ASX Announcement
20 May 2025

Update on Avecho's Phase III CBD Program: New sites Commence Recruitment for Avecho's Pivotal Phase III Clinical Trial

Highlights:

- Avecho's Phase III insomnia trial now benefits from new sites in Sydney and the Gold Coast
- A further ~150 patients are targeted for completion in 2025 before a planned interim analysis
- Avecho and Sandoz AG met to commence planning the pathway to TGA registration and commercialization
- Sandoz to assist with patient recruitment on the Trial

Melbourne, Australia, 20 May 2025: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") is pleased to provide an update on its oral cannabidiol ("CBD") TPM®-enhanced capsule ("the Product") development program, currently being investigated in a pivotal Phase III clinical trial (the "Trial") for insomnia.

The Company licensed the Australian commercial rights to the Product to Sandoz AG ("Sandoz") in March 2025 ("the Agreement"). Following the Sandoz Agreement, regulatory preparations commenced to activate three new clinical trial sites; two located in Sydney and one on the Gold Coast. This work is now complete and all three new sites have commenced screening and recruitment. Notably, the new sites maintain independent databases of insomnia patients, providing an immediate and valuable pool of prospective Trial participants.

The Trial will complete dosing of approximately 210 subjects before conducting a planned interim analysis. As of December 2024, approximately 70 participants had received study medication. Recruitment was paused over summer to avoid the holiday period but resumed in March 2025. Amendments to the inclusion and exclusion criteria, as well as the addition of the new sites, was designed to augment the rate of recruitment. Avecho aims to complete dosing for the cohort of patients required for the interim analysis during 2025, with results of the interim analysis available early 2026.

Avecho CEO, Dr Paul Gavin, said: *"The licensing agreement with Sandoz has delivered the capital required to accelerate patient recruitment ahead of our interim analysis — a key milestone in the value development of the program. Our priority remains advancing the study to this critical inflection point as efficiently as possible. Beyond funding, Sandoz brings deep operational and regulatory expertise, and we are already leveraging this to strengthen execution and enhance the overall potential of the Trial."*

The Avecho and Sandoz project teams held the first strategic meeting in April 2025 to commence planning for the future regulatory submission and commercial launch of the CBD product in Australia. Large-scale commercial supply and Trial support were the primary focus points, with Sandoz committing internal expertise to accelerate patient recruitment on the Trial and regulatory strategies to position the interim analysis in the best light for the Australian Therapeutic Goods Administration ("TGA").

Avecho CEO, Dr Paul Gavin, said: "*We are excited to maximise our collaboration with Sandoz and early interactions endorse this company as an ideal development partner. Sandoz' well-established relationships with patient advocacy groups and the TGA are anticipated to shorten timelines to recruitment and TGA registration. We are on the cusp of a major clinical trial milestone for an Australian biotechnology company and attracting this level of support and at such an important time is equal parts rare and deeply exciting."*

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This announcement has been authorised by the Board of Directors of Avecho Biotechnology Limited.

About Sandoz
Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure more than 900 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,300 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2024, Sandoz recorded net sales of USD 10.4 billion.

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 lead asset is a proprietary cannabidiol ("CBD") TPM soft-gel capsule demonstrated to increase CBD absorption. The CBD soft-gel capsule is currently undergoing Phase III clinical development for the treatment of insomnia.

See more here - avecho.com.au

About Insomnia
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, characterised 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 10-30% of the global population have symptoms of insomnia, with 10-15% classified as chronic[1]. Based on the current global population, up to 237M people are affected by insomnia, with the sleep economy and sleep aids market estimated to reach US$950Bn by 2032[2]. 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 A$19.1 billion[3]. In August 2023, the Australian Government issued a statement indicating that sleep health should be considered a national priority as important as fitness and nutrition[4].

1 https://www.thegoodbody.com/insomnia-statistics/

2 https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html

3 https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html

4 https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf

About Avecho's Phase III Trial Program

The Company is currently conducting a pivotal (Phase III), multi-centre, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of CBD TPM soft-gel capsules in adults for use in the reduction of insomnia severity. The trial is the largest of its kind testing cannabidiol, taking place at multiple sites around Australia. Aided by advice from international sleep and regulatory experts, the trial has been designed to meet the requirements of the Australian Therapeutic Goods Administration ("TGA"), US Food and Drug Agency and the European Medicines Agency. 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.

Further information about the study can be found at ClinicalTrials.gov (Study Identifier: NCT05840822)

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. Initial projections estimated the Australian over-the-counter CBD market would grow to over US$125M per annum[5].

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.

5 Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021