ASX Announcement
26 March 2024

Avecho's Phase III Clinical Trial for Insomnia Commences

Highlights:

- Recruitment has now begun on Avecho's pivotal Phase III Clinical Trial testing its oral cannabidiol TPM®-enhanced soft-gel capsule for insomnia: a global market estimated at more than $4 billion[1].
- The trial is the largest insomnia study of its kind, recruiting 519 patients across sites located in Melbourne, Sydney, Central Coast, Brisbane and Perth.
- The trial will compare nightly doses of Avecho's proprietary oral cannabidiol TPM®-enhanced soft-gel capsules at doses of 75 and 150mg cannabidiol with placebo over an 8-week dosing period.
- The trial has been designed to suit the requirements of the TGA, US FDA and the EMEA, aided by advice from a number of international sleep experts.

Melbourne, **Australia, 26 March 2024**: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), an Australian Biotechnology company focused on developing and commercialising innovative products using its proprietary Tocopheryl Phosphate Mixture ("TPM®") drug delivery system, has commenced patient recruitment for its pivotal Phase III clinical trial (the "Trial") testing its oral cannabidiol TPM®-enhanced soft-gel capsule for insomnia.

The Trial is the largest insomnia study of its kind testing cannabidiol, seeking to recruit 519 patients across sites located in Melbourne, Sydney, Central Coast, Brisbane, and Perth. The treatment groups will compare nightly cannabidiol doses of 75 and 150mg cannabidiol with placebo over an 8-week dosing period.

The Trial has been designed to meet the requirements of key global regulatory agencies, including Australia's key regulatory body, the Therapeutics Goods Administration "(TGA"). **Avecho is focused on proving the efficacy of its enhanced cannabidiol formulation to become the first company to commercialise a cannabidiol treatment for insomnia as a registered pharmaceutical medicine.**

Australia's unique regulatory environment provides an outstanding commercial opportunity to Avecho. During 2020, the TGA announced it would allow oral cannabidiol products registered on the Australian register of therapeutic goods ("ARTG") to be sold as over the counter medicines without a prescription. This change was intended to incentivise pharmaceutical development and a shift away from unregistered cannabinoid products. To date, no Phase III cannabidiol trials in Australia have succeeded, with Avecho aiming to be the first company to gain an approval with its oral cannabidiol TPM soft-gel capsule for the treatment of 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. 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. The global insomnia market is estimated at more than $4 billion[1].

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

Avecho's Trial will recruit eligible participants who are 18 years or older; who have had difficulty getting to sleep, staying asleep and/or waking up earlier in the morning than desired, for at least the past three months (or are diagnosed with insomnia); and/or have a regular time period spent in bed, either sleeping or trying to sleep.

Avecho CEO, Dr Paul Gavin, said: *"Avecho's pivotal Phase III clinical trial testing our oral CBD TPM-enhanced soft-gel capsule is the largest and most robust trial of its kind assessing cannabidiol's effect on insomnia, and will aim to prove, with meticulous trial design and regulatory compliance, a place for CBD in the treatment of insomnia. It presents an incredible commercial opportunity for Avecho, and we look forward to first working toward interim analysis results by the end of the calendar year. It's a huge feat to prepare for and fund a late-stage trial of this magnitude, and I would like to thank our entire team and valued investors for supporting us to reach this defining milestone for Avecho and Australia's innovation sector at large."*

Deputy Director of Monash Lung and Sleep, and Director of Monash Health Sleep Service and Principal Investigator for the trial, Associate Professor Darren Mansfield, said: *"Existing over-the-counter medications for insomnia either have poor efficacy or are associated with a high degree of next day impairment. There is currently an unmet treatment need for an over-the-counter, effective, fast-acting treatment for insomnia that provides natural, restorative sleep. It is important to establish what role cannabidiol might play for the treatment of insomnia in the future."*

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

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

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.

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