ECOFIBRE

ASX ANNOUNCEMENT

ASX: EOF

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Human Research Ethics Approval for Phase IIb clinical trial in Australia

- Ecofibre is undertaking a Phase IIb double-blind, randomised placebo-controlled, multi-site clinical trial for CBD for sleep disturbances in a healthy population
- The study has received Human Research Ethics Committee (HREC) approval and will look to begin patient enrolment in Q4FY21
- The purpose of this study is to support Ecofibre's TGA application to supply Ananda Hemp products via the Australian S3 OTC pharmacy market. The investment in this research is ~$1.2m.
- The findings of this study will also support Ananda Hemp's existing full and broad sprectum (THC free) products available via the Special Access Scheme (SAS-B) and Authorised Prescriber pathways
- This study is part of Ecofibre's broader research portfolio on hemp-derived products across a range of disease states

Ecofibre Limited (**Ecofibre, Company**) (**ASX:EOF, US ADR: EOFBY**) is pleased to announce that it has received Human Research Ethics Approval for its major Australia-based clinical trial in support of its TGA S3 application.

Dr. Janet Schloss of Southern Cross University (SCU) has been appointed as chief investigator for the study, which is titled "Phase IIb Double-Blind, Placebo-Controlled Randomised Clinical Trial for CBD for sleep disturbances in a healthy population" (the "Ananda CBD Sleep Study").

Ecofibre Chairman Barry Lambert said, "today's announcement of the Ananda CBD Sleep Study is a major step forward for Australians to eventually access hemp-derived CBD products 'over the counter' at their local pharmacy".

Ecofibre CEO, Eric Wang said, "The study protocol has been rigorously designed and will be appropriately powered to deliver sufficient data for statistical significance. The trial will be conducted at four separate sites across Australia with several hundred participants. The team have taken significant care in designing the study to ensure it meets the high standards of the TGA for S3 medicine registration".

"We are using the Ananda Hemp Broad Spectrum (THC-free) soft gels. This product has been available in the US since 2018 under the Ananda Professional brand which is the #1 US Independent Pharmacy brand. The product is available in all 50 States".

"This product is also being used in our FDA authorised clinical trial on agitation in patients with Alzheimer's disease. This phase II clinical trial is being conducted at Eastern Virginia Medical School with Dr. Henry Okravi as the principal investigator. This study is enrolling patients and expects to be completed by early 2022".

Australian S3 Market

The regulatory framework for the S3 market was established following an announcement by the TGA on 15 December 2020[1] to down-schedule certain low dose cannabidiol (CBD) preparations from Schedule 4 (Prescription Only Medicine) to Schedule 3 (Pharmacist Only Medicine) from 1 February 2021.

There are currently no TGA approved products on the Australian Register of Therapeutic Goods (ARTG) that meet the Schedule 3 criteria.

Eric Wang said, "we are very pleased with the TGA's decision to allow for the down-scheduling of low-dose CBD products. While estimates on the size of Australian OTC CBD market vary, based on our significant experience with CBD in the US OTC pharmacy market, we see a strong opportunity to help many Australians live a better life".

"As the leading US pharmacy CBD brand, we understand there are many foundational elements that go beyond the product itself that need to be put in place to support pharmacists in dispensing and educating patients on CBD. We have begun the process of delivering our platforms to Australia and are working with specific national pharmacy groups and education bodies at this time".

Ecofibre currently sells two of its existing US manufactured Ananda Hemp (CBD dominant) products in Australia via the Special Access Scheme (SAS-B) and Authorised Prescribers. Both of these products are widely available in the US and have been sold in all 50 US States for several years.

[1] https://www.tga.gov.au/media-release/over-counter-access-low-dose-cannabidiol

Update on Ecofibre clinical research program

A component of the overall platform to support pharmacists in recommending CBD products is clinical research. Ecofibre continues to invest appropriately in this area to ensure we can provide our customers with the support required for our product set. The following table provides a short update on our research program.

Study	Product	Status	Comments

Effects of CBD on opioid use and quality of life for chronic pain patients	Ananda Full Spectrum soft gel	Published 2019	- Observational study: Statistically significant improvements were noted in both pain and sleep
			  - 53% reduced their use of opioids
			  - 94% reported improvements in quality of life indices, specifically sleep, pain and/or mood.

