ASX Limited
Market Announcements Office

TPM® Cannabinoid Development Program Proceeding to Human Clinical Trials

Highlights:

- *In vivo* studies conducted at Bioneer:FARMA demonstrate significantly increased cannabidiol (CBD) bioavailability from oral TPM® cannabidiol formulations in rats
- Avecho Biotechnology Limited is now advancing its cannabinoid formulations to human clinical trials

Melbourne, Australia, 19 October 2020: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") today announced that it is proceeding to the next phase of its recently announced cannabinoid development program – human clinical trials. This decision is supported by positive results from preliminary *in vivo* studies which confirmed significantly increased cannabidiol (CBD) bioavailability from oral TPM® cannabidiol formulations in rats.

Avecho Chief Executive Officer, Dr Paul Gavin, said: "We presented to the market in June, that Avecho had begun the development of pharmaceutical cannabinoid products combined with our TPM® technology. These products aim to increase the oral absorption of cannabinoids, overcome the limitations associated with poor bioavailability and high variability in absorption, and improve the cost and benefits to patients."

The development program consists of three main components; (i) *in vitro* testing in simulated gastro-intestinal digestions, (ii) animal studies to assess *in vivo* bioavailability of candidate formulations, and (iii) subsequent human trials testing the best formulations.

"Our latest study results demonstrate a compelling increase in cannabinoid bioavailability produced by our TPM® formulations, confirming we have appropriate candidate formulations to take into human clinical studies. This is an exciting milestone for our Company," said Dr Gavin.

Researchers at Bioneer:FARMA, located within the University of Copenhagen, had previously completed the *in-vitro* testing, demonstrating that formulations containing TPM® significantly increased CBD solubility during gastric and intestinal *in vitro* digestion. In the subsequent study, single doses of these same formulations were administered to rats using an oral gavage to characterise the CBD absorption profile over 24 hours.

The average area-under-the-curve (AUC) of the CBD absorption profile and peak plasma concentration (Cmax) were calculated for each formulation. AUC and Cmax are standard measurements used to characterize drug absorption. For this study, they were used to compare the amount of CBD absorbed between different formulations. CBD absorption from formulations containing TPM® was compared against a commonly prescribed CBD product comprising CBD at 100 mg/ml.

Study results:

- All TPM® formulations produced higher mean AUC and Cmax than the commercial CBD formulation.
- Increases in AUC produced by TPM® formulations ranged from ~4-40 times
- Increases in Cmax produced by TPM® formulations ranged from ~6-41 times
- These increases were statistically significant for the best performing TPM® formulations.

Further animal work may be conducted, but the dramatic increases in CBD absorption are already sufficiently compelling to initiate formal human clinical trials. Planning for these studies is already underway, with dosing expected to begin Q1 2021.

Market Opportunity:

The medicinal and consumer cannabinoid market is expected to grow from around AU$8B (2019) to greater than AUS$25B in 2025. While the market continues to expand, the lack of differentiation between products has already becoming apparent. A rapidly changing regulatory environment, including the possibility of over-the-counter CBD in Australia, further compounds the limitations associated with existing medicinal cannabis dosage forms. A growing number of companies are looking for ways to formulate and commercially differentiate their medicinal cannabis products. Cannabinoid products with enhanced absorption, such as those identified in our recent animal studies, could offer significant therapeutic benefits to patients with commensurate commercial benefits to Avecho and its partners.

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

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.