



ASX Announcement

7 March 2024

Avecho receives Ethics Approval for amendments to Phase III Insomnia Clinical Trial

Highlights:

- Avecho's Pivotal Phase III clinical trial testing its oral CBD TPM®-enhanced soft-gel capsule for insomnia has gained final Ethics Approval.
- Patient recruitment for the Phase III is on track to commence this month for clinical trial sites located in Melbourne, Sydney, Central Coast, Brisbane, and Perth.

Melbourne, Australia, 7 March 2024: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), a biotechnology company focused on developing and commercialising innovative products using its proprietary Tocopheryl Phosphate Mixture ("TPM®") drug delivery system, is pleased to announce it has received Ethics Approval for its pivotal Phase III clinical trial testing its oral CBD TPM-enhanced soft-gel capsule for insomnia, after the Company submitted amendments to the study in December 2023.

The approval includes measures to streamline and enhance efficiency within the trial, (i) reinforcing the planned study design, further separating the methodology away from that employed in unsuccessful Phase III trials for CBD in the treatment of insomnia in Australia to date - as well as (ii) more efficiently deploying funds made available to the Company following its capital raise in 2023.

The changes also include the addition of new clinical trial sites, with a total of five to be used for the study, located in Melbourne, Sydney, Central Coast, Brisbane, and Perth.

Avecho CEO, Dr Paul Gavin, said: *"We are very pleased to complete one of the final steps in our Phase III trial program prior to commencement, with the formal approval of changes that will allow for a more efficient study. In addition to this, we've continued preparations with our team of clinical trial providers, finalized the key manufacturing elements, and we have had constructive dialogue with the TGA. We expect that all of this sets a strong foundation for what will be the largest and most robust Phase III CBD study in Australia thus far. We are now excited to start."*

Avecho's Phase III study will test its oral CBD TPM-enhanced softgel 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.

Recruitment for the Phase III trial is on schedule to commence this month, with potential participants encouraged to stay tuned to the [Avecho website](#) for instructions on how to register their interest to get involved.

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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

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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