



ASX Announcement

14 March 2024

TGA meeting confirms pathway for Avecho Phase III Clinical Trial

Melbourne, Australia, 14 March 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 advise that Company met with the Australian Therapeutic Goods Administration ("TGA") to present the final Phase III insomnia clinical trial design and planned submission strategy. The TGA has not recommended any changes to the trial design and submission strategy and the program will commence as planned.

Although non-binding and given without prejudice the positive response from the TGA reinforces Avecho's confidence that the trial if successful may support an Australian Regulatory approval.

Avecho CEO, Dr Paul Gavin, said:

"We have maintained transparent dialogue with the TGA as we approach the imminent commencement of our Phase III trial. We were very pleased with the reception we received for decisions made in the design of our program. This most recent meeting allows us to commence patient recruitment with confidence that a successful result may lead to a favourable assessment of this treatment by regulators and commercial partners. With the largest and most robust Phase III CBD trial in Australia to date, the Avecho team is eager to get started and is carefully planning each step forward to yield a positive outcome."

During 2020, the TGA announced it would allow cannabidiol products to be sold over the counter in Australia subject to appropriate regulatory approvals, therefore incentivising pharmaceutical development and a shift away from unregistered cannabinoid products. To date, no Phase III cannabidiol trials in Australia have succeeded: Avecho is targeting to be the first company to gain such approval with its oral CBD TPM soft-gel capsule for the treatment of insomnia.

Avecho's study has been designed to be relevant to the requirements of the TGA, the FDA and the EMEA using the help of a number of international sleep experts. In refining the final trial design, Avecho also reviewed the protocols and reported results of the unsuccessful Phase III trials, to ensure its study incorporated the learnings to maximise its strengths. A review of the key differentiating features of Avecho's study was presented to the TGA for comment during the meeting.

As ethics approval for the trial has also recently been received, Avecho expects to commence recruitment for the Phase III trial this month, with a total of five sites to be used for the study, located in Melbourne, Sydney, Central Coast, Brisbane and Perth.

Avecho's Phase III study will test its proprietary oral CBD TPM soft-gel capsule for the treatment of insomnia, targeting enrolment of 519 patients across three treatment groups to compare nightly CBD doses of 75 and 150mg CBD with placebo over an eight-week dosing period.

- 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.

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.

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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