



U.S. Department of Health and Human Services

**Proprietary IHL-42X for
Obstructive Sleep Apnoea ("OSA")
a Potential Candidate for FDA 505 (b)(2)
Accelerated Drug Approval**

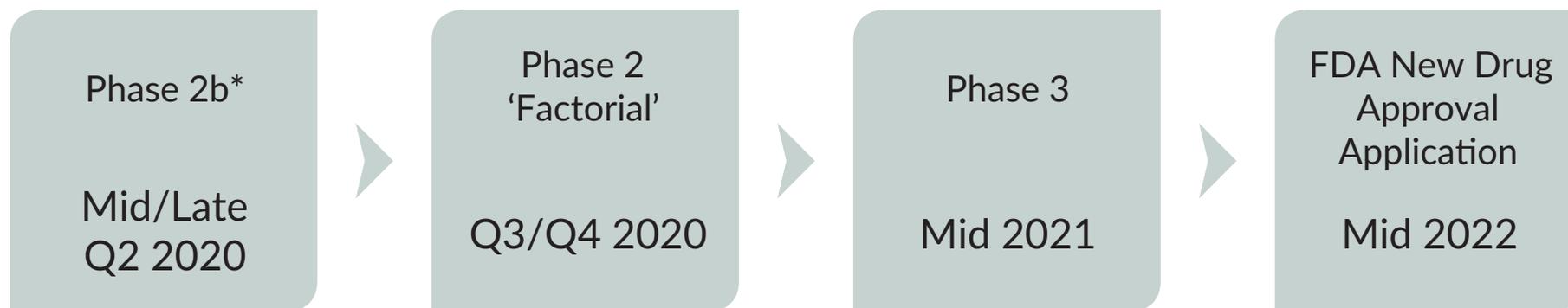
Independent Strategic Assessment Report

- IHL commissioned Camargo Pharmaceuticals Services ('Camargo') to provide an independent strategic assessment report on the FDA approval pathway for cannabinoid IHL-42X
 - Camargo is an expert FDA advisory having advised upon more than 250 successful FDA applications over 17 years
- Camargo has confirmed that IHL is a potential candidate for the 505(b)(2) New Drug Approval ('NDA') pathway, reducing time and cost to commercialisation, subject to successful clinical assessment
- Plan to bring IHL-42X to market in approximately 2.5 years, rather than up to 12 years for new molecular entities
- Camargo affirmed the substantial body of existing research determining that the constituents of IHL-42X work to stabilise sleep-related respiratory rhythm, and reduce the symptoms of OSA, as determined by the Apnoea Hypopnea Index



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IHL-42X Program Indicative Timeline



- IHL is not required to complete pre-clinical and phase 1 clinical trials prior to commencing phase 2 studies for its FDA new drug application for IHL-42X
- Why? Extensive existing publicly available clinical information (including safety data) on the primary constituents of IHL-42X
- Animals toxicology bridging study to run concurrently with Phase 2 “Factorial Study”

**Pending no significant delays related to COVID-19*

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Unregistered Sales Prior to Registration



- Sales achievable prior to FDA registration and after initial Phase 2b clinical trial commencing mid/late Q2 2020
- Unregistered sales achievable via Special Access Scheme in Australia and through dispensaries in United States, Canada and other jurisdictions
- Registration will facilitate prescription by all doctors, physician marketing and access of public reimbursement bodies, e.g. PBS in Australia

