



ASX Announcement

19 September 2022

TPM® Enhances Cannabinoid Bioavailability in Canine Study versus FDA approved CBD product, Epidiolex®

Highlights

- *In vivo* studies in dogs conducted at Labcorp (UK) demonstrate increased cannabidiol (CBD) bioavailability after administration of Avecho's TPM® CBD formulations, when compared to Epidiolex alone.
- Adding TPM® directly to Epidiolex increased CBD absorption
- Despite the increases in absorption, no increases in gastrointestinal irritation were observed.

Melbourne, Australia, 19 September 2022 - Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") today announced interim results from comparative pharmacokinetic studies conducted in the UK, showing that Avecho's oral cannabidiol ("CBD") product under development has increased bioavailability compared to Epidiolex®, the only FDA approved CBD product.

Avecho Chief Executive Officer, Dr Paul Gavin, said: "We have previously shown that our proprietary TPM® formulations could increase the oral absorption of CBD in rats when compared to simple CBD oil formulations currently prescribed to patients in Australia. These formulations are now in clinical trials and will be entering Phase III clinical trials for an insomnia related indication. Despite having a different clinical indication, we were frequently asked how our formulations compared to Epidiolex, the only FDA approved CBD product".

The current study characterized and compared the CBD absorption profile from single dose of (i) the Avecho TPM® CBD formulation, (ii) CBD dissolved in the simple oil vehicle (MCT), (iii) the commercial Epidiolex® formulation and (iv) a formulation with TPM® dissolved directly into the commercial Epidiolex® formulation (Epidiolex + TPM®).

All test formulations were administered to fasted dogs via oral gavage and characterized over 24 hours.

The average area-under-the-curve ("AUC") of the CBD absorption profile and peak plasma concentration (Cmax) were calculated for each formulation. AUC represents the amount of drug absorbed after administration and is used to compare relative drug absorption between treatments. Both AUC and Cmax are standard measurements used to characterise drug absorption.

Study results:

- Avecho's clinical CBD TPM® formulation produced higher average AUC and Cmax than the CBD MCT control and the commercial Epidiolex® formulation.
- The Avecho CBD formulation increased average AUC by ~4 and average Cmax ~2.5 times when compared to Epidiolex®.
- The Epidiolex® + TPM® formulation increased average AUC by ~4 times and average Cmax by ~3 times when compared to Epidiolex®.
- No symptoms of gastro-intestinal ("GI") irritation were observed for the clinical Avecho CBD formulation or the Epidiolex® + TPM® formulation, despite the four-times increase in average CBD absorption.
- The study is ongoing and will now assess the absorption of these formulations when accompanied by a meal; a factor known to increase the absorption of CBD.



While the increased bioavailability produced by formulations containing TPM® is important, it was equally significant that the increase in absorption from TPM® formulations did not produce any observable GI issues. Increasing the dose of CBD products, including Epidiolex®, can cause diarrhea and GI distress. This GI irritation can be prohibitive for indications requiring high doses of CBD, and industry has been looking for a way to increase the CBD dose without increasing the associated irritation. Dogs are an especially sensitive model for the assessment of GI irritation. No GI irritation was observed for the Avecho formulation or the Epidiolex + TPM® in dogs, despite the four-fold increase in CBD absorption. TPM® formulations may therefore be appropriate in the future for indications that require very high doses of CBD.

The increased absorption of the Avecho CBD formulation versus controls has now reproduced across two independent animal models; rodent and dog. These results validate the Company's choice of formulation for use in human trials seeking low dose CBD approval, and gives the product maximal chance of success in the upcoming Phase III.

Market Opportunity:

The performance of the Epidiolex +TPM® formulation is especially noteworthy, as it demonstrates that TPM® may be added to further products to increase their effectiveness. At a time when CBD and cannabis are rapidly becoming a simple commodity, differentiation of products will be key to maintain brand position.

The medicinal and consumer CBD market is expected to grow from around AU\$8B (2019) to greater than AUS\$25B in 2025. While the market continues to expand, the lack of differentiation between products has already become apparent. A rapidly changing regulatory environment, including the possibility of over-the-counter CBD in Australia, further compounds the limitations associated with existing medicinal cannabis dosage forms.

A growing number of companies are now looking for ways to formulate and commercially differentiate their medicinal cannabis products. Cannabinoid products with enhanced absorption, such as those identified in our recent animal studies, could offer significant therapeutic benefits to patients with commensurate commercial benefits to Avecho and its partners.

In alignment with this, Avecho has recently begun formal business development outreach to the larger recreational cannabis space in North America, with this new data to be a feature of these discussions.

For enquiries, please contact

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

**About Avecho**

Avecho Biotechnology Limited (ASX: AVE) develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called TPM® (Tocopherol Phosphate Mixture). 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, 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

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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