ASX Limited
Market Announcements Office

Positive Results For Phase II Topical CBD Osteoarthritis Study

Highlights:

- Avecho announces positive results of its Phase IIa Study examining its proprietary topical CBD gel for the management of pain associated with arthritis of the hand.
- During 4 weeks of dosing, the Study demonstrated statistically significant daily improvements in hand pain, hand functionality, grip strength, finger stiffness and anxiety.
- The Study was run in collaboration with the Lambert Initiative, a highly respected academic institute for the discovery, development, and optimisation of safe cannabinoid therapeutics.

Melbourne, Australia, 29 March 2022: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") today announces positive results for its Phase IIa Study ("the Study") examining the effects of its topically applied CBD formulation on the symptoms of osteoarthritis ("OA").

The Study was run by Principal Investigator, Dr Daniel Lewis, from the Daniel Lewis Rheumatology Centre; and Co-Investigator, Professor Iain McGregor, from the Lambert Initiative, Australia's leading research group for the discovery, development, and optimisation of safe cannabinoid therapeutics.

Hand OA is a common, painful, progressive, and irreversible condition that significantly impairs hand strength and function. There are limited treatment options available and current therapies primarily involve symptom relief and preservation of function. Systemic administration of CBD has shown promise in animal models of OA, however, topical therapeutics are of particular interest in diseases such as OA due to their targeted application and avoidance of first-pass metabolism.

Four week treatment with Avecho's proprietary topical CBD formulation resulted in highly significant improvements ($p<.001$) in patient observed (i) reductions in pain, (ii) increases in grip strength, (iii) improvements in hand functionality, (iv) self-reported stiffness of the fingers and (v) self-reported anxiety.

Principal Investigator, Dr Daniel Lewis, said: "*There is an unmet need for effective treatment in this condition which has a significant impact on the quality of life. We are very encouraged by these results which will need to be confirmed with a longer placebo-controlled trial in a larger number of patients in due course. If further trials replicate the benefits seen in this initial trial then we believe this topical therapy will become a cornerstone therapy for the management of hand osteoarthritis.*"

Avecho has begun working with prescribing physicians, including Dr Daniel Lewis, to make the formulation available immediately through compounding pharmacists.

Co-Investigator, Professor Iain McGregor, said: "*The available quality evidence for the use of CBD in pain is limited. Despite being a small trial, we had hoped this Study could see signs of a measurable impact on pain from this topical CBD formulation that would justify larger, placebo controlled studies. The results have surpassed our expectations and clearly warrant further clinical exploration to tease out the specific effect of the CBD and an associated mechanism of action.*"

While Avecho remains focused on the development of its oral CBD capsule for initial TGA registration, the results of this study warrant further development of its topical cannabinoid products.

Avecho CEO, Dr Paul Gavin, said: "*We have already received commercial interest in a topical CBD formulation and are confident the data from this Study will be of interest to potential licensees. The addition of topical cannabinoid products to our cannabinoid portfolio would be of immense value, not just for pain indications, but also in fields like dermatology*."

Avecho will now plan larger placebo-controlled studies in collaboration with the Lambert Initiative. Results of the current Study will also be presented by the Lambert Initiative at the 32nd Annual International Cannabinoid Research Society Symposium (ICRS) in Galway, Ireland, in June 2022. The ICRS conference is the premier annual meeting for cannabinoid research.

Phase IIa Study Clinical Trial Results

The single-centre proof-of-concept trial investigated the effects of a topical CBD gel on symptomatic, painful OA of the hand, affecting the fingers and/or thumb. A group of 15 patients applied Avecho's proprietary TPM® formulation daily to the affected joints of a single hand. The Study was run over a 6 week period, including 1 week of baseline measurements, 4 weeks of treatment, and a subsequent 1 week of washout after the conclusion of dosing.

Participants were asked to complete a range of daily assessments. The primary outcome measure was the change from baseline in daily hand pain (average and maximum) as measured by the *10-point Numeric Pain Rating Scale (NPRS).* The secondary objectives involved hand functionality including *grip strength* measured daily via an electronic squeeze ball dynamometer connected via Bluetooth to a smartphone-based recording app, and the *Functional Index for Hand Osteoarthritis (FIHOA) score*, completed at baseline and weekly until study exit.

The reduction in pain scores was highly significant ($p<.001$) for both the average daily NPRS pain scores (1.32-point difference, baseline = 4.38,) and maximum daily NPRS pain scores (1.62-point difference, baseline = 5.57).

Improvements in grip strength and functionality were also highly significant ($p<.001$) with functionality measurements (relative to the baseline) in the treated hand markedly improving during the first week of treatment and being maintained over the 4-week dosing period.

Most participants also saw improvements in functional index for hand osteoarthritis (FIHOA) functionality scores with treatment. Weekly declines in self-reported stiffness of the fingers and anxiety were also reported, with these changes over time also statistically significant ($p<.001$) by the end of week 4.

All measured parameters began to return to baseline the week after the cessation of dosing.

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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.

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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