ASX Announcement

22 June 2023

Avecho passes two-year stability milestone for its pharmaceutical CBD soft-gel capsule

Highlights:

- The first batch of Avecho's proprietary oral TPM®-enhanced CBD soft-gel capsule has passed a pivotal two-year milestone in ongoing stability trials.
- CBD remained at 99.5% of the original label claim after two years, supporting a future two-year shelf life.
- Two-year stability is an essential requirement for a future pharmaceutical TGA/FDA registration.

Melbourne, Australia, 22 June 2023: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") has today announced it has passed a crucial two-year stability point milestone for its TPM®-enhanced cannabidiol ("CBD") soft-gel capsule.

Cannabinoids are susceptible to degradation from a number of external sources, including oxygen, light, heat and pH, which can make long-term pharmaceutical stability difficult. Furthermore, specific cannabinoids such as the non-psychoactive CBD, can be converted into psychoactive cannabinoids, such as tetrayhydrocannabinol ("THC"). A CBD product with significant chemical degradation, or interconversion to additional cannabinoids, would be unable to be registered as a pharmaceutical medicine.

In addition to increased bioavailability, Avecho's TPM-enhanced CBD soft-gel capsule underwent specific formulation optimisation to protect the CBD from chemical degradation over time. Commercially appropriate pharmaceutical stability of two years is critical given the Company's intention to register the finished product with the Therapeutic Goods Association ("TGA").

Formulation development work was completed in May 2021, resulting in a soft-gel capsule containing 75 mg of CBD. This 75mg unit dose was 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. These initial batches of 75mg CBD capsule were submitted to formal stability studies to determine the chemical stability of CBD over time in the capsule.

After two years at room temperature, no significant changes were observed for Avecho's CBD capsule. Assessments of the physical attributes of the product, including the hardness of the capsule and its dissolution profile, remained unchanged. Critically, no degradation of the CBD was observed over time, with drug levels remaining at 99.5% of the label claim. These results confirm the stability of the CBD TPM formulation which is required to gain a two-year shelf life for the product upon approval.

Notably, the TGA's over-the-counter opportunity allows for up to 2% of additional cannabinoids to be present in the approved product, with a maximum allowable THC content of 1% of the total cannabinoid content. Avecho's TPM-enhanced CBD soft-gel capsule, which includes ultra-high purity CBD, did not contain any additional cannabinoids above the limit of quantitation after two years.

Avecho CEO, Dr Paul Gavin, said: "*Cannabinoids are not as stable as everyone assumes, especially when they are held to pharmaceutical standards. We saw CBD degradation in early prototypes that required further formulation optimization to overcome. Passing two year-stability is an important milestone, as it proves the additional formulation work we conducted was successful over the longer time-frame. The product can be manufactured reproducibly, whilst maintaining stability and potential effectiveness over time, which is an essential requirement of pharmaceutical registration. In anticipation of our Phase III Study testing our CBD soft-gel capsule for the treatment of insomnia, we are now manufacturing product for use in the clinical trial as well as formal registration batches that will be included in future TGA and FDA submissions*."

Avecho's imminent Phase III Study (the "Study") for its proprietary CBD soft-gel capsule is the largest of its kind to date and will enroll 540 patients across three treatment groups to compare nightly CBD doses of 75 and 150 mg CBD with placebo over an 8-week dosing period. The Study is marked to be of relevance to the TGA, the FDA and the EMEA – a key factor to support potential product registration in leading global healthcare markets.

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

Questions related to the announcement are welcome via our InvestorHub platform.

Investor + General Enquiries

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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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