Effects of CBD on patients with chemotherapy induced peripheral neuropathy (CIPN)	Ananda Full Spectrum soft gel	Enrolling patients / complete early '22	- Phase II randomized, triple-blind, placebo-controlled study. - FDA Authorised – IND granted - Lankenau Institute for Medical Research. Philadelphia, USA
Effects of CBD on agitation in patients w/Alzheimer's Disease	Ananda Broad Spectrum soft gel (THC free)	Enrolling patients / complete early '22	- Phase II randomized, triple-blind, placebo-controlled study. - FDA Authorised – IND granted - Eastern Virginia Medical School. Virginia, USA
Efficacy analysis of CBD on endometrial lesions	Ananda Broad Spectrum oil (THC free)	In progress phased results beginning Jun 21	- Test on human avatar models - Efficacy analysis on endometrial lesions, dose optimisation and efficacy curves - Analysis of blood vessels and nerve fibres on different types of endometriosis - Identification of mechanism of action - University of Newcastle, NSW
Effects of CBD on sleep disturbances in healthy adults	Ananda Broad Spectrum soft gel (THC free)	HERC approval / complete early '22	- Phase 2b randomized, double-blind, placebo controlled study - To support Australian TGA S3 application - Southern Cross University, NSW

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About Ecofibre

Ecofibre is a provider of hemp products in the United States and Australia.

In the United States, 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 and Authorised Prescriber pathways. See www.anandahemp.com.au.

In Australia, the Company grows and produces hemp food products including protein powders, de-hulled hemp seed and hemp oil. See www.anandafood.com.

The Company also develops and produces innovative hemp-based textile products in the United States. See www.hempblack.com.

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 Eric Wang, Managing Director.

Attachment 1 - Phase IIb Double-Blind, Placebo-Controlled Randomised Clinical Trial for CBD for sleep disturbances in a healthy population ('Ananda CBD Sleep Study')

Title	*A Phase IIb Double-Blind, Randomised, Placebo-Controlled Clinical Trial for CBD for sleep disturbances in a healthy population.*
Chief Investigator	Dr Janet Schloss
Phase	*Phase IIb*
Purpose	To assess the efficacy of cannabidiol (CBD) for sleep disturbances in healthy adults.
Primary Outcome	To evaluate the efficacy of a botanical CBD for sleep disturbances compared to placebo via the PROMIS sleep disturbance instrument.
Methodology	Double-blind, randomised, placebo-controlled clinical trial
Study Duration	Each participant receives a daily dose of the intervention or placebo for 8 weeks. Titration will occur for two weeks prior to commencement of the 8-week period so participants start at a set CBD dose.
Study Centre(s)	Multi centre – 4 sites
Number of Subjects	We plan to include n=438 participants into the trial.
Main Inclusion Criteria	1. Adults aged between 18 and 65 years old 2. Considered to be generally healthy. 3. A self-reported complaint of poor sleep quality 4. Self-reports sleep difficulty occurring three nights a week or more for three months.
Main Exclusion criteria	Anyone with an acute disease, history of an unmanaged chronic disease, and other relevant pre-existing conditions or attributes.
Study Product, Dose, Route, Regimen	Will involve a 15mg CBD soft capsule or placebo. The dose will be 1 soft capsule in the morning and 1 soft capsule at night 30 minutes to one hour before bed. This will be titrated up in the first two weeks to tolerance. Maximum CBD dose is 150mg as per the schedule 3 requirements in Australia.
Duration of administration	8 weeks per person (10 weeks in total including a 2-week titration period)

Reference therapy	Placebo
Recruitment	Via the general population, via social media, advertising.
Ethical approval	SCU HREC committee
Rationale	Sleep is a complex behavioural state which has been associated with a variety of behavioural, emotional, psychological and physical conditions. Sleep disturbances has been linked with anxiety, pain, depression, stress, alcohol, recreational or illicit drug use, caffeine intake, in addition to medication or disease states. Unpacking some of the conditions that people with sleep disturbances have will add value to the data collected in this trial.