13 July 2020

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) refers to its announcement dated 2 July which included details of the Coala-T-CBD Study™ (ClinicalTrials.gov Identifier: NCT04398446) and also a second phase II clinical trial on the impact of moderate-dose CBD on agitation, sleep and mood in dementia patients (ClinicalTrials.gov Identifier: NCT04436081).

Details of the studies were provided by reference to the following URLs at the US National Library of Medicine:

- Coala-T-CBD Study™ - https://clinicaltrials.gov/ct2/show/NCT04398446
- Dementia Study - https://clinicaltrials.gov/ct2/show/NCT04436081

At the request of the Australian Securities Exchange (ASX) the published text describing these studies is reproduced in Attachments 1 and 2 herewith.

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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.

Attachment 1 - Effect of Hemp-CBD on Patients with CIPN (Coala-T-CBD)

SUMMARY	
ClinicalTrials.gov Identifier	NCT04398446
Sponsor	Main Line Health
Responsible Party	Dr Marisa Weiss, Main Line Health
Brief Summary	The purpose of this study is to assess the effect of a hemp-based cannabidiol (CBD) product, Ananda Hemp Spectrum Gelcaps, on the severity and duration of chemotherapy-induced neuropathy (CIPN) among non-metastatic breast, colorectal, and ovarian cancer patients who received neoadjuvant or adjuvant therapy that included neurotoxic chemotherapeutic agents.
Condition or Disease	Chemotherapy-induced Peripheral Neuropathy Colorectal Cancer Stage II Colorectal Cancer Stage III Breast Cancer Ovarian Cancer
Intervention / Treatment	Drug: Hemp-based CBD Other: Placebo oral tablet
Phase	Phase 2
Detailed Description	CIPN is a common complication of many effective cytotoxic agents that can negatively impact patients' treatment course and quality of life. The incidence of CIPN in cancer patients receiving multidrug regimens is estimated at 38%, with frequencies approaching 100% with certain known neurotoxic drug classes. Taxanes (e.g., paclitaxel, docetaxel) and platinum-based agents (e.g., oxaliplatin, cisplatin, carboplatin) in particular, are two commonly used chemotherapy classes that are associated with a high incidence of CIPN. Symptoms of chemotherapy-induced peripheral neuropathy include distal extremity numbness, tingling and pain. Chronic, cumulative symptoms can severely impact quality of life and result in dose reductions and/or drug discontinuation in up to 30% of patients. Consumers use cannabis products for various reasons including pain, stress, anxiety, and insomnia. The neuro-modulatory effects of phytocannabinoids, tetrahydrocannabinol (THC) and cannabidiol (CBD) in particular, have been documented at both the molecular and clinical level. The endocannabinoid system consists of CB1 receptors and CB2 receptors that act as an inhibitory G-protein within the central and peripheral nervous system, respectively. Several animal models have demonstrated the role endocannabinoids play in neuropathic pain development by showing enhanced neuropathic pain with CB1 receptor deletion and reduced manifestations of neuropathic pain with CB2 receptor overexpression. The therapeutic properties of cannabis-based products have also been illustrated in several randomized double-blind trials that have shown significant pain relief versus placebo in the treatment of neuropathy related to diabetes, spinal cord injury, multiple sclerosis, and HIV associated polyneuropathy. Studies specifically looking at the role of CBD in chemotherapy-induced neurotoxicity have shown a neuroprotective effect of CBD in mouse models. Studies have demonstrated that a 14-day dosing regimen of CBD prevented the onset of paclitaxel-induced mechanical and thermal sensitivity. These intriguing results suggest that cannabinoid agents could potentially reduce the severity and duration of CIPN in the clinical setting.

