

ASX ANNOUNCEMENT

7 September 2023

Large scale cannabis study findings released

Results find medicinal cannabis significantly improves pain, quality of life & fatigue

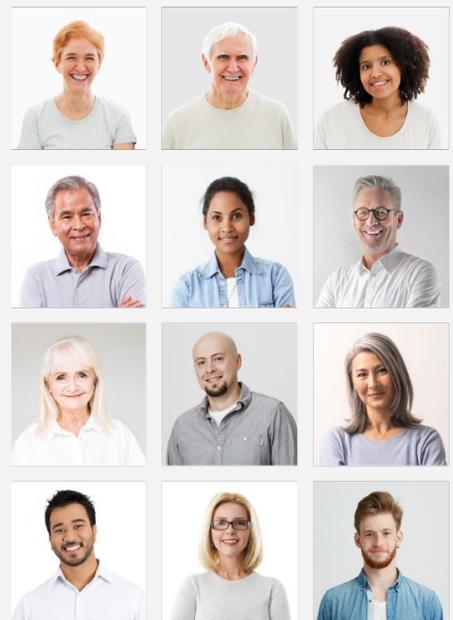
Little Green Pharma (ASX: LGP) wishes to advise of a media release issued today relating to the analysis of the initial three-month results from the QUEST Initiative¹.

A copy of that media release is appended to this announcement.

Analysis of the initial three-month follow-up results from 2,327 Australian patients participating in the QUEST Initiative show:

- very strong evidence of clinically meaningful improvements for those suffering health-related quality of life (HRQL) and fatigue
- clinically meaningful reductions in pain and significant improvements for moderate-severe anxiety and depression

Analysis of 12-month results is currently being undertaken to see if such improvements are maintained over the longer term.



Overview

The QUEST Initiative, sponsored by LGP, was one of the world's largest longitudinal clinical studies investigating the effect of medicinal cannabis on patient quality of life and health economic impacts. The study was led by a leading Australian university with LGP exclusively supplying the medicinal cannabis products to patients enrolled in the study and with Study costs fully funded from patient participation fees.

¹Refer to ASX announcement dated 18 February 2021.

The study was also supported by not-for-profit private health insurance provider Health Insurance Fund of Australia (HIF) and guided by an experienced advisory group and endorsed by a range of national bodies, such as MS research Australia, Chronic Pain Australia, Arthritis Australia and Epilepsy Australia.

For a full analysis of the results, please refer to the media release attached.

ENDS
BY ORDER OF THE BOARD



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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, with its Danish facility being one of the largest GMP medicinal cannabis production sites in Europe (if not the largest) and its West Australia site a premium indoor GMP production facility specialising in premium hand-crafted cannabis strains.

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

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



Media Release

Australian clinical study finds medicinal cannabis significantly improves pain, quality of life, fatigue, moderate-severe anxiety and depression

Highlights

- The Quality of Life Evaluation Study (QUEST Initiative) is one of the world's largest longitudinal clinical studies investigating the effect of medicinal cannabis on patient quality of life
- Analysis of 3-month follow-up results from 2,327 Australian patients participating in the QUEST Initiative show:
 - Very strong evidence of clinically meaningful improvements for those suffering health-related quality of life (HRQL) and fatigue
 - Clinically meaningful reductions in pain and significant improvements for moderate-severe anxiety and depression
- Analysis of 12-month results underway assessing whether improvements are maintained over the longer term
- Peer reviewed findings available in open-access journal PLOS ONE: [\[https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0290549\]](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0290549)

Little Green Pharma (ASX: LGP) is pleased to advise analysis of initial results from the award-winning¹, QUEST Initiative has found significant improvements in overall HRQL, fatigue levels as well as improvements in anxiety, depression and pain among Australian patients who have been part of the medicinal cannabis study during the initial three-month period.

The QUEST Initiative, sponsored by LGP, was one of the world's largest longitudinal clinical studies investigating the effect of medicinal cannabis on patient quality of life and health economic impacts. The study was led by the University of Sydney with LGP exclusively supplying the medicinal cannabis products to patients enrolled in the study.

The study was also supported by not-for-profit private health insurance provider Health Insurance Fund of Australia (HIF) and guided by an experienced advisory group and endorsed by a range of national bodies, such as MS research Australia, Chronic Pain Australia, Arthritis Australia and Epilepsy Australia.

¹ <https://www.cannabiz.com.au/cannabizawards/>

Overview

Adult patients in Australia who were newly prescribed medicinal cannabis for health conditions – including chronic pain, fatigue, sleep, depression and anxiety – between November 2020 and December 2021 were invited to participate in the study.

Participants completed a questionnaire before starting medicinal cannabis treatment and then subsequent questionnaires two weeks after commencing treatment, and every 1 – 2 months thereafter for up to one year.

Overall, 2,327 Australian patients aged between 18 to 97 years (average 51 years) participated in the study of which 63% of overall participants were female. Patients were recruited across six states by 120 independent doctors, a point of difference to the study.

The most-reported conditions being treated were chronic pain (69%); sleep disorders (23%); anxiety (22%); and anxiety/depression (11%); half of patients were being treated for more than one condition.

