

ASX Limited
Market Announcements Office

Avecho Secures Product License and Supply Agreement with Medterra Pharma LLC for CBD Arthritis Treatment

Highlights:

- Avecho today announced it has entered into a licensing and supply agreement with Medterra Pharma LLC ("Medterra") for its CBD soft-gel capsule for the treatment of arthritis
- Medterra is a successful US-based CBD company, now actively pursuing opportunities in the pharmaceutical space
- Medterra will develop Avecho's CBD soft-gel capsule product as an oral treatment for arthritis indications, with the intent to support FDA approval

Melbourne, Australia, 20 December 2021: [Avecho Biotechnology Limited](#) (ASX:AVE, "Avecho", or "the Company") has today announced it has entered into a product license and supply agreement (the "Agreement") with Medterra granting Medterra exclusive rights to develop and commercialise Avecho's soft-gel CBD capsule for the oral treatment of arthritis (other than in Australia and New Zealand).

The Agreement signals a strategic step forward in Avecho's ambitions to secure Food and Drug Administration ("FDA") approval for its soft-gel CBD product – and will occur in parallel to its existing work to register the product for sleep indications with the Therapeutic Goods Administration ("TGA") in Australia.

Medterra is one of the most successful CBD companies in the United States, known for developing and selling science-backed products in the consumer space. Its business development activities are now shifting to emerging opportunities in the pharmaceutical space, with the launch of Medterra Pharma.

Medterra will develop Avecho's CBD soft-gel capsule product as an oral treatment for arthritis indications including osteoarthritis and rheumatoid arthritis. Medterra scientists have already demonstrated the therapeutic potential of CBD for the treatment for arthritis in preclinical models. In vitro and in mouse models, CBD significantly attenuated the production of proinflammatory cytokines IL-6 and TNF- α while elevating levels of anti-inflammatory IL-10. In canine models of osteoarthritis, CBD significantly decreased pain and increased mobility in a dose-dependent manner.

Medterra's first human study using the CBD soft-gel in osteoarthritis already has Institutional Review Board approval with an Investigational New Drug Application ("IND") to be submitted to the FDA Q1 2022. The study will be a 6-week, randomized, double-blind placebo-controlled study exploring the therapeutic potential of the CBD soft-gel for reducing pain in patients with osteoarthritis of the knee. The study will be conducted at the Michael E. DeBakey Veterans Affairs Medical Center in Houston, Texas.

Medterra Pharma LLC CEO, Matt Halpert, said: *"This licensing and supply agreement with Avecho Biotechnology is an important and strategic part of our Company's commitment to expanding our profile of evidence-based CBD pharmaceutical products. Specifically, we have been looking for a novel CBD product with pharmaceutical applications, increased absorption, patent protection, and an appropriate early phase dossier. Avecho's product meets all these criteria and we look forward to supporting the progress of the soft-gel product towards FDA approval."*

The target indication of arthritis represents a promising opportunity for development. The osteoarthritis therapeutics market is projected to reach USD 11.0 billion by 2025 from USD 7.3 billion in 2020, at a CAGR of 8.7% from 2020 to 2025. The rheumatoid arthritis market is considerably smaller in population, but more lucrative based on existing treatment options. By 2029, this market may begin to approach \$30B. It is a chronic disease, a poorly managed pain condition, with limited treatments available beyond NSAIDs and steroid injections.

Pursuant to the terms of the Agreement, Avecho will receive US\$50,000 upon execution of the Agreement and up to an additional US\$800,000 in milestone payments triggered by the submission of INDs for subsequent clinical trials. Avecho will receive 2% royalties on net sales upon the successful commercialisation of the CBD soft-gel product, and can receive a further profit-share of up to 20% dependent upon Medterra Pharmaceuticals development plans for arthritis treatments and Avecho's ongoing patent protection.

Avecho will retain the manufacturing rights for the soft-gel product, which will be supplied to Medterra (based on its published pricing) using a third party contract manufacturer. Avecho will manufacture and supply the TPM for use in the product. Avecho will retain all rights for the soft-gel product for the treatment of arthritis in Australia and New Zealand, while Medterra is granted the development and commercialisation rights to the indication for the rest of the world. Avecho also retains all rights to the soft-gel product anywhere in the world for other indications, including "over-the-counter" applications and treatment of "acute pain" indications not specific to treatment of arthritis indications.

The Agreement is effective immediately and will continue in perpetuity unless terminated by either party due to a material breach of the Agreement or terminated by Medterra due to discontinuation of development of commercialisation of the soft-gel product for technical, scientific, medical or regulatory reasons.

Avecho CEO, Dr Paul Gavin, said: *"We have known for some time that our CBD soft-gel product has a wide range of promising pharmaceutical indications, which are beneficial to potential research and commercial partners. While Avecho focuses on a sleep related indication, this Agreement allows Medterra to fund the development of the CBD soft-gel product for an additional indication, providing Avecho with potential upside for an indication we do not have the bandwidth to pursue ourselves. Using this strategy, we plan to collaborate with reputable, well-resourced partners to progress our products towards regulatory approval on a number of parallel indications – and we are very excited to commence this work."*

In parallel with this agreement, Medterra will also explore the use of Avecho's TPM technology for use in its consumer productlines that are sold online and with retailers across the world.

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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.

No representation, warranty or assurance (express or implied) is given or made by Avecho 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, Avecho 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.

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