STUDY DESIGN

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	100 participants
Allocation	Randomized
Intervention Model	Parallel Assignment
Masking	Triple (Participant, Care Provider, Investigator)
Primary Purpose	Treatment
Official Title	Coala-T-CBD Study: A Study of the Effect of Hemp-CBD on the Severity and Duration of Chemotherapy-Induced Peripheral Neuropathy in Patients Receiving Neurotoxic Chemotherapy for Non-Metastatic Breast, Ovarian and Colon Cancer
Actual Study Start Date	May 27, 2020
Estimated Primary Completion Date	October 1, 2021
Estimated Study Completion Date	April 1, 2022

ARMS AND INTERVENTIONS

Experimental: Hemp-based CBD	Drug: Hemp-based CBD 3x Daily dosing for 12 weeks Other Name: Ananda Hemp CBD Spectrum Gelcaps
Placebo Comparator: Placebo Oral Tablet	Other: Placebo oral tablet 3x Daily dosing for 12 weeks

OUTCOME MEASURES

Primary Outcome Measures

1. Change in pressure/touch sensation during intervention and at follow-up [Time Frame: Every two weeks for twelve weeks during intervention; Every month for three months follow-up]. At regular intervals, CIPN will be assessed by Semmes Weinstein Monofilament Examination using Touch-Test Sensory Evaluator Kit to determine pressure sensation.
2. Change in pain sensation during intervention and at follow-up [Time Frame: Every two weeks for twelve weeks during intervention; Every month for three months follow-up]. At regular intervals, CIPN will be assessed by pinprick examination to determine pain sensation.
3. Change in vibration sensation during intervention and at follow-up [Time Frame: Every two weeks for twelve weeks during intervention; Every month for three months follow-up]. At regular intervals, CIPN will be assessed by 128Hz tuning fork vibration test to determine vibration sensation.
4. Change in quality of life [Time Frame: Every two weeks for twelve weeks during intervention; Every month for three months follow-up]. Quality of life will be measured by European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 Questionnaire, a validated 30-item questionnaire to assess treatment impact on quality of life in cancer patients on 4-point scales, where 4 is most severe.
5. Change in CIPN symptom severity [Time Frame: Every two weeks for twelve weeks during intervention; Every month for three months follow-up]. CIPN symptoms will be measured by EORTC QLQ-CIPN20 Questionnaire, validated 20-item questionnaire to assess symptom severity of chemotherapy-induced peripheral neuropathy on 4-point scales, where 4 is most severe.

	6. Change in pain severity [Time Frame: Every two weeks for twelve weeks during intervention; Every month for three months follow-up]. Pain severity will be measured by Brief Pain Inventory (BPI) Short Form, validated 9-item questionnaire to assess the severity of pain and the impact of pain on daily functions on 10-point scales, where 10 is most severe. 7. Change in sleep quality [Time Frame: Every two weeks for twelve weeks during intervention; Every month for three months follow-up]. Sleep quality will be measured by Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance Questionnaire, validated 8-item questionnaire to assess sleep quality on 5-point scales, where 5 is the most severe.
Secondary Outcome Measures	1. Receptivity and accrual rate to clinical studies involving cannabis-based substances. [Time Frame: 1 Day]. Receptivity to clinical trials as well as to the use of CBD will be assessed using a questionnaire that will be distributed to all patients at the first encounter. Responses to this questionnaire will provide information regarding in the use of CBD was influencing factor for those who chose to participate or deferring factor for those who decline participation. 2. Adherence to CBD Products [Time Frame: Daily, 12 weeks]. Adherence will be assessed with a Dosing Diary. 3. Rate of side effects using medical-grade CBD concentrates [Time Frame: Daily, 12 weeks]. Side effects will be assessed at each encounter clinical evaluation by patient report in a Dosing Diary. All side effects thought to be secondary to CBD will be documented.

ELIGIBILITY CRITERIA

Ages Eligible for Study	21 Years and older (Adult, Older Adult)
Sexes Eligible for Study	All
Accepts Health Volunteers	No
Inclusion Criteria	• Non-metastatic breast cancer patients who developed CIPN (CTCAE sensory grade 2 or 3, motor grade <2) after receiving taxane-based chemotherapy in pre-operative or post-operative setting. • Colorectal cancer patients with high risk stage II and stage III disease who developed CIPN (CTCAE sensory grade 2 or 3, motor grade <2) after receiving oxaliplatin in the adjuvant setting. • Ovarian cancer patients who developed CIPN (CTCAE sensory grade 2 or 3, motor grade <2) after receiving taxane-containing chemotherapy in the neoadjuvant or adjuvant setting.
Exclusion Criteria	• Family history of genetic/familial neuropathy • Routine use of recreational or medicinal marijuana products (defined as > 4 times per month) or illicit drug use (positive urine drug screen including opioids, cocaine, amphetamines, PCP, LSD) • Known underlying liver disease (Child-Pugh B or C) or baseline elevation in ALT, AST or total bilirubin ≥1.5 x upper limit of normal • Patients taking certain medications will be excluded due to potential CBD-drug interaction. CBD may prevent appropriate drug metabolism increasing risk for toxicity. Co-administration of study product and the following medications will be contraindicated and may lead to participant exclusion: clarithromycin, itraconazole, erythromycin, fluconazole, clopidogrel, rifampin, sulfamethoxazole, warfarin, any opioids, warfarin, antiepileptic