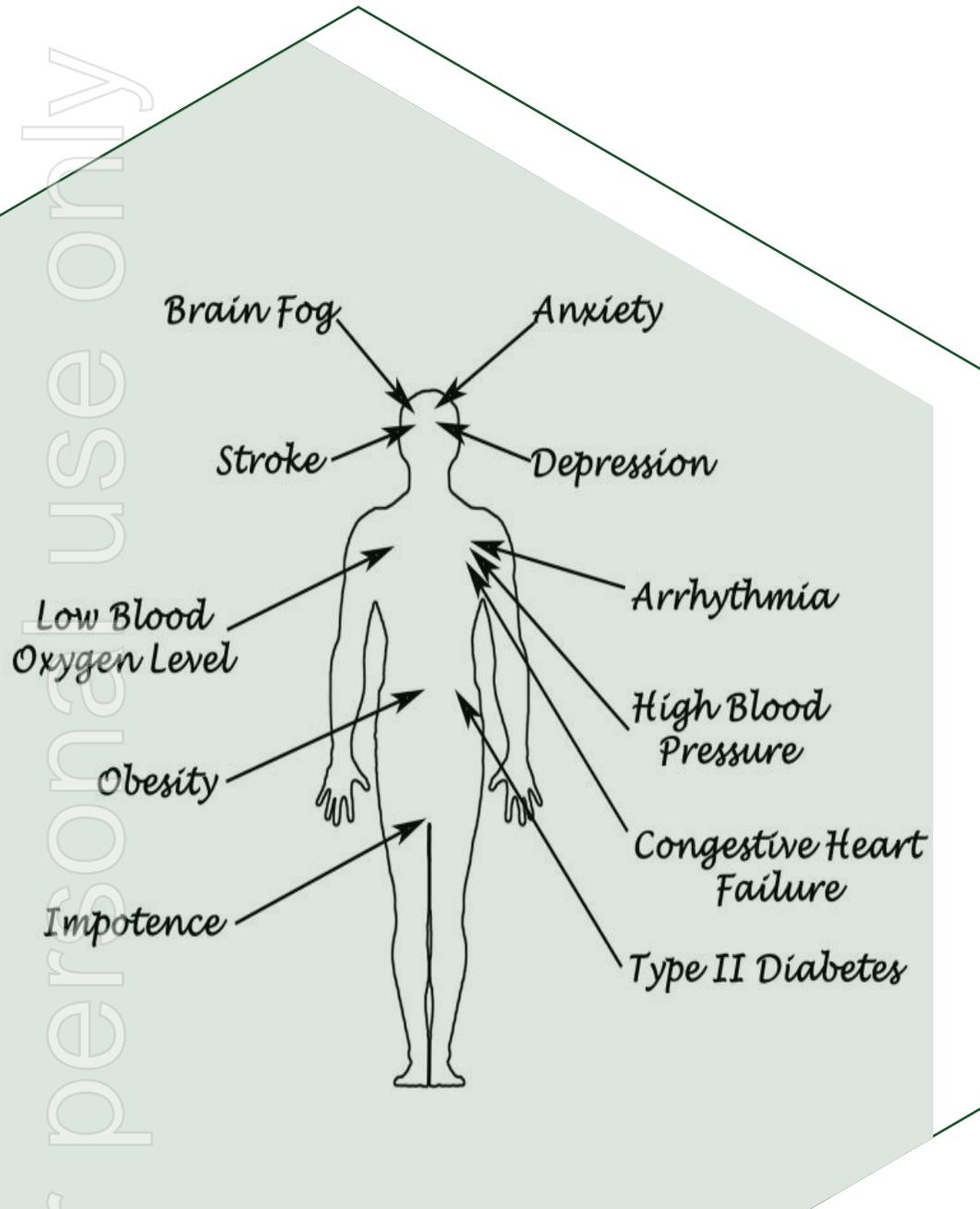
'Expedited Review' Programs – Camargo Expert Advice

- OSA is a serious and life-threatening condition over which IHL-42X addresses an unmet medical need
- There is no pharmaceutical (drug) treatment approved for OSA in any jurisdiction
- Therefore, IHL-42X is a candidate for one or more of the FDA expedited review programs:
 - Breakthrough Designation
 - Accelerated Approval
 - Priority Review
 - Fast-track
- If granted, FDA will assist in hastening the drug review process, further reducing time to commercialisation.



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OSA is an Urgent Global Health Priority



- According to the American Academy of Sleep Medicine, the diagnosis and effective treatment of OSA in adults is an urgent health priority (Ramar et al. 2018)
- OSA is a lethal disease that increases the risk of numerous health complications, affecting approximately 40M adults in the USA alone.
- Untreated OSA is associated with an increased risk of cardiovascular morbidity

Economic Opportunity

- Patient compliance to CPAP devices is low due to discomfort and claustrophobia (Wolkove et al. 2008)
- Greatly improved patient compliance is expected from an oral pharmaceutical product, such as IHL-42X
- The current direct global annual market size for OSA detection and treatment using CPAP devices is over US\$10B per annum and growing.

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Contact Details

Mr. Joel Latham

Chief Executive Officer and MD

joel@impression.healthcare

Dr. Sud Agarwal

Chief Medical Officer

sud@impression.healthcare

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