Results

Results from the first three-months of patients using medicinal cannabis found there was very strong evidence ($p < 0.001$) of clinically meaningful improvements in HRQL and fatigue across all health conditions assessed.

"Clinically meaningful results" in a study refer to findings that have a significant and important impact on a person's health or well-being. These results are not just small or insignificant changes; instead, they are substantial and can make a real difference in how healthcare professionals understand or treat a medical condition².

Patients also reported clinically meaningful reductions in pain and significant improvements for moderate-severe anxiety and depression.

However, three-month results for those patients assessed for sleep disorders found no change despite the very strong evidence of statistical improvement in feelings of fatigue. It is worth noting that these findings reflect the grouping of all medicinal cannabis oil formulations used by participants and that further analysis of the 12-month findings will seek to identify whether specific product formulations had differing impact on sleep.

These outcomes hold substantial clinical significance, particularly given the strict eligibility criteria for medicinal cannabis prescription in Australia, where patients must have exhausted conventional treatment options. It is remarkable for a single medication to exhibit a positive impact on treatment-resistant patients across such a broad range of medical conditions³.

² Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. *J Clin Epidemiol.* 2003 May;56(5):395-407. doi: 10.1016/s0895-4356(03)00044-1. PMID: 12812812.

³ Abelev S, Warne LN, Benson M, Hardy M, Nayee S, Barlow J. Medicinal Cannabis for the Treatment of Chronic Refractory Pain: An Investigation of the Adverse Event Profile and Health-Related Quality of Life Impact of an Oral Formulation. *Med Cannabis Cannabinoids.* 2022 Feb 9;5(1):20-31. doi: 10.1159/000521492. PMID: 35950052; PMCID: PMC9235063.

Dr. Jamie Rickcord, an independent General Practitioner involved in the QUEST Initiative, stated: *“The QUEST results show that medicinal cannabis provides statistically, and more importantly, clinically significant improvements in pain levels, fatigue and quality of life for patients. Doctors can have confidence in offering medicinal cannabis treatment as an option to those who qualify for it as result of emerging real-world data provided by initiatives such as QUEST”.*

Next steps

Analysis of 12-month results is currently being undertaken to see if improvements are maintained over the longer term. In addition, due to the positive findings of this study, a new investigation called the [Global QUEST Initiative](#) is recruiting patients to determine the health economic impact of medicinal cannabis.

Commenting on the three-month findings, Little Green Pharma Head of Research & Innovation Dr Leon Warne said:

“Little Green Pharma is extremely proud to support this significant study into the effect of medicinal cannabis on patient quality of life.

“These initial results are highly encouraging, highlighting meaningful improvements in health-related quality of life and fatigue levels as well as improvements to health conditions associated with anxiety, depression and pain among Australian patients who participated in the study.

“As well as the medical benefits to patients, this study was able to provide access to experienced prescribers and more affordable medication.

“We now look forward to what the 12-month results show in terms of longer-term impact of medicinal cannabis on QUEST patients.”

Results from The QUEST Initiative comes after the recent launch of the new QUEST Global study (<https://www.thequestinitiative.com>), led by another Australian university and sponsored by Little Green Pharma and HIF, to assess whether medicinal cannabis reduces the economic impact of chronic disease by reducing both the number of medications a patient requires and their need for healthcare services.

In 2020, HIF became the first major Australian health fund to declare support for access to medicinal cannabis treatments and research in Australia.

HIF CEO Justin James said studies like the QUEST Initiative provide insights that are valuable not just for HIF and its members but the health insurance industry as a whole.

“We are always interested in supporting studies into the health effectiveness of medicinal cannabis,” Mr James said. “They allow us to gain more information about the effectiveness of using medicinal cannabis to treat chronic conditions and how we can make these types of medications more economical going forward.”

Mr James said he was encouraged by the three-month findings from the QUEST Initiative and was looking forward to the 12-month results and understanding whether improvements are maintained over the longer term.

HIF has also pledged its support for the next phase of the study, [QUEST Global](#).

“HIF proudly provides choice to members so they can have the flexibility to control their own medical outcomes,” he said. “Supporting members with medicinal cannabis as a treatment option is another choice that we are proud to provide members.

“HIF members will once again have priority access to QUEST Global as participants, provided they meet the eligibility criteria.”

For media enquiries / interview requests:

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About Little Green Pharma

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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

About HIF

HIF has been supporting its members and their families' health and wellbeing for over 65 years. A not-for-profit health fund, HIF provides choice to its members. Whether it's choice of hospital, specialist, or other provider, HIF gives members total freedom to make these decisions when it comes to their health.

For more information about HIF go to <https://www.hif.com.au/>

About Dr Jamie Rickcord

Dr Jamie Rickcord is the founder of Ananda Clinics with a passionate focus on patient-first medicine, innovative treatment options. Practising in the Northern Rivers region of NSW, Dr. Jamie has developed his specialty in Integrative Medicine, Trauma Informed Psychotherapy and the therapeutic application of plant-based medicines.