



7 September 2021

Ecofibre Limited – Update on Australian S3 (OTC) CBD Research

Ecofibre Limited (Ecofibre, Company) (ASX:EOF, ADR: EOFBY) has previously announced that it received Human Research Ethics Committee approval to undertake a Phase IIb double blind, randomised, placebo-controlled, multi-site clinical trial for sleep disturbances.

Enrolment in the study is progressing despite the impact of COVID-19 restrictions in Australia. A number of online screening surveys have been received and are being reviewed in accordance with study criteria, and the study's first participant has now been enrolled.

A copy of a press release by Southern Cross University (SCU), and Dr Janet Schloss the chief investigator of the study, is attached.

Ecofibre Chairman Barry Lambert said "Ecofibre and SCU have worked together to minimise COVID-19 disruption for this study, which is an important community initiative."

"The study is particularly relevant where there are reports of 'black market' cannabis being used in the community for sleep, pain and anxiety. Australians deserve a professionally prepared and researched legal alternative and it is important that scientific studies of this nature are not delayed by COVID-19 lock downs."

The SCU sleep study is an important part of Ecofibre's broader clinical research portfolio and the Company's strategy to be a first mover in the Schedule 3 (Pharmacist only medicine) over-the-counter market in Australia.

Mr Lambert commented "the process of undertaking S3 research and product registration is rigorous and lengthy, but we expect in the future this will be a large, well-regulated and highly accessible channel for Australian patients."





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About Ecofibre

Ecofibre is the leading diversified hemp company globally.

In the United States, Ananda Hemp is the leading pharmacy brand for hemp-derived CBD products. The Company produces nutraceutical products for human and pet consumption, as well as topical creams and salves. See www.anandahemp.com and www.anandaprofessional.com. The Company also supplies its leading Ananda Hemp CBD products to Australians via the SAS-B program. See www.anandahemp.com.au.

Hemp Black manufactures and sells sustainable, high-performance textile products in the United States. See www.hempblack.com.

In Australia, Ananda Food is the leading grower and producer of a range of hemp food products including protein powders, de-hulled hemp seed and hemp oil. See www.anandafood.com. The Company is also a leading provider of quality industrial hemp genetics in the United States.

The Company owns or controls key parts of the value chain in each business, from breeding, growing and production to sales and marketing. Our value proposition to customers is built on strong brands and quality products.

Authorisation

This document is authorised to be given to the Australian Securities Exchange (ASX) by the Chairman of the Company.



MEDIA RELEASE

7 September 2021

Australia's largest CBD clinical trial commences to investigate over-the-counter medicinal cannabis for sleep disturbances

Southern Cross University researchers have commenced Australia's largest clinical trial investigating the efficacy of an over-the-counter botanical cannabidiol (CBD) product to help with sleep disturbances in a healthy population.

Dr Janet Schloss, Clinical Trials Fellow, is the lead investigator together with Associate Professor Romy Lauche, Deputy Director of Research from the National Centre for Naturopathic Medicine. The trial, funded by Australian Hemp company Ecofibre, will compare the effects of their Ananda Hemp CBD extract to a placebo on participants' self-reported changes in sleep disturbances.

"Approximately 33-45% of Australians currently suffer from sleep disturbances which can impact both our physical and mental health, when left untreated. We are currently investigating if a low-dose botanical CBD soft gel will assist people with sleep disturbance compared to a placebo, which is an inactive substance" stated Dr Schloss.

"Given many Australians are reporting less quality sleep during current lockdowns across the country, there has never been a more important time to help Australians with such an essential, yet often neglected, aspect of their health" says Georgie Rist, Ananda Hemp's Vice President Global Accounts.

After a historic decision made in December 2020, when the [TGA \(Therapeutic Goods Association\) down scheduled CBD](#) to a Schedule 3 (Pharmacist Only Medicine) from a Schedule 4 (Prescription Only Medicine), there are still no TGA approved CBD products that pharmacists can prescribe.

This exciting clinical research comes after the [1 February 2021 legalisation](#) in Australia allowing the purchase of CBD containing products over the counter as a pharmacist-only medicine.

"Currently there are no registered CBD products that pharmacists can dispense, even though it has been rescheduled and thus approved for over-the-counter sales," stated Dr Schloss.

"Additionally, no clinical trials on low-dose CBD have been undertaken to see what amount works for sleep disturbances. Trials like this will add to the current evidence for pharmacists, doctors and patients which is important moving forward in this space" she said.

How to participate

Researchers are seeking generally healthy individuals aged 18-65 years old, who have self-reported poor sleep. This may include people who have difficulty initiating sleep, maintaining sleep, or are waking earlier than desired. Participants can partake in the trial in Melbourne, Sydney, Brisbane or Lismore. In total, 438 participants will be included in the trial, each participating in the trial for 10 weeks.

For further information about the trial, or to complete the online screening survey, visit <https://redcap.link/h1m0851q> or email ncnmtrials@scu.edu.au.

This research has been approved by Southern Cross University Human Research Ethics Committee, SCU/HREC no. 2021/031.

The [National Centre for Naturopathic Medicine](#) at Southern Cross University is an internationally recognised centre of excellence and innovation in naturopathic medicine and health education, research and practice. NCNM creates, promotes and advocates a strong culture of incorporating evidence-based science into healthcare education and clinical practice.

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