ASX Limited
Market Announcements Office

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Athenex takes Avecho's Vitamin K injection to US FDA with pre-IND meeting request

Highlights:

- Athenex has submitted Avecho's TPM®-enhanced phytonadione injectable product to the FDA for feedback via a pre-IND meeting request.
- If FDA feedback is favorable, Athenex will sign a license and development agreement with Avecho for the product and complete the remaining development work and registration for US commercialization.

Melbourne, Australia, 12 January 2023: Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") announced today that its TPM®-enhanced Vitamin K (phytonadione) injectable product has been presented to the FDA by Athenex Pharmaceutical Division, LLC in a pre-Investigational New Drug (pre-IND) meeting request.

Athenex is a global biopharmaceutical company based in New York, US. Athenex's Pharmaceutical Division (APD) operates their specialty pharmaceuticals business, sourcing injectable and oral products for the US market through license and development agreements with a network of global partners.

Phytonadione (Vitamin K1) injections are used to treat bleeding or clotting problems caused by Vitamin K deficiency, reactions to certain medications, or other medical conditions that lead to thinning of the blood. It is routinely administered to infants at birth as a prophylactic, providing protection against bleeding, and in 2021 the US had an overall adult and pediatric approximate market size of $87M USD, with over 4.9M units sold. Phytonadione is an insoluble oil that requires formulation with an emulsifying agent in order to dissolve the drug in a formulation suitable for injection. These excipients are typically hydrogenated castor oil (Cremophor EL) or polysorbate, both of which are associated with adverse side effects when given by injection.

In lieu of the adverse excipients traditionally used, Athenex has interest in commercialising Avecho's phytonadione formulation, that uses TPM® to dissolve and solubilise the drug. The FDA's feedback to the pre-IND submission will define the amount of development work remaining before a New Drug Application (NDA) for the product could be filed with the FDA for formal review. If the FDA response to the pre-IND submission is generally favorable, and the remaining development work is commercially feasible, the parties will proceed to a license and development agreement to complete the phytonadione product development work for the NDA submission to the US FDA and product commercialisation. The final commercial terms of a subsequent agreement will be determined once FDA feedback is received.

Avecho CEO, Dr Paul Gavin, said: "It is encouraging to attract interest from a reputable partner for a legacy product in our portfolio – particularly one that can prime us for positive engagement with the FDA. We are hopeful that this will be the first of many injectable products we develop and enhance in partnership with Athenex once they have a chance to assess the full capabilities of TPM® and the viability of US commercialisation for our phytonadione product with the FDA."

In addition to the phytonadione product, Athenex and Avecho are currently in discussions to select a TPM-enhanced product to for possible commercialization in the US market, subsequent to phytonadione, where Athenex will hold first right of refusal for the product.

Athenex Inc.'s Chief Operating Officer and President of Athenex Pharmaceutical Division, Jeffery Yordon, said: "*Injectable products with solubility challenges are still using solubilising excipients with poor safety profiles. We believe Avecho's TPM®* platform *may provide a unique opportunity for the reformulation of multiple injectable drugs by solubilising these drugs using TPM®. Pending favorable FDA feedback for the phytonadione product, we are keen to investigate what additional products could benefit from reformulation using TPM®.*"

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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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