Ethics approval secured for phase IIB clinical trial for new Schedule 3 CBD product for the Australian market

- **Ethics approval has been granted by Bellberry Ethics Committee for Bod's planned phase IIB clinical trial – trial being undertaken by Australia's leading sleep research organisation, the Woolcock Institute**
- **The clinical trial will investigate the efficacy of a uniquely developed Schedule 3 CBD formulation on symptoms associated with insomnia in 200 participants over 8 weeks**
- **Schedule 3 (Pharmacist Only) products can be sold to Australian consumers over-the-counter without a prescription**
- **Ethics approval allows the commencement of participant recruitment for this significant clinical study**
- **Phase IIb clinical trial is the final step in R&D for new product and will provide sufficient data for application to register a low dose CBD product with the TGA**
- **Bod is one of the first Australian companies to undertake a clinical trial for Schedule 3 CBD products and expects to have one of the first products in market – this provides a significant competitive advantage**
- **Insomnia provides a major opportunity – market has demonstrated a 4.2% CAGR since 2017 and is expected to reach $5.48 billion by 2023**[i]
- **Discussions with numerous potential partners for Schedule 3 CBD products are well advanced**
- **Pharmacist-only CBD market in Australia expected to reach $250 million capturing ~2 million consumers**[ii]

Sydney, Australia – 24 January 2022: Medicinal cannabis and hemp healthcare products company, Bod Australia Limited ("Bod", or "the Company") (ASX: BOD) is pleased to advise that the Company's planned phase IIB clinical trial to be undertaken at the Woolcock Institute of Medical Research has received ethics approval from Bellberry Limited. The trial will investigate the efficacy of a new unique Schedule 3 (pharmacist only) CBD formulation on symptoms associated with insomnia. This is a major milestone for the Company allowing the immediate commencement of participant recruitment for the study.

The Woolcock Institute of Medical Research is Australia's leading sleep and respiratory research organisation. The trial will be a double blind, randomised and placebo-controlled investigation of the effect of administering a 50mg and 100mg oral CBD product per day, versus a placebo, over a 8-week period with over 200 participants (refer ASX announcement: 22 September 2021). The clinical trial is one of the first registered in Australia for a Schedule 3 CBD product.

Following completion of the study, Bod expects to have sufficient data to commence product registration for a Schedule 3 low dose CBD product with the Therapeutic Goods Administration (TGA) and for the product to be included on the Australian Register of Therapeutic Goods (ARTG). It is anticipated that completion of this process will provide Bod with a low dose CBD product that can be sold over-the-counter by a pharmacist to Australian consumers without a prescription. This unlocks another channel to market for the Company and has the potential to significantly increase domestic sales, underpinning additional revenue growth.

Insomnia provides a large opportunity for Bod. In an estimated global market of $5.4Bn by 2023[i], current pharmacological interventions for the treatment of insomnia have major limitations including abuse and dependence, questionable or uncertain efficacy and hangover effects. The successful development of Bod's product will provide it with a defined pathway to market and an opportunity to grow its market share.

Ethics approval underpins Bod's strong momentum bringing its Schedule 3 products to market. Participant recruitment will commence shortly and Bod is also in advanced discussions with a number of potential partners for its Schedule 3 CBD products and expects to provide additional updates on these over the coming months.

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CEO Jo Patterson said: *"Its very pleasing that ethics approval has been secured from the Bellberry Ethics Committee. This highlights our positive progress and brings us one step closer to commencing our planned clinical trial. Participant recruitment initiatives will commence shortly. Given the ongoing issues associated with pharmacological interventions designed to treat insomnia, we are very confident that there will be strong demand to participate in our trial.*

"The completion of this trial will provide us with basis to submit an application to the TGA, allowing Bod to become one of the first ASX-listed companies to register a Schedule 3 product for the Australian market. Additionally, we have engaged in numerous encouraging discussions with both our existing distribution networks and new potential partners to provide immediate sales upon registration."

Head of the Sleep and Circadian Group at the Woolcock Institute, Professor Ron Grunstein *"We are excited that ethics approval has been received for this clinical trial, as the trial designed in collaboration with the Company, will provide critically needed data on the effectiveness of CBD in insomnia as an alternative treatment route to existing pharmacological interventions."*

-ENDS-

About Bod Australia:

Bod Australia Limited (ASX:BOD) Bod is a cannabis centric healthcare company.

With a global focus and a mission to innovate and transform the way we live and enjoy life.

Delivering premium, proven and trusted products for both the consumer markets and medicalmarkets.

Leading the way in research and development, through collaborations with research partners onclinical trial programs.

Committed to supporting the healthcare professional on Cannabinoid applications through education, research and trials.

For more information please contact:

This release has been approved by the Board of Directors of BOD Australia Limited

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[i] https://www.alliedmarketresearch.com/insomnia-market

[ii] https://www.proactiveinvestors.com.au/companies/news/950040/australian-medicinal-cannabis-market-expected-to-exceed-2021-growth-expectations-hitting-200-million-mark-950040.html