ASX Announcement

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ASX Market Announcements
ASX Limited
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TGA pre-submission meeting for insomnia related CBD soft-gel product

Highlights:

- Development of a pharmaceutical grade soft-gel cannabidiol (CBD) product is underway: initial target is an over-the-counter insomnia related indication.
- Avecho is proceeding to a TGA pre-submission meeting to discuss plans for the development and registration of the CBD soft-gel product.
- Cannvalate is engaged to prepare the TGA pre-submission meeting.
- The soft-gel product contains TPM® which was demonstrated to increase CBD bioavailability and is scheduled for an Australian Phase I PK study to characterise the absorption profile of CBD.

Melbourne, Australia, 26 May 2021: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") has today announced it is proceeding to a pre-submission meeting with the Therapeutic Goods Administration (TGA) to present plans for the development and registration of its pharmaceutical cannabidiol (CBD) soft-gel product: its first target being for an insomnia related indication.

The meeting will examine the proposed indication and appropriateness of Avecho's planned clinical program to support product registration as a Schedule 3 (S3) pharmacist only medicine in Australia. It will address specific design aspects of a pivotal phase III study, together with the available safety information related to the cannabidiol and the specific soft-gel product.

The TGA announced its decision to allow the sale of registered pure CBD products by pharmacists in December last year. Potential S3 registration is now limited to oral, oral mucosal or sublingual products with a maximal daily dose of 150 mg that are packaged securely in child-proof containers. Avecho's soft-gel product contains 75 mg per capsule, allowing for efficient once or twice per day dosing within the TGA's established dosing guidelines. Avecho's soft-gel product also contains TPM®, which was shown to increase the oral bioavailability of CBD.

Avecho has engaged the services of Cannvalate for the TGA pre-submission. Cannvalate has developed the Medicinal Cannabis Research Collaboration as a premier Contract Research Organisation specialising in the clinical development of medicinal cannabis products. Cannvalate has already participated in TGA-presubmission applications for other medicinal cannabis companies, and is uniquely placed to help Avecho in optimising engagement with the TGA.

Avecho CEO, Dr Paul Gavin said: *"We are committed to working closely and constructively with the TGA and other key regulators as we develop our clinical trial program and products, to ensure our Company is primed to register our CBD soft-gel product in key markets. We have engaged the Cannvalate team to run the TGA pre-submission meeting, due to their extensive experience in the Australian medicinal cannabis space wih an emphasis on TGA interactions."*

Whilst Avecho's CBD soft-gel has the potential to treat a number of candidate indications, the Company has determined that insomnia should be the basis for the initial indication. Clinical trial data has demonstrated that CBD can increase sleep duration when compared against placebo, in addition to reducing the time it takes to fall asleep. Some of these results were obtained using CBD doses above 150 mg, potentially biasing success in this indication toward products with increased bioavailability.

Avecho CEO, Dr Paul Gavin said: *"We believe the choice of initial indication is crucial in determining who will be both clinically and commercially successful. The available S3 indications are typically subjective in nature and rely on self-reported patient questionnaires describing how they are feeling. Studies of this kind are more susceptible to placebo effects, which can increase the difficulty of seeing a beneficial medicinal effect. In addition to being a commercially attractive endpoint, our research indicated that the insomnia related studies were less susceptible to placebo effect than some of the other candidate indications that were considered."*

The Australian market for insomnia related products is currently ~$250M and incorporates a mixture of prescription, non-prescription and complementary medicines. Avecho's complete product development strategy will be refined after the TGA pre-submission meeting and presented to market in Q3.

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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

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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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