

30 November 2022



## ASX ANNOUNCEMENT

# Ethics approval received for Phase III clinical trial for Australian Schedule 3 CBD drug registration



### Highlights:

- LGP has secured Human Research Ethics Approval for its Phase III SleepWell Study in support of proposed Australian Schedule 3 CBD product registration for stress reduction and improved quality of sleep
- The estimated global market for insomnia is \$5.4 billion by 2023<sup>1</sup> with the Pharmacist-only CBD market in Australia expected to reach \$250 million and over 2 million consumers at market maturity
- Schedule 3 (Pharmacist Only) products can be sold to Australian consumers over-the-counter without prescription. There are currently no OTC CBD products available in the Australian market
- LGP's proposed Schedule 3 CBD product development is part of LGP's wider product and drug delivery innovation strategy, with the Company now considering various funding and partnering options to progress the SleepWell Study and Schedule 3 product registration

Little Green Pharma Ltd (ASX: LGP, "LGP" or the "Company") is pleased to announce it has obtained Human Research Ethics Approval ("**Ethics Approval**") for its proposed Australian-based, multi-site, placebo-controlled pharmacokinetic and Phase III efficacy and safety trial of the Company's LGP Classic CBD 50 cannabis medicine for stress reduction and improved quality of sleep in healthy adults ("**SleepWell Study**").

Successful completion of the Phase 3 SleepWell Study will support the future registration of LGP's Classic CBD 50 medicinal cannabis oil with the TGA as a schedule 3, over-the-counter treatment (OTC) for stress reduction and improved quality of sleep.

1. <https://www.alliedmarketresearch.com/insomnia-market>



*LGP's Chief Executive Officer and Managing Director, Fleta Solomon, said:*

"We are delighted to receive ethics approval for LGP's SleepWell Study, which is yet another significant achievement for the LGP team and its product and drug delivery innovation strategy. This represents a significant milestone for Australian patients along the pathway to ultimately accessing Australian made CBD products at their local pharmacy 'over the counter'"

The global market for insomnia treatments is estimated at \$5.4 billion by 2023<sup>1</sup>, with many of the current treatments for insomnia having major limitations including abuse and dependence, questionable or uncertain efficacy, and hangover effects; while the Pharmacist-only CBD market in Australia is expected to reach \$250 million and over 2 million consumers at market maturity.<sup>2</sup> There are currently no Schedule 3 registered CBD products in the Australian medicinal cannabis market.

LGP's decision to progress Ethics Approval for a proposed Schedule 3 registration follows the Therapeutic Goods Administration ("TGA")'s decision in December 2020 to down-schedule certain CBD preparations from a Schedule 4 (Prescription Only Medicine) to a Schedule 3 (Pharmacist Only Medicine) product. The Company is now considering funding and partnering options for the SleepWell Study in order to progress to Schedule 3 CBD product registration.

**ENDS  
BY ORDER OF THE BOARD**

A handwritten signature in black ink, appearing to read "Alistair Warren".

**Alistair Warren**  
Company Secretary

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

For further information please contact:

**Alistair Warren**  
**Company Secretary**  
Little Green Pharma  
E: [a.warren@lgp.global](mailto:a.warren@lgp.global)  
T: +61 8 6280 0050

**Fleta Solomon**  
**Chief Executive Officer**  
Little Green Pharma  
E: [f.solomon@lgp.global](mailto:f.solomon@lgp.global)  
T: +61 8 6280 0050

## About Little Green Pharma

Little Green Pharma is a global, vertically integrated and geographically diverse medicinal cannabis business with operations from cultivation and production through to manufacturing and distribution.

The Company has two global production sites for the manufacture of its own-branded and white-label ranges of GMP-grade medicinal cannabis products, being a 21,500m<sup>2</sup> cultivation and 4,000m<sup>2</sup> GMP manufacturing facility capable of producing over 30 tonnes of medicinal cannabis biomass per annum located in Denmark (EU) and an indoor cultivation and manufacturing facility located in Western Australia capable of producing ~3 tonnes of medicinal cannabis biomass per annum.

Little Green Pharma products comply with all required Danish Medicines Agency and Therapeutic Goods Administration regulations and testing requirements. With a growing range of products containing differing ratios of active ingredients, Little Green Pharma supplies medical-grade cannabis products to Australian, European and overseas markets.

The Company has a strong focus on patient access in the emerging global medicinal cannabis market and is actively engaged in promoting education and outreach programs, as well as participating in clinical investigations and research projects to develop innovative new delivery systems.

For more information about Little Green Pharma go to: [www.littlegreenpharma.com](http://www.littlegreenpharma.com)

## Help us be Green

LGP investors are encouraged to go paperless and receive Company communications, notices and reports by email. This will ensure efficient communication during COVID-19 while also helping to reduce our costs and environmental footprint.

To easily update your communication preferences, visit: [www.computershare.com.au/easyupdate/lgp](http://www.computershare.com.au/easyupdate/lgp)