

## **Incannex expands IHL-675A indications to include COPD, asthma, bronchitis, and other inflammatory lung conditions - after receiving positive results from additional *in vivo* studies**

### **Highlights:**

- IHL reports positive results from another *in vivo* study that has further assessed the anti-inflammatory capability of its proprietary IHL-675A
- Results indicate that IHL-675A has superior anti-inflammatory activity compared to CBD and HCQ in a mouse pulmonary inflammation model
- IHL-675A reduced assessed inflammatory markers by 31.9 to 40.3 percent, normalised to the vehicle, versus CBD, which reduced inflammatory markers by 2.8 to 26.7 percent; representing a range of outperformance against CBD of 1.19x to 12.25x (Appendix 1, Table 1)
- IHL-675A reduced Interleukin 6 ('IL-6') by 40.3%, normalised to the vehicle, versus CBD that reduced IL-6 by 14.8%
- Incannex has expanded target indications, and broadened claims within initial patent filings, for IHL-675A to include COPD, asthma, bronchitis, and other inflammatory lung conditions
- The Global COPD and asthma drugs market is expected to reach US\$50.4B by 2022, growing at a CAGR of 3.7% from 2016 to 2022<sup>3</sup>.

Clinical stage pharmaceutical development company, Incannex Healthcare Limited (ASX: IHL, 'Incannex' or the 'Company'), is pleased to announce that it has received positive results from another *in vivo* (animal) study that has further assessed the anti-inflammatory capability of its proprietary IHL-675A, which is a drug that combines cannabidiol ('CBD') and hydroxychloroquine ('HCQ').

Previous studies undertaken by Incannex have demonstrated potent anti-inflammatory activity of IHL-675A to make it an excellent candidate for prevention and treatment of sepsis associated acute respiratory distress syndrome ('SAARDS').

Following the results relevant to SAARDS, Incannex also assessed the anti-inflammatory effect of its proprietary IHL-675A formulation on Pulmonary Neutrophilia. This condition is a primary underlying cause of chronic obstructive pulmonary disease ('COPD'), asthma, bronchitis, and other inflammatory respiratory conditions. Incannex is pleased to report encouraging results (presented below), which facilitate a substantial expansion of the potential uses for IHL-675A and represent new patient treatment opportunities.

