

## **Bod Softgel offers over 400% greater bioavailability than CBD isolate**

- Positive results achieved from Bods Phase 1 Clinical Trial evaluating safety, tolerability and pharmacokinetic (PK) profile of Bod ECS BioAbsorb Softgel Capsule against Epidyolex and CBD Oil
- Novel softgel delivery format being used in Bod's clinical trial to progress Schedule 3 (pharmacist only, over the counter without prescription) Cannabidiol (CBD) product shows superior bioavailability and faster maximum concentration in clinical pharmacokinetic (PK) study
- The study comprised of 3 oral treatment arms: Bod ECS BioAbsorb Softgel Capsule, Epidyolex Oil and CBD Oil, delivered as a single dose in a crossover design in 14 healthy subjects between 18-50 years old.
- All 14 subjects completed the trial with no safety or tolerability issues reported
- Maximum concentration of CBD after single oral administration of Bod ECS BioAbsorb Softgel was 600% greater than CBD Oil solution and over 60% greater than Epidyolex (TGA & FDA-approved, plant-derived, purified prescription CBD)
- Bod ECS BioAbsorb Softgel was twice as fast to reach maximum concentration of CBD after single oral administration of Epidyolex and five times faster than CBD Oil solution
- The PK study forms a critical and required step for the Company's Schedule 3 dossier submission to the TGA (Therapeutic Goods Association)

**Sydney, Australia – 22 November 2022:** Cannabis focused drug development and product innovation company, **Bod Australia Limited** ("Bod" or "the Company") (ASX: BOD), is pleased to provide the following statistical summary from its Phase 1 cannabidiol (CBD) pharmacokinetic (PK) study.

The PK study, undertaken as part of a number of elements within Bod's Schedule 3 (pharmacist only) project, forms a critical and required step for the Company's dossier submission to the TGA (Therapeutic Goods Association). Bod's ongoing Phase IIb clinical trial underpins the Company's drive to develop a new Schedule 3 (pharmacist only) CBD product to be made available to the Australian market. This supports Bod's strategy of consistently selling products through SAS-B channels since 2018<sup>1</sup> which has allowed the Company to build a strong foothold in the market.

The PK study consisted of three (3) oral treatment arms delivered as a single dose in a crossover design in 14 healthy subjects between 18-50 years old, each equating to 100mg CBD per day:

1. Bod ECS BioAbsorb Soft Gel Capsule<sup>2</sup>
2. Epidyolex Oil (a TGA & FDA-approved, plant-derived, purified prescription cannabidiol)
3. CBD isolate in MCT oil (a supplement made from a structure of fat termed medium-chain triglycerides)

Statistical analysis received on the study supports the potential for Bod's unique ECS BioAbsorb Soft Gel to be the benchmark delivery format for the over the counter CBD market.

The below outcomes were reported in relation to the trial's primary and secondary endpoints:

- Bod ECS BioAbsorb Softgel showed over 20% greater concentration of CBD in the blood than Epidyolex
- Bod ECS BioAbsorb Softgel showed over 400% greater concentration of CBD in the blood than CBD Isolate Oil solution
- The maximum concentration of CBD after a single oral administration of Bod ECS BioAbsorb Softgel was over 60% greater than Epidyolex
- The maximum concentration of CBD after a single oral administration of Bod ECS BioAbsorb Softgel was 600% more than CBD Oil solution
- The time to reach the maximum concentration of CBD after single oral administration of Bod ECS BioAbsorb Softgel was twice as fast as Epidyolex and five times faster than CBD Oil solution

**Bod's Chief Executive Officer, Ms Jo Patterson said:**

*"These reported findings from Bod's PK study provide us great assurance as we progress toward the dossier submission for the TGA, and subsequent registration our Schedule 3 CBD product.*

*"Bod considers our uniquely developed softgel format product to be at the forefront of the Schedule 3 CBD space in Australia and we look forward to reporting further on our clinical trial as we continue to move through each stage.*

*"We're pleased to see indicators that continue to de-risk our pathway to launching Bod ECS BioAbsorb Softgel, which will introduce a new delivery format for Australian consumers."*

Overall, Bod ECS BioAbsorb Softgel showed significantly higher concentrations, faster delivery and greater bioavailability of CBD (Cannabinoid), than the other delivery formats assessed within the study (Epidyolex and CBD (cannabidiol) isolate in MCT oil) and complement the Company's existing products that are being used to alleviate a range of conditions including chronic pain, anxiety and insomnia amongst others.

**Schedule 3 Clinical Trial and Product Background**

Bod is undertaking a Phase IIb clinical trial for the development of a new CBD product. The Company will progress the development of the new product in line with Therapeutic Goods Administration (TGA) requirements, which will be made available to Australian consumers over the counter as a Schedule 3 (Pharmacist Only) medicine, as well as other key international markets.

The clinical trial will test the efficacy of the Company's unique CBD formulation on symptoms associated with insomnia. The clinical trial is designed to be double blind, randomised and utilises both a parallel and placebo-controlled group. The study will look to investigate the effect of the administration of a 50mg and 100mg per day oral CBD product, versus a placebo, over an 8-week period.

The Company has secured ethics approval for the initiative, allowing for participant recruitment<sup>3</sup> which is well underway with the trial ongoing through the Woolcock Institute.

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

**-ENDS-**

**About Bod Australia:**

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

Bod is focused on progressing R&D and a defined clinical trial pathway to commercialise and deliver premium, scientifically proven and trusted products for the consumer and medical markets.

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

**For more information please contact:**

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<sup>1</sup> ASX Announcement - 25 October 2018: Bod secures first medicinal cannabis prescription

<sup>2</sup> ASX Announcement - 23 June 2022: Bod to launch low dose CBD schedule 3 product into the Australian market via SAS-B channel

<sup>3</sup> ASX Announcement - 24 January 2022: Ethics approval secured for phase IIb clinical trial for new Schedule 3 CBD product for the Australian market