

## Clinical Trial Authorisation secured to commence UK-based trial into medicinal cannabis efficacy on long-COVID

- Clinical Trial Authorisation granted by the UK's Medicines & Healthcare Products Regulatory Agency – allows Bod to commence a clinical trial into the effectiveness of medicinal cannabis on long-COVID
- Six-month clinical trial to be undertaken in collaboration with the UK's leading independent scientific body on drugs, Drug Science UK
- Long-COVID refers to the extended effects following an initial COVID-19 infection – symptoms include chronic pain, anxiety, sleep disturbances and fatigue
- Clinical Trial Authorisation follows final protocol design and ethics approval – allows for immediate commencement participant recruitment process
- 30 trial participants suffering from long-COVID to be recruited and administered daily doses of Bod's medicinal cannabis product, MediCabilis® 5%
- Trial allows Bod to pursue a large market opportunity – an estimated 1.3m people in the UK are suffering long-COVID with one in forty COVID-19 infections having symptoms lasting upwards of three months
- There is currently no leading treatment for long-COVID despite global prevalence
- This trial will allow Bod to build important IP and data, providing a pathway towards the commercialisation of a potential treatment product which can be sold throughout the UK and other countries
- Bod's medicinal cannabis products, MediCabilis®, are currently prescribed to patients with conditions including chronic pain, anxiety and sleep disorders

**Sydney, Australia – 17 January 2022:** Medicinal cannabis and hemp healthcare products company, Bod Australia Limited ("Bod", or "the Company") (ASX: BOD) is pleased to advise that it has secured Clinical Trial Authorisation ("CTA") from the United Kingdom's Medicines & Healthcare Products Regulatory Agency ("MHRA") to commence an open label clinical trial in association with Drug Science UK ("Drug Science") ([www.drugscience.org.uk](http://www.drugscience.org.uk)) to explore the effectiveness of Bod's medicinal cannabis product, MediCabilis® 5% ("MediCabilis®") on symptoms associated with the long term impact of SARS-CoV-2 ("COVID-19"), commonly referred to as long-COVID.

This initiative provides Bod with an important opportunity to build on the growing body of evidence for the use of MediCabilis®, as well as insight into the potential use of the product as a treatment against long-COVID. Upon completion of the trial and pending successful results, Bod will embark on the commercialisation of a MediCabilis® product which can be used to treat the condition. The Company anticipates that this will lead to increased sales volumes across the UK and other territories.

The clinical trial will be led by Principle investigator, Dr Elizabeth Iverson and is being undertaken in collaboration with UK's leading independent scientific body on drugs, Drug Science UK (refer ASX announcement: 18 March 2021). Drug Science was founded in 2010 by Professor David Nutt and is the only completely independent, science-led drugs charity in the UK. The group is focused on bringing together leading experts from a wide range of fields to provide an evidence base, free from political and commercial influence, to create the foundation for sensible and effective drug laws.

Long-COVID is an emerging condition referring to persistent or new symptoms that develop at least eight weeks following an initial COVID-19 infection. Long-COVID may include the continuation of symptoms from when an individual is first infected, or new symptoms where individuals feel they have improved and a month after being infected symptoms arise again.

There are a wide range of long-COVID indications, including shortness of breath, fatigue, worsening chest discomfort,

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loss of concentration, chronic pain, anxiety and insomnia. Many of these symptoms may be amenable to treatment with cannabis-based medicinal products, highlighting a significant opportunity for Bod.

Following the receipt of CTA, Bod has begun initiatives to commence the clinical trial. A trial protocol has been finalised and ethics approval has been secured from the Yorkshire Research Ethics Committee, Health Research Authority. Bod and Drug Science are now undergoing the patient recruitment process and seek to enlist up to 30 participants over the age of 18 suffering from long-COVID.

Under the clinical trial setting, recruits will be administered Bod's medicinal cannabis product, MediCabilis®, on a daily basis, over a six-month period. Each participant will undertake monthly and daily self-reporting assessing common long-COVID symptoms such as breathlessness, fatigue, cognition and pain via a smartphone app. The collective results will determine the feasibility of medicinal cannabis and MediCabilis® in the treatment of the condition and whether it is safe to use.

Success in the initiative would unlock a large market opportunity for Bod to capitalise on. The UK's Office for National Statistics (ONS) estimates that 1.3m people in the UK currently suffer from the condition and that approximately one in every forty people with COVID-19 has symptoms lasting at least three months.

Bod is confident that its medicinal cannabis product, MediCabilis® may provide a solution to the emerging condition, given MediCabilis® is already being used to alleviate a number of conditions which are common in people suffering long-COVID. The Company looks forward to providing additional updates on the patient recruitment process and commencement of the clinical trial.

**Bod Australia CEO Jo Patterson said:** *"Securing CTA is a major achievement for Bod and follows a considerable amount of preparation undertaken alongside our partner, Drug Science to finalise the design of clinical trial protocols, achieving ethics approval and delineating relevant outcomes."*

*"Patient recruitment is now underway and we anticipate that the interest to participate will be significant. COVID-19 continues to plague the United Kingdom and many other countries around the world, with symptoms lingering for many."*

*"While there aren't any existing treatments for long-COVID, our medicinal cannabis products have been used to treat and alleviate a number of similar conditions. We anticipate that this clinical trial will provide us with great insight into its potential to treat long-COVID and build on the body of evidence for the use of cannabis-based medicines, in place of other pharmaceuticals. We will utilise the data generated to gain a better understanding of whether MediCabilis® can be used as a potential treatment and how we can expedite further product commercialisation, which will underpin ongoing sales growth."*

**Principal investigator Dr Elizabeth Iverson said:** *"We are excited that Clinical Trial Authorisation has been granted so that we can commence this trial into the potential use of medicinal cannabis products to treat long-COVID. Given the ongoing and global prevalence of COVID-19 and its long term effects, it is important to take a scientifically focused approach towards the potential treatment mechanisms associated with the condition."*

**Drug Science Founder and Chief Scientific Officer Professor David Nutt added:** *"Long-COVID shares symptoms with disorders that medical cannabis has been proved to treat. So this new study could be an exciting and important step for both patients and for our wider understanding of these medicines. Long-COVID is a problem in many different countries, our hope is that this UK-based research will lead to help for patients all over the world."*

**-ENDS-**

#### **About Bod Australia:**

Bod Australia Limited (ASX:BOD) Bod is a cannabis centric healthcare and medical 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 through education, research and trials.

**This announcement was authorised for release by the Board of Directors of Bod Australia Limited.**

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