



ASX Announcement

23 December 2020

ASX Market Announcements
ASX Limited
Level 4
Stock Exchange Centre
20 Bridge Street
Sydney NSW 2000

Avecho begins observational study testing enhanced cannabidiol formulation

Highlights:

- Avecho initiates the clinical testing phase of its oral CBD TPM[®] formulation.
- Avecho joins Australia's largest running observational study of medicinal cannabis products, the CA Clinics Observational Study (CACOS).
- Participation in the trial will shape the future development of Avecho's oral cannabinoid product; providing real world customer feedback; prioritising indications of value for Phase II studies; and to explore the potential for SAS-B prescribing of a differentiated product.

Melbourne, Australia, 23 December 2020: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") today announced it has begun participation in Australia's largest running observational study of medicinal cannabis products, the CA Clinics Observational Study (CACOS). Avecho will test the performance of its enhanced oral cannabidiol (CBD) TPM[®] formulation in human patients being prescribed medicinal cannabis for a range of indications.

Avecho's oral CBD TPM[®] formulation has been shown to increase the oral bioavailability of CBD in animal models and will be tested for the first time in humans in the CACOS study. The Company aims to gather real world feedback on how the product performs in patients currently utilising medicinal cannabis therapy across a range of indications. Performance will be compared against commonly prescribed CBD formulations. Recruitment for the study will begin immediately, and continue on an ongoing basis throughout 2021 to maximize the number of patients dosed with both the CBD TPM[®] and commercial comparator formulations.

The CACOS study aims to recruit a total of 3000 patients nationwide through a network of medicinal cannabis prescribing clinics and will utilise questionnaires to examine the side effects, dosage response, and treatment satisfaction of medicinal cannabis formulations on patients' health status. Data generated will help shape the future development and clinical indications for the Company's pharmaceutical CBD products, whilst also exploring the potential for SAS-B prescribing.

"The Avecho team is excited and optimistic about our plan to develop CBD products enhanced by our TPM[®] technology. This trial is an important step in gathering real world evidence from patients. Entering into an existing trial framework provides Avecho with both cost and speed advantages. The observational trial design allows the product to be used in a range of indications, which may prioritise specific indications for further development, or eliminate indications where the treatment is less effective," said Avecho CEO, Dr Paul Gavin.

Increasing the absorption of cannabinoids will allow for differentiated cannabinoid products on market, with greater therapeutic potential and/or reduced cost to patients, which is timely given the changing regulatory landscape for these products in Australia.



Earlier this month, the TGA made its down-scheduling of CBD official. In the future, registered CBD products with a maximum dose of 150 mg/day may be available to purchase directly from a pharmacist without a prescription.

"The down-scheduling of CBD is fantastic news for patients, but a 150mg dose is on the limits of efficacy for a range of indications. We believe increased bioavailability will be a key value driver that will positively differentiate our products in this growing competitive market," said Dr Gavin.

The CACOS study forms the companion piece to a Phase I clinical trial currently scheduled to begin toward the end of Q1 2021. The Phase I trial will assess the absorption of CBD from the Avecho product. Together, the data from these studies will direct the pharmaceutical CBD TPM[®] formulation towards the most appropriate clinical indications for product registration.

For investor and general enquiries, please contact

Ms Melanie Leydin
Company Secretary
Avecho Biotechnology Limited
+61 3 9002 5000

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.

No representation, warranty or assurance (express or implied) is given or made by AVE that the forward-looking statements contained in this announcement are accurate, complete, reliable or adequate or that they will be achieved or prove to be correct. Except for any statutory liability which cannot be excluded, AVE and its respective officers, employees and advisers expressly disclaim any responsibility for the accuracy or completeness of the forward looking statements and exclude all liability whatsoever (including negligence) for any direct or indirect loss or damage which may be suffered by any person as a consequence of any information in this announcement or any error or omission therefrom.

Subject to any continuing obligation under applicable law or relevant listing rules of the ASX, AVE disclaims any obligation or undertaking to disseminate any updates or revisions to any forward looking statements in these materials to reflect any change in expectations in relation to any forward looking statements or any change in events, conditions or circumstances on which any statement is based. Nothing in these materials shall under any circumstances create an implication that there has been no change in the affairs of AVE since the date of the announcement.