associated with COVID-19 coronavirus infection and is also a leading cause of mortality from other lung, urinary tract, stomach, and skin infections[4,5].

There is significant unmet need in the treatment of SAARDS and has been for many decades. The best treatment continues to be the use of oxygen ventilators to treat symptoms of ARDS, but not the underlying cause. There is currently no registered pharmacotherapy (drug) treatment for SAARDS, however, the global medical community continues to investigate numerous drug treatments in its search for a new standard of care in response to COVID-19 coronavirus.

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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References:

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6429642/
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3294426/
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4823184/
[4] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30628-0/fulltext
[5] https://www.sepsis.org/sepsisand/ards/

About Impression Healthcare Limited (ASX: IHL)

Impression Healthcare Limited (IHL.ASX) is developing unique medicinal cannabis products for the treatment of Obstructive Sleep Apnoea (OSA), Traumatic Brain Injury (TBI)/Concussion, Acute Respiratory Distress Syndrome (ARDS) and Temporomandibular Joint Disorder (TMD). FDA registration, where being sought, is subject to clinical success.

Each indication represents major global markets and currently have no existing registered pharmacotherapy (drug) treatment, raising the possibility of patients receiving Government subsidies for products that demonstrate suitable safety and efficacy profiles in clinical trials.

There is an established body of research validating the hypothesis for the cannabinoids being used in Impression's chosen therapeutic areas and 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 in conjunction with its medical advisory board.

Further to its clinical programs, Impression has its Australian license to import, export and distribute medicinal cannabis products and has launched a line of cannabinoid oil products under the brand, "Incannex". The cannabis-based oils are sold under Impression'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 IHL.

Yielding growing revenues to Impression is its customised oral devices manufacturing business. The oral devices division delivers high-quality products both direct to the consumer and via a growing B2B preferred practitioner network of dentists.

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