

ASX Limited
Market Announcements Office

Dosing Commences for Phase I Human Clinical Trial Measuring CBD Absorption in Healthy Volunteers

Highlights:

- Avecho has commenced dosing subjects for its Australian Phase I pharmacokinetic (PK) study to characterise the absorption profile of cannabidiol (CBD) from its CBD soft-gel product.
- The Study will test Avecho's soft-gel CBD product, which is being produced by Catalent Inc (CTLT, NYSE), at two separate doses.
- Results from the Study are expected in Q4 CY21.

Melbourne, Australia, 4 October 2021: [Avecho Biotechnology Limited](#) (ASX:AVE, "Avecho", or "the Company") has today announced that it has commenced dosing in a cohort of 16 healthy volunteers for its Australian Phase I pharmacokinetic (PK) study ("the Study") designed to characterise the absorption profile of cannabidiol (CBD) from its TPM[®]-enhanced pharmaceutical CBD soft-gel product.

Avecho's oral CBD formulation has already been demonstrated to increase the oral bioavailability of CBD in animal models when compared to standard CBD preparations. This Study will demonstrate the absorption profile of the Company's CBD formulations in humans for the first time and support Avecho's strategic focus of developing pharmaceutical CBD products that leverage its proprietary TPM[®] formulations.

The Study will assess the safety and absorption profile of Avecho's 75 mg CBD soft-gel product, which has been developed and manufactured by Catalent Inc at its facility in Florida, US. Subjects in the study will receive two separate doses (75 mg and 150 mg) over a period of two weeks.

Healthy volunteers received their first dose at the CMAX Clinic in Adelaide on Saturday 2 October 2021, with no adverse events of concern reported. The second dose will commence on the 9th of October. Blood samples will be analysed for CBD, TP, T2P and tocopherol (the components of Avecho's TPM[®] formulation) and the results used to investigate a range of standard pharmacokinetic variables. These include the maximum drug concentration in the blood (C_{max}), the time taken to reach the maximum drug concentration (T_{max}) and the total drug exposure over time (AUC).

Avecho CEO, Dr Paul Gavin, said: *"We are delighted to commence this Study and complete the first dose in the cross-over. While we won't have the CBD absorption results until later in the year, it is already good to see that the CBD dose was well tolerated by subjects."*

The Study has been designed to form a key piece of a future regulatory submission, as well as to inform ongoing research and development for Avecho's CBD product portfolio and potential commercial partnerships in this space.

High level results are expected in December 2021, which will mark a significant milestone for the program.

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This announcement is authorised for release by the Board of Directors of Avecho Biotechnology Limited.

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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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