ASX Announcement
13 April 2021

Avecho receives Ethics Approval for a Phase I Human Clinical Trial to Characterise Drug Absorption from its Enhanced Cannabidiol Product

Key highlights

- Avecho has received ethics approval to conduct an Australian Phase I PK study to characterise the absorption profile of cannabidiol (CBD) in healthy volunteers
- The Avecho CBD formulation is currently being manufactured as a pharmaceutical soft-gel product by Catalent Inc (CTLT, NYSE)
- The Company is already participating in the CA Clinics Observational Study (CACOS), Australia's largest running observational study of medicinal cannabis products in patients
- Increasing the absorption of cannabinoids will support the development of differentiated cannabinoid products on market, with greater therapeutic potential and/or reduced cost to patients
- Avecho has commenced detailed planning for its development program beyond Phase I, with a focus on TGA registration

Melbourne, **Australia, 13 April 2021** - Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") is pleased to advise that it has received ethics approval for its Phase I clinical trial, that will characterise the absorption profile of cannabidiol (CBD) from its TPM®-enhanced pharmaceutical CBD product in healthy volunteers.

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. Increasing the absorption of cannabinoids will support the development of differentiated cannabinoid products on the market, with potential for greater therapeutic potential and/or reduced cost to patients. The Company is already participating in the CA Clinics Observational Study (CACOS), Australia's largest running observational study of medicinal cannabis products in patients, to gather real world feedback on how this product will perform for a range of indications that currently utilise medicinal cannabis therapy.

Today, Avecho announced another critical step forward in its CBD program, having received ethics approval to progress a Phase I human clinical trial to characterise CBD absorption from the enhanced CBD formulation.

Avecho CEO, Dr Paul Gavin, said: *"Avecho's oral CBD formulation is now being taken into formal Phase I clinical trials, which is the first step toward our primary goal of developing differentiated CBD products for pharmaceutical registration."*

The study will measure the safety and absorption profile of the CBD 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

Catalent is currently supporting the development of the CBD soft-gel capsules at its St. Petersburg, Florida, facility in the U.S. based on Avecho's prototype formulation for use in the clinical trial. 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). Catalent is a leading global provider of advanced drug delivery

technologies, development, and manufacturing solutions to help life science innovators develop and launch successful pharmaceuticals, cell and gene therapies, and consumer health products.

Avecho CEO, Dr Paul Gavin, said: *"We are focused on producing a high-quality product that meets regulatory requirements for a pharmaceutical product. Consequently, the chemistry, manufacturing and control requirements are extensive – and something we are carefully executing to ensure we are successful. The work being conducted by Catalent will aim to turn our prototype formulation into a pharmaceutical dosage form and will form a significant component of future regulatory dossier."*

Exact timelines for dosing in the Phase I clinical trial are subject to the evolving chemistry, manufacturing and controls (CMC) work at Catalent, but are anticipated to be early Q3. Avecho is now planning a larger development program beyond this Phase I study. This includes the clinical indication that will be targeted in a future pivotal clinical trial, as well as the regulatory, clinical, CMC and safety studies required to submit a dossier to the TGA for product registration.

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

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.

See more here - avecho.com.au

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