ASX Announcement

21 May 2021

ASX Market Announcements
ASX Limited
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Melbourne VIC 3000

Pharmaceutical CBD soft-gel product design completed

Highlights:

- The composition and design of the finished dosage form of Avecho's cannabidiol (CBD) soft-gel product has now been completed by Catalent (CTLT, NYSE).
- The soft-gel product is the focus of Avecho's Australian clinical trial campaign to support registration, beginning with the recently approved Phase I PK study.
- Cannabinoid product(s) with increased absorption of cannabinoids have the potential to be positively differentiated in an increasingly crowded market, providing the prospect for greater therapeutic potential and/or reduced cost to patients.

Melbourne, Australia, 21 May 2021: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") has today announced that the appointed manufacturer of its cannabidiol (CBD) soft-gel product, Catalent (CTLT, NYSE), has completed the composition and design of the dosage form intended for registration with the TGA.

Avecho has previously developed prototype CBD oil formulations with increased bioavailability, and has engaged Catalent, a leading global provider of advanced drug delivery technologies, development, and manufacturing solutions, to adapt these into pharmaceutically acceptable soft-gel capsules. These CBD capsules will be used in Avecho's upcoming clinical trial campaign which includes Phase I and a pivotal efficacy study, and are the planned dosage form to be registered with the TGA.

Avecho's leading prototype CBD oil formulation was refined at Catalent's St. Petersburg, Florida facility in the U.S. The refinements are designed to ensure the formulations are appropriate for inclusion in commercial capsule manufacturing lines, are compatible with candidate gelatin capsules, and most importantly, have appropriate physical and chemical stability. Commercially appropriate stability is critical given the Company's intention to register the finished product with the TGA. The finalised composition will contain 75 mg of CBD per soft-gel capsule.

Avecho CEO, Dr Paul Gavin said: *"This is an important milestone on the critical path for the development of our pharmaceutical CBD product. It cannot be emphasised enough how important it is to get the chemistry, manufacturing and controls aspect of a formulation correct. Positive results from this process are as critical as successful clinical trials. We have been thorough and forward-thinking in our approach to manufacturing the soft-gel product, by ensuring we produce a GMP finished product that is appropriate for scale up and registration with the TGA."*

With this milestone achieved, Avecho's CBD soft-gel product will move toward GMP manufacturing for use in the Company's current clinical trial program. Production will first begin at small scale to validate the manufacturing process and analytical methods, as well as to assign the finished product specifications. Successful characterization of the prototype batch will allow formal GMP manufacture of the CBD soft-gel which will be used for formal stability and the planned human clinical trial campaign.

The GMP manufacturing timelines are now being finalised and will provide clarity on timing for the Phase I PK study and potential efficacy studies. At this stage, the clinical trial is anticipated to begin toward the end of Q3.

Avecho CEO, Dr Paul Gavin said: *"While it is always tempting to accelerate the start of clinical trials using product compounded locally, trial results generated using material manufactured in this manner are not admissible in TGA submission. We have therefore invested early in a quality controlled manufacturing process with a reputable supplier, which we believe not only optimizes the quality and chance of success of future regulatory approvals but ultimately also benefits speed to market."*

In parallel with this work, the Company is finalising its plans to meet with the TGA to discuss the entire development program, with a view to defining the clinical indication and supporting pivotal trial design.

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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.

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.

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