- medications (including carbamazapine, phenytoin, valproic acid, but excepting of gabapentin, clonazepam or diazepam).
- Underlying history of epilepsy/ recurrent seizure disorder or unexplained seizure within past 6 months
- Patients with uncontrolled cardiovascular disease defined by myocardial infarction, stroke or transient ischemic attack, or need for coronary stent placement within past six months.
- Patients with uncontrolled psychiatric illness (who meet DSM-V criteria) or who are at increased risk for suicidality based on baseline Columbia-Suicide Severity Rating Scale.
- Women who are pregnant or breastfeeding or who refuse to practice an effective form of birth control (condoms, diaphragm, birth control pill, IUD)

CONTACTS AND LOCATIONS

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MORE INFORMATION

Publications	• Lee G, Grovey B, Furnish T, Wallace M. Medical Cannabis for Neuropathic Pain. Curr Pain Headache Rep. 2018 Feb 1;22(1):8. doi: 10.1007/s11916-018-0658-8. Review. • Brzeziński K. Chemotherapy-induced polyneuropathy. Part I. Pathophysiology. Contemp Oncol (Pozn). 2012;16(1):72-8. doi: 10.5114/wo.2012.27341. Epub 2012 Feb 29. • Brzeziński K. Chemotherapy-induced peripheral neuropathy. Part II. Prevention. Contemp Oncol (Pozn). 2012;16(3):258-61. doi: 10.5114/wo.2012.29296. Epub 2012 Jul 6. • Saif MW, Reardon J. Management of oxaliplatin-induced peripheral neuropathy. Ther Clin Risk Manag. 2005 Dec;1(4):249-58. • Wang WS, Lin JK, Lin TC, Chen WS, Jiang JK, Wang HS, Chiou TJ, Liu JH, Yen CC, Chen PM. Oral glutamine is effective for preventing oxaliplatin-induced neuropathy in colorectal cancer patients. Oncologist. 2007 Mar;12(3):312-9. • Ward SJ, Ramirez MD, Neelakantan H, Walker EA. Cannabidiol prevents the development of cold and mechanical allodynia in paclitaxel-treated female C57Bl6 mice. Anesth Analg. 2011 Oct;113(4):947-50. doi: 10.1213/ANE.0b013e3182283486. Epub 2011 Jul 7.
Other Study ID Numbers	F/N-R19-3893L
Plan to Share Individual Participant Data	No
Studies a US FDA regulated Drug Product	Yes
Studies a US FDA regulated Device Product	No

Attachment 2 - Effects of THC-Free CBD Oil on Agitation in Patients With Alzheimer's Disease

