ASX Announcement
16 May 2024

First Patient Dosed in Phase III Insomnia Trial

Highlights:

- Avecho doses first patient in Phase III Clinical Trial testing its oral CBD TPM®-enhanced soft-gel capsule for insomnia
- The trial is the largest sleep study of its kind, targeting 519 patients across sites located in Melbourne, Sydney, Central Coast, Brisbane, and Perth
- The treatment groups will compare nightly CBD doses of 75mg and 150mg CBD with placebo over an 8-week dosing period
- The trial has been designed to suit the requirements of the TGA, FDA and the EMEA, aided by advice from a number of international sleep experts

Melbourne, Australia, 16 May 2024: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), focused on developing and commercialising innovative products using its proprietary Tocopheryl Phosphate Mixture ("TPM®") drug delivery system, is pleased to announce that the first patient has been dosed in its Phase III clinical trial (the "Trial") testing its oral CBD TPM®-enhanced soft-gel capsule for insomnia.

The trial is the largest of its kind testing cannabidiol and has been designed to suit the requirements of the Australian Therapeutic Goods Administration ("TGA"), US Food and Drug Agency and the European Medicines Agency, aided by advice from international sleep and regulatory experts. The trial target is 519 participants across multiple Australian cities including Melbourne, Sydney, Brisbane, Central Coast, and Perth. Trial Participants will be randomly assigned to one of three groups to receive nightly doses of either 75mg or 150mg of CBD, or a placebo for eight weeks. Participants will use validated questionnaires and daily sleep diaries over the course of the study to record the duration and quality of their sleep.

A successful Phase III trial is Avecho's final clinical step in support of a submission to the TGA for pharmaceutical registration of the CBD TPM soft-gel capsule for the management of insomnia. This opportunity is particularly significant in Australia, where regulatory changes in 2020 allow for over-the-counter sales of CBD products direct from pharmacy without a prescription, provided they gain appropriate approvals. Avecho has an opportunity to be the first in this area as no other Phase III CBD trials in Australia have succeeded.

Insomnia is a sleep disorder defined as dissatisfaction with sleep quantity or quality associated with difficulty initiating sleep, difficulty maintaining sleep and the inability to return to sleep on awakening. It can manifest as a primary indication or be symptom of other disorders, including anxiety and depression. Chronic insomnia is the most prevalent manifestation, characterized by insomnia symptoms occurring at least three nights per week and for at least three months. Consequences of insomnia include daytime sleepiness, poor memory function, decline in concentration with negative impacts on social and work activities. Approximately 30% of the population in the United States display chronic symptoms. In Australia, as many as 60% of the

population have at least some symptoms of insomnia with a total cost to the Australian economy estimated to be $19.1 billion[1].

National media coverage of the trial in March and April 2024 produced significant public interest, with over 1600 applicants registering for participation in the study. These initial applicants have undergone a first round of screening for eligibility, with 135 meeting the strict inclusion criteria for the study. These patients have now been referred to clinical trial sites to confirm eligibility with further assessments, and those that remain eligible will commence dosing immediately. The first patient has now been dosed.

"We are thrilled to commence dosing patients on our pivotal Phase III insomnia trial, marking a significant milestone not only for Avecho but also for the potential relief of millions suffering from this debilitating condition", said Dr Paul Gavin, CEO of Avecho Biotechnology.

"This trial is central in our quest to offer the first over-the-counter CBD-based insomnia treatment in Australia, leveraging Australia's regulatory changes. Our commitment to rigorous scientific validation and patient safety is at the core of this effort, and we are optimistic about leading the way in providing a new, effective option for insomnia sufferers."

Patients interested in participating are invited to visit the clinical trial recruitment portal at cbdinsomniastudy.com

- ENDS -

This announcement is authorised for release by the Board of Directors of Avecho Biotechnology Limited.

Questions related to the announcement are welcome via our InvestorHub platform.

Investor + General Enquiries
Dr Paul Gavin
Chief Executive Officer
Avecho Biotechnology Limited
+61 3 9002 5000

About Avecho

Avecho Biotechnology Limited develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called Tocopheryl Phosphate Mixture (**TPM®**). TPM® is derived from Vitamin E using unique, proprietary and patented processes and is proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

Avecho's major projects include delivering TPM® enhanced injectable, oral and topical products for the human health market and is also developing TPM® to enhance the feed efficiency and health of livestock.

[1] Rise and try to shine: The social and economic cost of sleep disorders in Australia, Sleep Health Foundation, Deloitte Access Economics, April 2021

Forward-Looking Statements

Certain statements in this announcement are forward looking statements. Forward-looking statements can generally be identified by the use of words such as "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", "may", "assume" and words of similar import. These forward-looking statements speak only as at the date of this announcement. These statements are based on current expectations and beliefs and, by their nature, are subject to a number of known and unknown risks and uncertainties that could cause the actual results, performances and achievements to differ materially from any expected future results, performance or achievements expressed or implied by such forward looking statements.

No representation, warranty or assurance (express or implied) is given or made by Avecho that the forward-looking statements contained in this announcement are accurate, complete, reliable or adequate or that they will be achieved or prove to be correct. Except for any statutory liability which cannot be excluded, Avecho and its respective officers, employees and advisers expressly disclaim any responsibility for the accuracy or completeness of the forward-looking statements and exclude all liability whatsoever (including negligence) for any direct or indirect loss or damage which may be suffered by any person as a consequence of any information in this announcement or any error or omission therefrom.

Subject to any continuing obligation under applicable law or relevant listing rules of the ASX, Avecho disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements in these materials to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any statement is based. Nothing in these materials shall under any circumstances create an implication that there has been no change in the affairs of Avecho since the date of the announcement.

Avecho's major projects include delivering TPM® enhanced injectable, oral and topical products for the human health market, including the recently announced application of TPM® to cannabinoids. The Company is also developing TPM® to enhance feed efficiency and health of livestock.

See more here - avecho.com.au