

## Update on IHL-42X Clinical Program for Obstructive Sleep Apnoea

## Highlights:

- Impression has received all relevant permits for the importation of key cannabinoid constituents of IHL-42X required for clinical trials
- IHL has commenced specific formulation development of IHL-42X with a qualified pharmaceutical chemist
- Precursory data and authorisations being compiled for the Phase 1B/2B clinical trial planned to commence in the second quarter of 2020 at the Austin Hospital in Melbourne, Victoria
- First patients for the clinical trial have been sourced, under the guidance of world-renowned sleep specialist and IHL medical advisory board member, Dr David Cunnington
- Key endpoints being observed in the clinical trial are set in an expanded protocol and include the following assessments;
  - Severity of Obstructive Sleep Apnoea measured by the Apnoea-Hypopnea Index
  - Number of Oxygen desaturation episodes that occur during patient nocturnal sleep
  - Daytime somnolence and cognitive performance measured by generally accepted neurocognitive tests
  - Influence on driving a study planned to occur at Swinburne University
- FDA consultant engaged to initiate the use of programs designed to fast-track FDA registration by using existing publicly available data
- Dr Mark Bleakley is appointed to position of chief scientific officer and has deep experience in clinical trial design and implementation; replacing outgoing Mr John Michailidis.

Impression Healthcare Limited ('Impression', 'IHL' or the 'Company'), developer of four unique medicinal cannabis products, owner of INCANNEX<sup>TM</sup> cannabis oils and oral devices manufacturer, is pleased to announce that it has received all relevant permits for the importation of key cannabinoid constituents of IHL-42X to treat Obstructive Sleep Apnoea ('OSA'). Simultaneously, IHL has commenced sophisticated product formulation development of IHL-42X to be used in upcoming clinical trial activities.

The Company has also commenced the compilation of precursory data and authorisations required for a Phase 1B/2B clinical trial planned to commence in the second quarter of 2020 and based at the Austin Hospital in Melbourne, Victoria. First patients for the clinical trial have been sourced, under the guidance of world-renowned sleep specialist and IHL medical advisory board member, Dr David Cunnington.

Key endpoints being observed in the clinical trial are set in an expanded clinical trial protocol and include the following assessments:

• Severity of OSA measured by the Apnoea-Hypopnea Index, which is the globally recognised score of OSA severity



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- Number of Oxygen desaturation episodes that occur during patient nocturnal sleep
- Daytime somnolence and cognitive performance measured by generally accepted neurocognitive tests

A key secondary endpoint includes any influence that the constituents of IHL-42X have on driving the morning after a dose of IHL-42X. This study will be a world first and a driver of project value, which will occur at clinically validated driver testing facilities managed by Swinburne University.

Impression has engaged an FDA consultant to commence the FDA registration process. Initial advice is that IHL should apply for registration under an FDA accelerated pathway. Doing so will eliminate the requirement to conduct certain pre-clinical steps due to widely accepted publicly available clinical data on certain constituents of IHL-42X. The accelerated pathway reduces both time and cost over the life of the clinical trial process to registration and marketability.

During January, Dr Mark Bleakley was appointed to the role of Chief Scientific Officer, managing the OSA and other clinical programs in conjunction with Dr Sud Agarwal, Dr David Cunnington, advisory board members and other research staff from Swinburne University. Dr Bleakley has a PhD in Cell Biology and Genetics from the University of British Columbia.

Dr Bleakley was hired by Dr Sud Agarwal and Mr John Michailidis due to his deep experience in clinical trial design and implementation; being named in 30 peer reviewed scientific publications during his career. Dr Bleakley has already demonstrated his clinical proficiency at Impression and is a suitable replacement to former Incannex appointee, Mr John Michailidis, who was unable to complete his contract due to personal reasons.

ENDS



## About Impression Healthcare Limited (ASX: IHL)

Impression Healthcare Limited (IHLASX) is a first-in-class innovator and developer of a diversified mix of medicinal cannabis pharmaceutical products for global export potential. The Company is currently undertaking clinical programs to develop 4 uniquely formulated medicinal cannabis products for the treatment of Obstructive Sleep Apnoea (OSA), Traumatic Brain Injury/Concussion, Temporomandibular Joint Disorder and Periodontitis (Gum Disease).

Each indication represents major global markets with significant yearly sales. 3 of the 4 indications 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 it develops its products in conjunction with its medical advisory board of global key opinion leaders.

Further to its clinical programs, Impression also has its Australian licenses in place to import, export and distribute medicinal cannabis products and has launched a line of EU GMP approved CBD oil products under the brand, "INCANNEX". The INCANNEX 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.

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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