

## Impression Enters Dronabinol Product Supply Agreement to Facilitate Sleep Apnoea Trial and Initial Sales

### Highlights:

- Impression enters a supply agreement for Dronabinol to use in the clinical trial for Sleep Apnoea
- The supply agreement is a necessary precursor to the imminent commencement of the clinical trial for Impression's own unique Dronabinol-based formulation designed to assess its use in the treatment of Sleep Apnoea
- A portion of the Dronabinol capsules will be retained for sale under the Special Access Scheme for loss of appetite in people with HIV/AIDS and nausea and vomiting caused by chemotherapy through Cannvalate's extensive distribution network
- IHL and its partners have applied for an import permit from the Office of Drug control ('ODC') for its first batch of Dronabinol product
- 4% of men and women in Australia (approximately 1M people) have symptomatic Obstructive Sleep Apnoea; potentially increasing due to an ageing population and rising obesity
- The global Sleep Apnoea devices market was valued at US\$5.5B in 2017. The CPAP medical device is considered the first line of defence against Sleep Apnoea; however, patient adherence has been a major factor limiting the efficacy of CPAP treatment due to severe patient discomfort and lack of convenience.

Impression Healthcare Limited ('Impression', 'IHL' or the 'Company') is pleased to announce that it has entered an agreement with Myoderm North America for the supply of Dronabinol and has also applied for an import permit from the Office of Drug control ('ODC') for its first batch of Dronabinol product for the trial. The Company expects delivery of the batch within coming weeks; post receipt of permits.

Part of the Dronabinol shipment will be used in conjunction with other pharmaceutical ingredients to create a uniquely formulated product for the potential treatment of Sleep Apnoea. And, a portion of the Dronabinol will remain unaltered and retained for immediate sale under the Special Access Scheme for Dronabinol's traditional indications, being loss of appetite in people with HIV/AIDS and nausea and vomiting caused by chemotherapy.

The unique formulation for the Sleep Apnoea trial has been designed with assistance from the Medical Cannabis Research Collaboration ('MCRC'), a partnership between Cannvalate Pty Ltd and the Swinburne University of Technology. The purpose for creating a unique formulation is to potentially enhance the medical profession's existing understanding of the effect of Dronabinol on Sleep Apnoea. IHL expects that the protocol for the clinical trial will be completed soon and will update the market when the trial formally commences upon registration.

Following the completion of a successful clinical trial, IHL can assess the potential for further trials and apply for special access scheme ('SAS') sales authorisation for any person with severe Sleep Apnoea in accordance with the rules of the SAS, as outlined by the Therapeutic Goods Administration.

### **About Sleep Apnoea**

Obstructive Sleep Apnoea ('OSA' or 'Sleep Apnoea') represents a significant global health challenge. According to SNORE Australia, around 9% of women and 25% of men in Australia have clinically significant OSA. 4% of men and women in Australia (approximately 1M people) have symptomatic OSA; potentially increasing due to an ageing population and rising obesity. The global Sleep Apnoea devices market was valued at US\$5.5B in 2017.

Sleep Apnoea is a serious sleep disorder that is characterised by interrupted breathing during sleep. "Apnoea" is the complete loss of breath for 10 seconds or longer and "Hypopnoea" is a partial loss of breath that lasts 10 seconds or longer. Sleep Apnoea increases the risk of health problems, including high blood pressure, stroke, heart failure, diabetes and mental disorders. In addition, untreated Sleep Apnoea may be responsible for poor performance in everyday activities resulting from fatigue.

The CPAP is considered the first line of defence; however, patient adherence has been a major factor limiting the efficacy of CPAP treatment due to severe patient discomfort and lack of convenience. Patients are known to experience soreness from the repeated use of nasal masks and have difficulty falling asleep with the CPAP device operating at the prescribed pressure. Therefore, there is a significant opportunity for alternative therapies; including pharmaceutical alternatives such as Dronabinol and variants of Dronabinol.

### **About Dronabinol**

Dronabinol was the first ever cannabinoid medicine permitted for patient use by the United States FDA (Food and Drug Administration) in the United States and a synthetic Dronabinol has been marketed under the trade name Marinol® since in 1986. Dronabinol, in its encapsulated final form is considered a Schedule III drug by the United States DEA (Drug Enforcement Agency). Any patents over Marinol have since expired. Abbvie Inc. (NYSE:ABBV), which is a recognised as a top-10 global pharmaceutical company by revenue, currently markets Marinol®.

Traditional uses of Dronabinol are for loss of appetite in people with HIV/AIDS and nausea and vomiting caused by chemotherapy. However, more recently, published studies have demonstrated that Dronabinol alone significantly improved Sleep Apnoea, as measured by the Apnoea Hypopnea Index.

**ENDS**



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### About Impression Healthcare Limited (ASX: IHL)

Impression Healthcare Limited is an innovative healthcare company that sells customised oral devices both direct-to-the-consumer and via the Company's growing B2B preferred practitioner network of dentists. With its own laboratory in Victoria, Australia, Impression offers best-in-class teeth-protection and helps its customers to combat bruxism, snoring, mild-to-moderate sleep apnoea and teeth discolouration with custom-fitted oral devices.

Impression has broadened its commitment to disruption in the healthcare sector by progressing multiple opportunities in the field of medicinal cannabis. IHL has its licenses in place to import, export and distribute cannabis products. In March of 2019, Impression executed a binding collaboration with Cannvalate and Swinburne University of Technology to undertake four medicinal cannabis clinical trials. Cannvalate is Australia's largest distributor of medicinal cannabis products.

IHL also has a collaboration agreement with leading US Cannabinoid therapeutics Company, AXIM Biotechnologies Incorporated; a license agreement with Resolution Chemicals for the production and distribution of Dronabinol in the USA, Canada, Australia and New Zealand; and also intends to distribute medicinal cannabis oils through the Cannvalate network of cannabis medicine prescribers throughout Australia.

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