SUMMARY	
ClinicalTrials.gov Identifier	NCT04436081
Sponsor	Eastern Virginia Medical School
Collaborators	Old Dominion University Ananda Hemp, Inc.
Responsible Party	Hamid Okhravi, M.D., Eastern Virginia Medical School
Brief Summary	This is a randomized, double-blinded, placebo-controlled, crossover trial that aims to 1) determine the efficacy of THC-free cannabidiol (CBD oil) in reducing the severity of agitation among participants and 2) determine whether THC-free CBD oil can reduce the burden on caregivers and increase the participants' quality of life.
Condition or Disease	Alzheimer Disease Dementia Major Neurocognitive Disorder With Aggressive Behavior
Intervention / Treatment	Drug: THC-free CBD Oil Drug: Placebo
Phase	Phase 2
Detailed Description	Individuals with Alzheimer's and other forms of dementia often go through a period of significant behavioral and psychological symptoms of dementia (BPSD). It is estimated that up to 90% of persons with dementia (PWD) experience behavior problems at some point. BPSDs can be challenging for both unpaid family caregivers as well as paid caregivers. Family caregivers provide the bulk of care for PWD and number over 15 million. One of the most common types of BPSDs is agitation with a prevalence of up to 87%, based on a recent systematic review. Agitation can lead to impaired daily functioning, prolongation of hospitalization, reduced time to institutionalization, and is associated with higher mortality. Additionally, agitated behavior is associated with increased injury to both patients and caregivers. Based on the 2018 Alzheimer's disease drug development pipeline report almost 70% of clinical trials related to BPSD are dedicated to agitation behavior. Finding ways to address agitation is necessary to improve overall quality of life for PWD and their caregivers. Currently, there are no medications available specifically for the treatment of BPSDs. The use of benzodiazepines, antipsychotics and mood stabilizing agents are common, but the risks and side effects often outweigh any benefits. Several small studies have investigated the use of cannabinoids in the treatment of pathology and symptomology of Alzheimer's disease (AD), as well as treatment of the agitation component of BPSD. A handful of these studies showed that the symptoms of BPSD were decreased with the use of cannabinoids. However, due to small sample sizes, study design, and short trial duration of these studies, the efficacy of these agents on BPSD cannot be confirmed. In addition, cannabinoids have demonstrated anti-oxidant and anti-inflammatory effects, and both processes have been indicated as major contributors to the neurologic effects of AD. Some evidence exists that agitation is related to this neuroinflammatory process. This study will examine the effects of cannabinoids on the behavioral and psychological symptoms of individuals with a dementia diagnosis.

STUDY DESIGN

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	40 participants
Allocation	Randomized
Intervention Model	Crossover Assignment
Masking	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose	Treatment
Official Title	Effects of THC-Free CBD Oil on Agitation in Patients With Alzheimer's Disease
Estimated Study Start Date	July, 2020
Estimated Primary Completion Date	October, 2021
Estimated Study Completion Date	December, 2021

ARMS AND INTERVENTIONS

Active Comparator: Hemp-based CBD oil Gelcaps	The intervention consists of 6 weeks oral administration of CBD oil Gelcaps, starting at a dosage of 15 mg twice per day with up titration to 45 mg twice per day. At any given dose, if participants develop side effects, the dosage will be reduced to the previous dose. Drug: THC-free CBD Oil Hemp-based CBD oil Gelcaps
Placebo Comparator: Oral Placebo Gelcaps	Participants in the control group will receive oral placebo Gelcaps that are identical in appearance to the CBD oil Gelcaps. Dosing will be identical to the intervention arm. Drug: Placebo Placebo Gelcaps

OUTCOME MEASURES

Primary Outcome Measures

1. Change in agitation and aggression. [Time Frame: Every two weeks for 15 weeks during study enrollment.]. Change in agitation and aggression will be measured by the Cohen-Mansfield Agitation Inventory (CMAI), a validated 29-item questionnaire to assess agitation. Each item is rated on a 7-point scale ranging from 1 "Never" to 7 "Several times per hour". Higher scores indicate greater agitation.
2. Change in caregiver burden. [Time Frame: Three times during the 15 weeks of study enrollment.]. Change in caregiver burden will be measured by the Zarit Burden Interview (ZBI), a validated 22-item questionnaire to assess caregiver burden. Each item is rated on a 5-point Likert scale that ranges from 0 "Never" to 4 "Nearly always," with the sum of scores ranging between 0-88. Higher scores indicate greater burden.
3. Change in the participant's quality of life. [Time Frame: Three times during the 15 weeks of study enrollment.]. Change in the participant's quality of life will be measured by the Quality-of-life assessment in dementia (DEMQOL-proxy), a validated 32-item questionnaire to assess the health related quality of life of people with dementia. Each item is rated on a 4-point scale ranging from 1 "A lot" to 4 "Not at all". Higher scores indicate a healthier quality of life.
4. Change in caregiver's quality of life. [Time Frame: Three times during the 15 weeks of study enrollment.]. Change in the caregiver's quality of life will be measured by the Measurement of quality of life in family carers of people with dementia (C-DEMQOL), a validated 30-item questionnaire to assess the quality of life for carers of someone with dementia. Each item is rated on a 5-point scale ranging from 1 "Completely" to 5 "Not at all." Higher scores indicate a healthier quality of life.

