

Commencement of Phase 2a Clinical Trial for Obstructive Sleep Apnoea using “IHL-42X” Medicinal Cannabis Formulation

Highlights:

- Impression has successfully registered a phase 2a randomised controlled clinical trial to investigate the effect of IHL-42X on Obstructive Sleep Apnoea versus a placebo
- Secondary outcome measures focused on sleep quality and patient mood
- The trial is considered a phase 2a randomised controlled clinical trial designed to investigate the effects of ‘nocturnal’ IHL-42X on the apnoea hypopnea index (‘AHI’) among 30 participants over a 6-week period
- It is hypothesised that the active treatment will reduce AHI, improve mood and improve well-being at the completion of the trial, compared to placebo
- Import permits have already been received for the key active pharmaceutical ingredients required for the IHL-42X formulation.

Impression Healthcare Limited (‘Impression’, ‘IHL’ or the ‘Company’), developer of four unique medicinal cannabis products and oral devices manufacturer, is pleased to announce that it has successfully registered its second clinical trial to investigate the efficacy of its unique IHL-42X medicinal cannabis formulation on obstructive sleep apnoea; with secondary outcome measures focused on sleep quality and patient mood.

The completed trial protocol has been registered on the Australian and New Zealand Clinical Trials Registry (‘ANZCTR’). Impression will now formalise approval for the trial from the Human Research Ethics Committee (‘HREC’), and other approvals as necessary, prior to patient recruitment and dosing; with updates to the ASX at key junctures. Patient recruitment is expected to commence in late September/early October.

The trial is considered a phase 2a randomised controlled clinical trial designed to investigate the effects of ‘nocturnal’ IHL-42X on the apnoea hypopnea index (‘AHI’) among 30 participants over a 6-week period.

In addition to close examination of the effect of IHL-42X on the AHI, a total of 36 secondary outcomes will also be measured, focused on sleep quality, using the Epworth Sleepiness Scale and Insomnia Severity Index, and patient mood, as measured by the long-established Beck Anxiety Inventory and Beck Depression Inventory. Safety of IHL-42X will be measured by the number and type of adverse events reported by trial participants.

It is hypothesised that the active treatment will reduce AHI, improve mood and improve well-being following the completion of the trial, compared to placebo.

The IHL-42X cannabinoid formulation for the clinical trial is being prepared to Good Manufacturing Practice (GMP) standards in Australia. Import permits have already been received for the key active pharmaceutical ingredients required for the formulation.

Impression Non-Executive Director and Chief Medical Officer, Dr Sud Agarwal said;

“Obstructive Sleep Apnoea Syndrome is one of the biggest unmet disease burdens in the western world for which there is no current, proven pharmacological treatments.

CPAP machines with cumbersome face masks and mandibular splints are the mainstay of treatment currently, but if there was a registered medicine which had the potential to reduce the number of apnoeas suffered, this would be an enormous disruption of the sleep device market.”

ENDS

About Impression Healthcare Limited (ASX: IHL)

Impression Healthcare Limited (IHL.ASX) is undertaking four clinical trials investigating the use of uniquely formulated medicinal cannabis products for the treatment of Obstructive Sleep Apnoea, Traumatic Brain Injury/Concussion, Periodontitis (Gum Disease) and Temporomandibular Joint Disorder. Each indication represents major global markets.

IHL has its Australian licenses in place to import, export and distribute cannabis products and has launched a line of EU GMP-approved CBD oil products under the brand, “Incannex”. Incannex oils may be sold under IHL’s product supply and distribution agreement with Cannvalate Pty Ltd – the largest network of cannabis medicine prescribers in Australia.

Impression also has a collaboration and “first right of refusal” agreement with leading US Cannabinoid therapeutics Company, AXIM Biotechnologies Incorporated and a license agreement with Resolution Chemicals for the production and distribution of Dronabinol in the USA, Canada, Australia and New Zealand.

Providing growing revenues to the Company; Impression continues to build its customised oral devices manufacturing business both direct-to-the-consumer and via the Company’s growing B2B preferred practitioner network of dentists.

Investors: investors@impression.healthcare

Website: www.impression.healthcare