# Bod's Schedule 3 Clinical Trial CBD 100mg displays statistical significance over placebo with p-value of 0.04 supporting commercialization pathway whilst primary endpoint on ITT population showed no statistical significance over placebo

- **CBD 100mg showed statistical significance over placebo for the primary endpoint of relief from short term insomnia with a p-value of 0.04 in the per protocol group**
- **The protocol set a statistical significance level of a p-value at 0.025 for primary endpoint analysis of the Intent-to-Treat group. A p-value of 0.05 and lower is typically used in clinical trials to demonstrate statistically significant results. Bod has identified commercial opportunities for the product for the statistically significant result seen in the per protocol group**
- **Safety and tolerability of CBD doses was assessed, no safety concerns were identified.**
- **Complete results are expected within 5 weeks.**

**Sydney, Australia – 6TH September 2023:** Cannabis focused drug development and product innovation company Bod Science Limited ("Bod" or "the Company") (ASX: BOD) is pleased to provide the following preliminary topline results from their phase IIB clinical trial for a new Schedule 3 CBD product for the Australian market. Complete results are expected within 5 weeks (including secondary and tertiary endpoints which include relief from anxiety and stress).

The trial assessed the efficacy of a uniquely developed Schedule 3 (Pharmacist Only over the over the counter (**OTC**) without prescription). CBD formulation on symptoms associated with insomnia in 208 participants over 8 weeks. The study design randomised patients to receive daily doses of double-blind study medication of either CBD 50mg, CBD 100mg, or placebo for the 8-week period. The statistically powered primary endpoint compares Insomnia Severity Inventory (ISI) scores for each dose compared to placebo. The ISI is a patient questionnaire completed at baseline (before study medication) then at week 4 and week 8. The study included an objective measure of sleep using actigraphy data gathered from a smart watch worn by patients for 7 days before taking study medication and then again for the final 7 days of study medication at Week 8. Anxiety and stress are secondary endpoints as measured by the DASS-21 questionnaire and will be reviewed as part of the complete and final results. The Phase IIB clinical trial enrolled 208 patients with insomnia; 194 completed the study and 208 were included in the intent-to-treat study population (all patients randomised to treatment). 180 were included in the per protocol study population (all patients completing the trial according to the protocol).

**Efficacy results:**

The primary endpoint analysis on the ITT population showed no statistically significant difference between either CBD dose compared to placebo when tested at the 0.025 statistical significance level.

Analysis of the primary endpoint on the per protocol population, showed a statistically significant benefit of CBD 100mg compared to placebo when tested at the 0.05 statistical significance level. A significance level of 0.05 indicates a 5% risk that the results occurred by chance. Bod is encouraged that the p-value of 0.05 shows a benefit between placebo vs 100mg. The Company plans to continue commercialisation discussions and meetings with the Therapeutic Goods Association (**TGA**) to discuss pathways towards Schedule 3 (OTC) registration which will be updated to the market in due course. Further detail can be viewed in the Annexure to this announcement.

**Safety results:**

Safety and tolerability of both CBD doses was assessed. Overall, adverse event incidence was similar between both CBD groups and placebo and no safety concerns were identified.

Schedule 3 products can be sold to Australian consumers over the counter without a prescription; Bod's unique CBD formulation is presented as a soft gel format and utilises a patent protected encapsulation technology that enhances and improves the bioavailability of the CBD extract.

When all results are available, Bod will meet with the TGA to discuss the registration pathway for our Schedule 3

low dose CBD product.

**Management commentary:**

**CEO Ms Jo Patterson said:** *"The trial completion marks a significant breakthrough for Bod for our uniquely formulated Schedule 3 CBD product. The singularity of this product is in its' soft gel format - utilising a patent protected encapsulation technology, presents enormous opportunity both through existing permitted pathways, and through other global markets.*

*"As we know, sleep is so central to our health and wellbeing, and the birth of this new product is certainly an exciting journey not only for our business but the cannabis market more broadly.*

**This announcement has been approved by the Board of Bod Science Limited.**

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**About Bod Science:**

Bod Science (ASX:BOD) is a cannabis focused drug development and product innovation company.