Secondary Outcome Measures	1. Assessment of change in neuropsychiatric symptoms. [Time Frame: Three times during the 15 weeks of study enrollment.]. Assessment of change in neuropsychiatric symptoms for the participant will be measured by the Neuropsychiatric Inventory (NPI), a validated questionnaire that assesses dementia-related behavioral symptoms. The NPI examines 12 sub-domains of behavioral functioning. Each sub-domain is rated on the frequency of the symptoms using a 4-point scale with 1 "Occasionally" and 4 "Very frequently", the severity of the symptoms using a 3-point scale with 1 "Mild" and 3 "Marked", and the distress the symptom causes them on a 5-point scale with 1 "Not at all" and 5 "Very severely or extremely". 2. Assessment of change in cognitive skills. [Time Frame: Three times during the 15 weeks of study enrollment.]. Assessment of change in cognitive skills for the participant will be measured by the Mini Mental State Exam (MMSE), a validated 30-item questionnaire used to measure cognitive impairment among the elderly. A 30-item, clinician-administered assessment of orientation, attention, calculation, learning and memory, language, and visuospatial skills. Each correct response is summed to produce a total score out of 30 possible points. 3. The effect of CBD oil on sleep quantity measured by Fitbit [Time Frame: Measured on a daily basis during the 15 weeks of study enrollment.]. The effect of CBD oil on sleep quality will be measured for the participant and caregiver using the actigraphy function of fit bit. These measures include the amount of total sleep, amount of rapid eye movement (REM) sleep and the amount of deep and light sleep.

ELIGIBILITY CRITERIA

Ages Eligible for Study	50 Years to 90 Years (Adult, Older Adult)
Sexes Eligible for Study	All
Accepts Health Volunteers	No
Inclusion Criteria	• Males/females over 50 years old. • Have a diagnosis of dementia due to AD or mixed AD with another type of dementia. • A Mini-Mental State Exam score (MMSE) ≤24 & >5. • Presence of agitation with a Neuropsychiatric Inventory (NPI)-agitation/aggression subscore > 3. • Participants and their informal caregivers must be fluent in English (includes reading, writing, and speech) and able to give informed consent. • For patients treated with cognitive-enhancing medications (cholinesterase inhibitors (ChEI) and/or memantine), the dosage must be stable for at least 3 months (90 days). If the ChEI and/or memantine has been discontinued, patients may enroll after 1 month (30 days). • Eligible caregivers must either live with the participant or have a minimum of 4 hours of daily contact with them.
Exclusion Criteria	• Diagnosis of non-AD or non-mixed dementias. • Very mild dementia or advanced dementia (MMSE: <24 or >5). • NPI-agitation-aggression score <3. • Having a serious or unstable medical illness including cardiovascular, hepatic, renal, respiratory, endocrine, neurologic or hematologic disease which might confound assessment of safety outcomes as determined by the study physician. • Presence or history of other serious psychiatric disorders or neurological conditions (e.g. psychotic disorders, bipolar disorder or schizophrenia). • Current abuse of/dependence on marijuana, current drug abuse, current alcohol abuse. • Having seizure disorders. • Indication of baseline delirium as determined by the Confusion Assessment Method (CAM).

- Current use of lithium.
- Inability to swallow CBD oil softgels.
- Changes in dosage of anti-depressives within 4 weeks before randomization and during the study.
- Changes in dosage of antipsychotics or benzodiazepines within 2 weeks prior to randomization and during the study.
- Contraindications to CBD oil (history of hypersensitivity to any cannabinoid).
- Frequent falling due to orthostatic hypotension.
- Use of tricyclic antidepressants (TCA), fluoxetine, and/or carbamazepine. -Patients who reside in nursing homes.

CONTACTS AND LOCATIONS

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MORE INFORMATION

Publications

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Other Study ID Numbers	06_20_EVMS
Plan to Share Individual Participant Data	No
Studies a US FDA regulated Drug Product	Yes
Studies a US FDA regulated Device Product	No