

# Australia-wide medicinal cannabis study commenced

- Study to gain further insight into the effectiveness of the MediCabilis™ range when prescribed for conditions including anxiety disorders, insomnia and PTSD
- Study aims to recruit 500 patients over a 12-month period through leading cannabis clinics
- Patients are expected to receive three to four MediCabilis™ prescriptions during the study
   further adding to growing prescription volumes
- Data will provide important insights for practitioners prescribing MediCabilis™ medicines and pave way for future clinical research and international product registration

**Sydney, Australia** – **16 July 2020:** Medicinal cannabis, CBD and hemp healthcare products company, Bod Australia Limited ("Bod", the "Company") (ASX: BDA) advises that it has commenced an Australia-wide, multi-clinic, open-label observational study into the effectiveness of its medicinal cannabis range, MediCabilis™, for indications including anxiety disorders, insomnia and Post Traumatic Stress Disorder (PTSD).

The study aims to collect data from 500 patients who will be prescribed MediCabilis™ over a 12-month period with the aim of generating insights into the efficacy of the product on patients suffering from particular conditions. The study builds on Bod's Phase I Clinical Study (refer ASX announcement: 26 March 2019) and also supports research being undertaken as part of Project Twenty21, Europe's largest medicinal cannabis registry (refer ASX announcement: 8 November 2019). The results will provide important data to support practitioners who are prescribing MediCabilis™ and assist Bod in modelling its planned future research and product development.

The initiative will be run through approved study sites across Australia, with reputable partners including Cannabis Doctors Australia, Compass Clinics, Cannabis Access Clinics and Tetra Health.

Bod anticipates that each patient will be prescribed MediCabilis™ three to four times over the course of the study, which will add to the Company's growing cannabis prescription sales pipeline. Further, the initiative will create additional visibility for the Company's product amongst healthcare professionals and patients.

Study design has been approved by the Bellberry ethics committee and will comply with Good Clinical Practice (GCP) standards. Data will be collected using scientifically validated methods and an FDA and TGA-compliant database, which will support the registration pathway for MediCabilis™ in the USA and other markets.

First patients are currently being recruited and Bod expects to receive first prescriptions from the study this month. Bod will release data generated to healthcare professionals throughout the study, as well as provide ongoing updates on prescription volumes.

**CEO Jo Patterson said:** "We are confident that the outcomes from this extensive trial will provide important insights for medical practitioners into how MediCabilis™ can be best utilised for patients suffering from a number of chronic conditions and common, yet debilitating disorders.

"The need to find alternative solutions to treat a range of chronic health disorders is ever-present and we are hopeful that this trial will further demonstrate the effectiveness of MediCabilis™ in helping sufferers. The prevalence of these conditions amongst the global population is considerable - up to 33.7% of people are affected by an anxiety disorder during their lifetime¹ with up to 30% not responding to regular treatment<sup>ii</sup>. Conditions such as chronic insomnia also have a significant impact on a sufferer's health and can result in considerable healthcare costs<sup>iii</sup>.

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 medical markets. Leading the way in research and development, through collaborations with research partners on clinical trial programs.

Committed to supporting the healthcare professional on Cannabinoid applications with education, research and knowledge.

#### **CAPITAL STRUCTURE**

ASX code BDA
Shares on issue 91.4m
Market Capitalisation ~\$23.8m

#### **BOARD & MANAGEMENT**

Mr Mark Masterson Non-Executive Chairman

Ms Jo Patterson
Chief Executive Officer

Mr Akash Bedi Non-Executive Director

Mr George Livery
Non-Executive Director

Mr Patrice Malard Non-Executive Director

Mr Simon O'Loughlin Non-Executive Director

Mr Stephen Kelly Company Secretary

#### CONTACT

Level 1, 377 New South Head Rd Double Bay, NSW 2028

T +612 9199 5018
E info@bodaustralia.com.au



"While MediCabilis™ uptake amongst patients and healthcare professionals continues to build, this study provides us with another sales channel and greater visibility in the Australian market. We look forward to updating shareholders on receipt of first prescription and study progress in the coming weeks."

Bod's Chief Scientific Officer Dr Adele Hosseini added: "One of the reasons doctors are hesitant to prescribe medicinal cannabis is because they do not feel there is sufficient high-quality evidence to support its safety and use. Bod is conducting this study to systematically collect validated, real-world data that will provide insight into how MediCabilis™ is being used and build the evidence base that will boost both practitioner and patient confidence and trust in the medicines."

Cannabis Doctors Australia Principal Investigator Dr Ben Jansen said: "Bod is to be commended for taking a pharmaceutical and scientific approach in gathering high-quality evidence to guide and support the use of their medicines. Our clinic regularly prescribes Bod's medicinal cannabis medicines due to the results we are seeing in our patients and are pleased with the reliability of the medicines. Treatment is improving outcomes for many of our patients, many suffer from chronic conditions that haven't responded to conventional treatment options and have limited options. We are in full support of this national study and I am proud to be the primary investigator leading this important research."

If you are interested in finding out more about the trial or potentially participating, please visit www.bodaustralia.com

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## **ABOUT BOD AUSTRALIA**

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### For more information please contact:

Jo Patterson Chief Executive Officer info@bodaustralia.com +61 2 9199 5018 Henry Jordan
Six Degrees Investor Relations
henry.jordan@sdir.com.au
+61 431 271 538

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4610617/

ii https://www.psychiatryadvisor.com/home/topics/anxiety/approaching-treatment-resistant-anxiety/

iii https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5353813/