Bod is focused on progressing research and development with a defined clinical trial pathway to commercialise and deliver premium, scientifically proven and trusted products for patients and consumers.

The company has a number of existing partnerships with large corporate companies and collaborations with leading research organisations to advance the use of Cannabis related medicines with therapeutic indications.

**For more information please contact:**


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**ANNEXURE**

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| **Name and any unique identifier of the trial:** | Phase IIB - The CANnabidiol use for REIief of Short Term insomnia (CAN-REST) A Randomised, Double-Blind, Placebo-Controlled Clinical Study<br>A Phase IIB, randomised, double-blind, placebo controlled clinical study of cannabidiol use for relief of short term insomnia. |
| **Blinding status:** | Double blind |
| **Treatment method, route, frequency and dose levels:** | To investigate the effect of the administration of a 50mg and 100mg per day oral CBD product versus a placebo over 8 weeks on **Insomnia Severity Index scores.** |
| **Number of trial subjects:** | Target sample size 198<br>208 participants were included in the study and randomised to treatment. |
| **Dropout rate:** | 194 of 208 (93%) participants completed the study, with dropouts occurring at low levels for placebo (n=5, 6.25%), CBD 50mg (n=34.6%), CBD 100mg (n=4, 6.4%). Two participants withdrew due to adverse events and both were in the placebo group. |
| **Subject demographics:** | The treatment groups were similar, with a mean age of 46.9 years overall (range19-65 years).<br>The study population was predominantly female (70.9%) of Caucasian descent (90.3%) |
| **Control group:** | Mean ISI scores at Baseline were similar across all treatment groups, equating to a moderate insomnia level |
| **Primary endpoint results:** | The primary objective of this study is to investigate the effect of the administration of a 50mg and 100mg per day oral CBD product *versus* a placebo over 8 weeks on insomnia severity index scores in adults aged 18-65 years old with insomnia symptoms.<br><br>The primary endpoint summary<br>• In the ITT analysis, neither CBD dose is shown to be statistically different from placebo at a p-value of 0.025<br>• However, the per protocol group showed a significant difference (p 0.04) in ISI between CBD 100 mg and placebo for the unadjusted p-value of 0.05. Following p-value adjustment to 0.025, this no longer showed significance (p 0.086)<br>• The statistical threshold in this study was very high at p 0.025; the statistical significance at p 0.05 indicates efficacy at CBD 100mg dose. |
| **Safety and tolerability:** | The benign safety profile of CBD was confirmed, with AE rates similar across all groups. A dose dependent pattern of moderate-severe adverse events was seen with CBD, with no concerns identified. |
| **Secondary endpoint results:** | Results are not yet available and Bod will update the market in due course.<br><br>Secondary objectives are to determine the effect of 8 weeks of 50mg or 100mg of CBD compared to placebo on: |

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| | • Wake after sleep onset (WASO) as assessed by actigraphy.<br>• Anxiety as assessed by the DASS-21 questionnaire.<br>• Stress Outcome as assessed by the DASS-21 questionnaire. |
| **Tertiary endpoint results:** | Results are not yet available and Bod will update the market in due course.<br><br>Tertiary objectives of this study are to determine the effect of 8 weeks of 50mg or 100mg of CBD compared to placebo on:<br>• Sleep onset latency (SOL), total sleep duration, sleep efficiency and other measures as assessed by actigraphy;<br>• Subjective sleep including WASO, SOL, total sleep duration, sleep quality and other indices as assessed by sleep diaries;<br>• Self-perception of improvement in sleep as assessed by a self-report questionnaire;<br>• Depression as assessed by the DASS-21 questionnaire<br>• Subjective sleep-related quality of life as assessed by the Functional Outcomes Sleep Questionnaire (FOSQ-10);<br>• Fatigue assessed by the Flinders Fatigue Scale;<br>• Health-related quality of life (HRQoL) assessed using the EuroQol five-dimensional five-level questionnaire (EQ-5D-5L);<br>• Determine relationship between efficacy endpoint and systemic concentrations of CBD and its' carboxy and hydroxy metabolites (i.e. 7- hydroxcannabidiol (7-OH-CBD) and 7- carboxycannabidiol (7- COOH-CBD)). |