ASX Limited
Market Announcements Office

Avecho Commences Enrolment for Phase I Human Clinical Trial Measuring CBD Absorption

Highlights:

- Avecho has today provided an update on its Australian Phase I PK study ('the Study'), announcing enrolment of the first healthy volunteers for the Study.
- The Study characterises the absorption profile of cannabidiol (CBD) from Avecho's CBD soft-gel product, at two separate doses.
- The Study aims to recruit a total of 16 healthy volunteers in Australia, with dosing scheduled to commence next month.
- Results from the Study are expected in Q4 2021.

Melbourne, Australia, 15 September 2021: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") has today provided an update on the progress of its Australian Phase I pharmacokinetic (PK) study ('the Study') designed to characterise the absorption profile of cannabidiol (CBD) from its CBD soft-gel product, announcing enrolment of the first healthy volunteers.

The Study will support Avecho's strategic focus of developing pharmaceutical CBD products that leverage its proprietary TPM® formulations.

The Study will assess 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 over a period of two weeks, with dosing due to begin in early October.

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.

Avecho CEO, Dr Paul Gavin, said: "*We are delighted to progress enrolment of healthy volunteers for this Study, and to commence formal clinical assessment of Avecho's CBD soft-gel product. We have invested time this year with Catalent further optimising and completing the product. Catalent is a respected global leader in the development of drug technologies and we believe that the collaboration and additional effort will ensure the dosage form reflects the highest possible standard. We are excited to see how it performs in human studies.*"

In parallel to the ongoing pharmaceutical development program, results from the Phase I Study will also be used to support development and licensing arrangements with third parties providing the potential to expand into further indications, separate additional territories and new markets.

Details of the Study:

The Study will measure the safety and absorption profile of the CBD soft-gel product developed with TPM® and the data will form an integral part of a future TGA submission and drug label. The Study will take place at CMAX in Adelaide with 16 healthy volunteers.

The study will be a cross-over design comparing the absorption of CBD after consumption of soft-gel capsules at two different doses; 75 mg and 150 mg. These clinical doses were chosen to align with the TGA's down-scheduling of CBD, which has specified that future over-the-counter CBD products must have a maximum daily dose of 150 mg.

The 75 mg CBD dose per soft-gel capsule will support twice daily dosing for indications benefiting from prolonged drug delivery (such as anxiety), or for the consumption of two capsules together for indications requiring a higher, single dose (for indications such as insomnia).

The study will also characterise the absorption and/or metabolism of TPM®, which will be a requirement for a future regulatory submission. Blood samples will be analysed for CBD, TP, T2P and tocopherol (the components of Avecho's TPM® formulation) in Canada.

High level results are expected to be received in December 2021.

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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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