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Ananda Health products used in first FDA authorized clinical trial on hemp-derived CBD to treat chemotherapy induced peripheral neuropathy

Ecofibre Limited (Ecofibre, Company) (ASX:EOF, OTC-NASDAQ Intl Designation: EOFBF) is pleased to announce that the Lankenau Institute for Medical Research¹ (LIMR) has begun patient enrollment in a Phase II clinical trial using Ananda Health hemp-derived CBD.

The purpose of this study is to assess the efficacy of a hemp-based cannabidiol (CBD) product, Ananda Health Spectrum gelcaps, on the severity and duration of chemotherapy-induced peripheral neuropathy (CIPN) among breast, colon, and ovarian cancer patients who received common types of neurotoxic chemotherapy.

Ecofibre and Ananda demonstrate their commitment to advancing the science of CBD with the launch of the Coala-T-CBD study² (ClinicalTrials.gov Identifier: NCT04398446). The phase II clinical trial began enrolling patients at LIMR in June.

The debilitating condition, CIPN, is often chronic, compromising patients' quality of life and limiting their ability to complete a full course of potentially life-saving treatments. Currently, there are no safe and effective medications to treat or prevent CIPN, but research in animals using CBD offers hope as a new treatment.

The Coala-T-CBD Study™ is the first clinical trial positioned to translate this success to humans and is led by oncologist Dr. Marisa Weiss, the founder and chief medical officer of www.Breastcancer.org and Director of Breast Radiation Oncology and Breast Health Outreach at Lankenau Medical Center.

"We are proud to be the first in the United States to study the impact of hemp-derived full spectrum CBD on CIPN, a condition that affects approximately 25-50% of pediatric and adult cancer patients undergoing neurotoxic chemotherapy," Weiss states. Among other milestones, the Coala-T-CBD Study™ received an IND (investigational new drug) by the Food and Drug Administration (FDA) and will use Ananda softgels in the study protocol."

"To our knowledge, this is the first phase II clinical trial using full-spectrum hemp extract for the treatment of CIPN to receive an FDA IND. This level of research is necessary to answer the



global call from the medical community, patients, and regulatory bodies seeking effective treatment of this difficult, common chemotherapy side effect,” says Weiss. The IND allows for Weiss’ team to conduct the highest-quality research using a randomized, double-blind, placebo-controlled clinical trial.

Ananda Health Research Portfolio

The FDA has publicly requested data on hemp-derived CBD regarding tolerability, drug interactions, toxicity, and dosing. Ecofibre responded early by investing an additional USD1.8 million in research across several studies.

In 2019, the company published a peer-reviewed study³ regarding the effects of low-dose CBD in chronic pain patients. The results demonstrated that low-dose CBD was well tolerated and improved pain, sleep, mood and opioid use.

The Coala-T-CBD Study™ contributes to Ecofibre’s growing clinical research portfolio of CBD use across age groups, populations, disease states, and doses. Importantly, the Coala-T-CBD Study™ will offer critical insights on the use of higher-dose CBD.

Ecofibre’s second phase II clinical trial⁴ (ClinicalTrials.gov Identifier: NCT04436081) will evaluate moderate-dose CBD on agitation, sleep and mood in dementia patients. The moderate-dose study is currently pursuing its own FDA IND and expects patient enrollment in August.

Both the Coala-T-CBD Study™ and the dementia study include comprehensive physician and laboratory analyses to determine the safety of moderate and higher-dose CBD.

In addition to its clinical trials in the U.S., Ecofibre will be supporting research on low-dose full spectrum CBD later this year in Australia.

Alex Capano, Ecofibre’s Chief Science Officer states, “These studies will provide solutions for patients and contribute valuable data on the safety and efficacy of hemp CBD products. We understand the critical need for more sophisticated, rigorous research and are dedicated to closing those gaps.”

Ecofibre CEO, Eric Wang adds, “A core foundation for Ananda Health has been to support quality research for patient and practitioner education. Whilst the recent pandemic has created market uncertainty, the Company remains highly committed to its long-term investment to support our customers and the FDA in creating the knowledge base to inform better decisions for our industry.”

“We are pleased to work with such a high-quality group of researchers and physicians at LIMR. The Coala-T-CBD Study™ will provide ongoing updates and anticipates completion in 2022.”

³ Details of the study are available at <https://www.tandfonline.com/doi/full/10.1080/00325481.2019.1685298>

⁴ Details of the study are available at <https://clinicaltrials.gov/ct2/show/NCT04436081>



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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.

In Australia, the Company produces 100% Australian grown and processed hemp food products including protein powders, de-hulled seed and seed oil. See www.anandafood.com.

The Company is also developing innovative hemp-based products in textiles and composite materials in partnership with TexInnovate 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.

About Main Line Health

Main Line Health® is a not-for-profit health system serving portions of Philadelphia and its western suburbs. At its core are four of the region's most respected acute care hospitals—Lankenau Medical Center, Bryn Mawr Hospital, Paoli Hospital and Riddle Hospital—as well as one of the nation's premier facilities for rehabilitative medicine, Bryn Mawr Rehabilitation Hospital.

Main Line Health also includes the Lankenau Institute for Medical Research, a non-profit biomedical research organization on the campus of Lankenau Medical Center, dedicated to advancing an understanding of the causes of cancer, diabetes and heart disease to help improve diagnosis and treatment as well as prevention

About Breastcancer.org

Breastcancer.org is a patient-centric resource for breast health and breast cancer information and support. Our research drives our ability to engage, educate, and empower people with breast cancer with expert information and dynamic peer support community to help them make the best decisions for their lives. The nonprofit organization was founded by breast oncologist Marisa C. Weiss, M.D. and born out of her conviction that women with breast cancer need more information and support than a physician visit can provide. Breastcancer.org receives more than 30 million visits each year. For more information about Breastcancer.org, please visit www.Breastcancer.org.

Authorisation

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