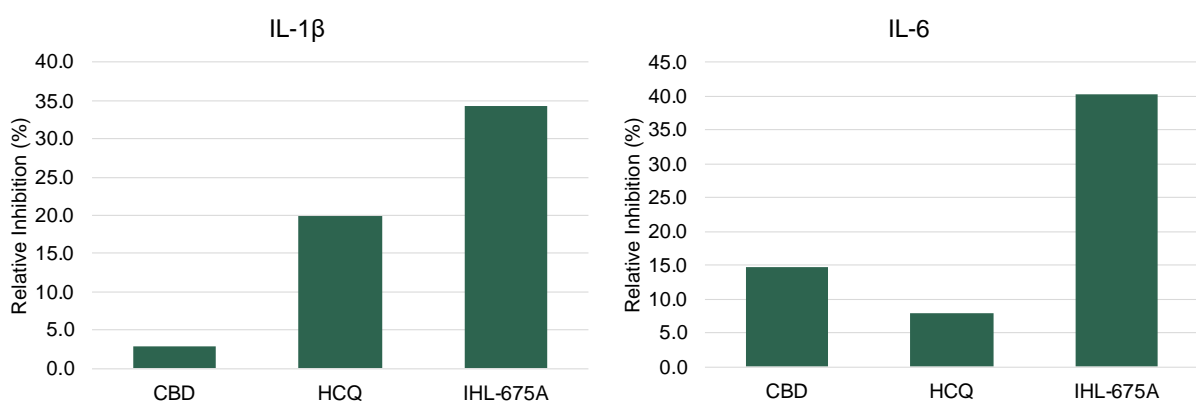
## Overview

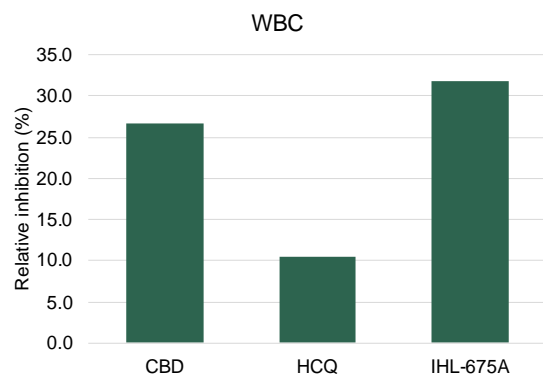
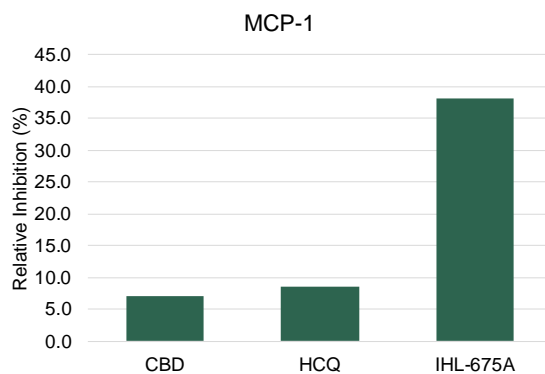
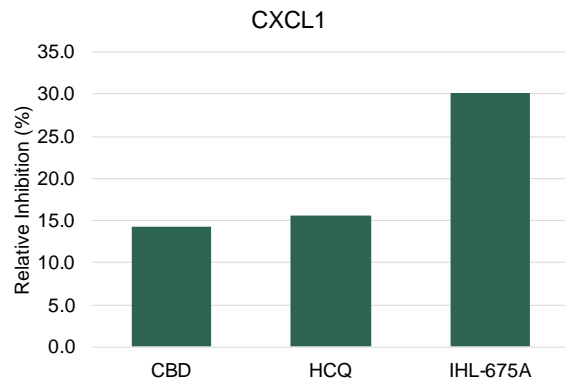
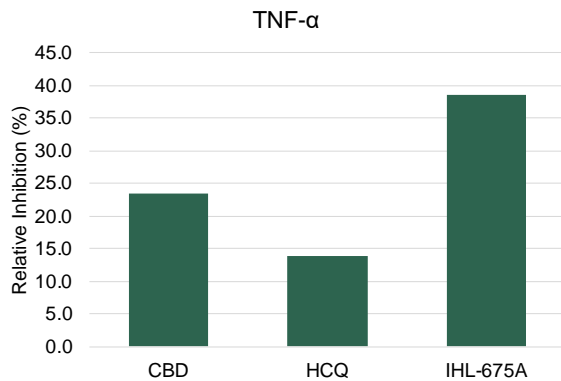
A Rodent Model was used in assessing the application of IHL-675A. In this model, ten groups of six mice each were pre-treated with either CBD, HCQ, or IHL-675A prior to intratracheal administration of bacterial lipopolysaccharide ('LPS'), which was then inhaled and acts as an inflammatory stimulus in the lungs. A sham group where LPS was not administered to the mice was also included as a control.

The lungs were flushed with a saline solution 24 hours after LPS administration and this fluid (bronchoalveolar lavage fluid ('BALF')) was analysed for cytokine levels using a Luminex based assay. Cytokines are proteins that mediate the inflammatory response and a reduction in cytokine levels is indicative of reduced inflammation. A white blood cell ('WBC') count was also performed on the BALF. When inflammation occurs in the lungs, WBCs are recruited as part of the inflammatory response. A reduction in WBC count is also indicative of reduced inflammation.

