ASX Limited
Market Announcements Office

Results for Phase I Human Clinical Trial Characterising CBD Absorption from Avecho's soft-gel capsule

Highlights:

- Avecho today released the results for its Australian Phase I PK study which characterises the absorption profile of cannabidiol from its CBD soft-gel product.
- Pharmacokinetic parameters for both the 75 mg and 150 mg doses were characterised, and are suitable for use in future regulatory submissions.
- No adverse events of concern were found related to the study medication.
- Initial data pack to support testing in a range of clinical indications now complete.

Melbourne, Australia, 8 December 2021: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") today released results for its Australian Phase I PK study ("the Study") characterising the absorption profile of cannabidiol ("CBD") from Avecho's proprietary CBD soft-gel product.

The primary objective of the study was to determine the single dose pharmacokinetics ("PK") of cannabidiol absorbed from a single 75 mg and 150 mg oral dose from proprietary CBD soft-gel products. This information is required for future product registration with the TGA or FDA. The 75 mg and 150 mg doses 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.

The Study was conducted at CMAX in Adelaide with 16 healthy volunteers. Subjects received both doses over a period of two weeks, with each dose preceded by an overnight fast. Blood samples were collected for 48 hours after each dose and assayed for CBD content. All 16 subjects completed both treatment periods.

The CBD absorption profile and pharmacokinetic parameters of both the 75 mg and 150 mg doses were well characterised. There was a linear relationship between doses with the average amount of drug absorbed from the 150 mg dose being approximately double that of the 75 mg dose. The two doses exhibit minor differences in delivery profile, with mean peak plasma concentrations for the 75 mg dose appearing 2 hours after dosing, whereas peak plasma concentrations for the 150 mg dose were evident three hours after dosing. The absorption period of the 150 mg dose was also longer, with CBD detected in the blood one week after dosing.

Both doses of the CBD soft-gel were well tolerated, with all adverse events characterised as mild and no adverse events of concern related to the study medication.

Avecho CEO, Dr Paul Gavin, said: "*We now understand the absorption profile from both doses of our proprietary CBD soft-gel in humans. The results are exciting and show that the delivery profiles from both doses could support utility across a range of potential indications, whether they require once per day, or twice per day, dosing.*"

The Study results support the further clinical development and subsequent registration of the CBD soft-gel product. They will form an important part of the pharmacokinetic section of a TGA submission dossier and future product label, and provide the critical bridging data required to reference CBD safety data in the public domain from previously registered CBD medications. The absorption profiles will also inform the dosing regimen to be used in subsequent clinical trials,

including the pivotal efficacy program being designed for an insomnia related indication. They will also form a key piece in partnering discussions.

Avecho CEO, Dr Paul Gavin, said: "*The Company has now assembled a thorough early phase data package to support the ongoing development and future registration of the CBD soft-gel product. This data package includes formulation development and animal data; the use of high-purity, synthetic CBD; soft-gel capsule development and GMP manufacturing; ongoing stability; human Phase I pharmacokinetics; and new IP for future patent protection. We believe this data package will not only support ongoing regulatory and ethics approvals but also highten interest from potential partners, especially those looking to avoid two years of product development and jump straight into efficacy studies for indications of interest*."

The Company's focus has already shifted to next steps for developing its CBD soft-gel product, which will be a major priority for 2022. These include the manufacturing scale-up; associated validations; and formal registration batches that will complete the CMC component of a future submission dossier and pivotal efficacy studies in an insomnia related indication.

- ENDS -

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

Investor + General Enquiries

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

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.

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.