

Update on IHL-216A Clinical Program for Traumatic Brain Injury ('TBI') and Chronic Traumatic Encephalopathy ('CTE')

Highlights:

- Clinical program design completed, and trials expected to commence late Q2 2020 for the assessment of IHL-216A in lessening the effects of TBI, the key risk factor of CTE
- Procured high-quality CBD isolate and sourced other APIs for the formulation of IHL-216A required for clinical trials
- Products satisfy World Anti-doping Authority ('WADA') and Australian Anti-Doping Authority's ('ASADA') specifications for use by elite athletes
- Phase 1b/2b in-human clinical trial and animal studies being undertaken to assess two forms of IHL-216A to maximise potential commercial opportunities
- Studies designed in conjunction with Impression's FDA consultant to pursue accelerated FDA registration and other programs that afford regulated market exclusivities
- CTE results from repeated head traumas and is widespread in contact sports and a critical medical issue for players and sporting organisations, such as the AFL and NFL.

Impression Healthcare Limited ('Impression', 'IHL' or the 'Company'), developer of four unique medicinal cannabis products and owner of INCANNEX™ cannabis oils, is pleased to announce that it has finalised the design of its clinical program for the assessment of IHL-216A on neurocognitive function after traumatic brain injury ('TBI') and concussion.

IHL-216A is being assessed on its ability to protect the brain against the main injury mechanisms that cause cell death and other negative consequences in the days and weeks following head trauma in sports, and all other applicable scenarios resulting in head trauma.

Clinical success will infer a wide array of implications and uses. Importantly, the Company will aggressively investigate the implications for a long-term Chronic Traumatic Encephalopathy ('CTE') prevention plan in contact sports in which CTE is prevalent.

Chief Medical Officer, Dr Sud Agarwal, said; *"The best evidence available today suggests that CTE is not caused by any single injury, but rather it is caused by years of regular brain trauma. By treating concussion in the days following those injuries, IHL will have effectively created a CTE prevention plan that lessens the effects of TBI in the short term whilst potentially lessening the patient's risk of developing CTE."*

As with the OSA clinical program, Impression has consulted its FDA consultant to commence the FDA registration process. 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-216A. The accelerated pathway reduces both time and cost over the life of the clinical trial process to registration and marketability.

In relation to product formulation, IHL has procured a high-quality CBD isolate and sourced the other APIs and placebo materials with local manufacturers. Two variants of IHL-216A are being used for both a Phase 1b/2b in-human clinical trial and animal trials. Critically, the products are designed to satisfy World Anti-doping Authority ('WADA') and Australian Anti-Doping Authority's ('ASADA') specifications for use by elite athletes at risk of TBI and CTE.

In-human trials will investigate neurocognitive function for up to 50 participants that have sustained a concussion and receive IHL-216A versus those that receive a placebo.

Clinical trial participants targeted are Australian MMA fighters who receive head knocks and show symptoms of moderate to severe concussion. Concussions will be measured and determined using the FitGuard concussive measuring smart mouthguard and FDA recognised neurocognitive tests.

The neurocognitive tests cover important aspects of cognition including attention, memory, language, reaction time and perception. Each fighter will complete baseline neurocognitive tests that will be repeated at various junctures post trauma to compare the IHL-216A and placebo cohorts.

Along with measuring duration to recovery (often called "return to play"), secondary endpoints will involve assessments of brain activity as defined by an electroencephalogram ('EEG') and an array of brain-injury related blood biomarkers.

Animal studies will provide important supportive data, providing more flexibility in a highly controlled environment to assess formula variations and to assess post-mortem data resulting from mild, moderate and severe head trauma.

ENDS

About Impression Healthcare Limited (ASX: IHL)

Impression Healthcare Limited (IHL.ASX) 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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