## Results

Cytokine levels were normalised to those detected in vehicle treated mice and then the relative inhibition was calculated. IHL-675A reduced levels of all assessed inflammatory cytokines IL-1 $\beta$ , IL-6, TNF- $\alpha$ , CXCL1 and MCP-1 to a greater extent than either CBD or HCQ alone. WBC counts were normalised using the same method used for cytokines and IHL-675A also reduced WBC counts to a greater extent than CBD or HCQ alone (as presented in Appendix 1, Table 1). These results indicate that IHL-675A has superior anti-inflammatory activity compared to CBD and HCQ in a mouse pulmonary inflammation model.





### ***Intellectual Property ('IP') Considerations***

Incannex has broadened claims within initial patent filings to cover new indications, most importantly for COPD and Asthma. IHL is continuously monitoring the results of its research and development programs, with a view to identifying and protecting new IP that aligns with its commercial objectives.

By taking a global approach to its IP strategy, IHL is pursuing patent protection in key global markets, including the US, Europe, Japan and Israel. This approach aligns with IHL's regulatory strategy, including the submission of a pre-IND meeting request to the US Food and Drug Administration ('FDA') for the SAARDS indication.

Following the results detailed in this announcement, Incannex will expand the IHL-675A SAARDS development program to facilitate continued assessment of COPD, asthma and other inflammatory lung conditions that represent major additional markets for the Company.

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## **Conditions caused by lung inflammation – COPD and Asthma**

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease that causes obstructed airflow from the lungs<sup>1</sup>. Symptoms include breathing difficulty, cough, mucus (sputum) production and wheezing. It is typically caused by long-term exposure to irritating gases or particulate matter, most often from cigarette smoke. People with COPD are at increased risk of developing heart disease, lung cancer and a variety of other conditions.

Asthma is a condition in which inflammation causes the airways narrow and swell and may produce extra mucus<sup>2</sup>. This can make breathing difficult and trigger coughing, a whistling sound (wheezing) during breathing and shortness of breath. For some people, asthma is a minor nuisance. For others, it can be a major problem that interferes with daily activities and may lead to a life-threatening asthma attack.

The Global COPD and asthma drugs market is expected to reach US\$50.4B by 2022, growing at a CAGR of 3.7% from 2016 to 2022<sup>3</sup>.

**CEO and Managing Director of Incannex Healthcare, Mr Joel Latham said;** "IHL-675A is consistently showing stronger anti-inflammatory properties than CBD. Continued research will reveal how important this will be to the cannabinoid sector in light of continued research globally on CBD and its application to inflammatory conditions. The synergistic action of IHL-675A allows us to substantially expand the potential uses for IHL-675A and presents new patient treatment opportunities".

## **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.

**Website:** [www.incannex.com.au](http://www.incannex.com.au)

**Investors:** [investors@incannex.com.au](mailto:investors@incannex.com.au)

### References:

- <sup>1</sup> Devine JF. Chronic obstructive pulmonary disease: an overview. Am Health Drug Benefits. 2008;1(7):34-42.
- <sup>2</sup> Papi, Alberto et al. Asthma. The Lancet, Volume 391, Issue 10122, 783 - 800
- <sup>3</sup> <https://www.alliedmarketresearch.com/asthma-COPD-drug-market>

## Appendix

**Table 1.** Reduction in inflammatory markers by CBD, HCQ and IHL-675A. All values are normalised to vehicle and presented as percent reduction relative to the maximum value in each assay.

	IL-1 $\beta$	IL-6	CXCL1	MCP-1	TNF- $\alpha$	WBC
CBD	2.8	14.8	14.3	7.0	23.4	26.7
HCQ	19.9	7.9	15.6	8.7	13.8	10.5
IHL-675A	34.3	40.3	30.1	38.2	38.5	31.9
IHL-675A > CBD*	12.25x	2.72x	2.10x	5.46x	1.65x	1.19x

\*IHL-675A multiple of outperformance relative to CBD only treatment.

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