ASX Limited
Market Announcements Office

Terumo return rights to TPM®/Propofol Injectable.

Melbourne, Australia, October 17, 2019 - Australian drug delivery company, Avecho Biotechnology Limited (ASX: AVE) announced today that Terumo Corporation will not progress further with the development of the TPM®/Propofol injectable for the Japanese market.

Propofol is a general anaesthetic used for the induction and/or maintenance of sedation during surgical procedures. Terumo and Avecho collaborated on the development of a reformulated TPM®/propofol product that was the focus of a joint patent application and formal toxicology program conducted at Charles River Laboratories, USA. The toxicology studies were designed to support the safety of injectable TPM®, as well as the acute and continuous 24 hour infusion of the TPM®/propofol formulation as indicated for the commercial product.

While safe for the induction and short term maintenance of anaesthesia, the vehicle used for the TPM®/propofol formulation did not prove safe for a complete 24 hour infusion. The observed toxicity was attributed to the inclusion of a specific combination of co-surfactants, polysorbate 80 and 20. The polysorbates are commonly used injectable surfactants, but the continuous 24 hour exposure increased the administered amounts above those used routinely. Without the ability to infuse for 24 hours, the labelled indication for the TPM®/propofol product would be restricted to the induction and short term maintenance of anaesthesia.

Given the size of the Japanese market, Terumo was unwilling to consider launching a propofol product with a restricted indication. In a statement to Avecho, Mr Masahito Takahashi, General Manager of the Pharmaceutical Group, Hospital Systems Division, General Hospital Company, Terumo Corporation, said, ”Disappointingly, the formulation which had passed all other testing to this point was not suitable for long-term infusion. The polysorbate exposure resulting from this length of infusion is higher than in currently approved Japanese products, and the results demonstrate a safety concern which would be difficult to address with the Japanese regulatory authority. We have therefore decided not to support further development of TPM®/Propofol”.

Dr Paul Gavin, CSO of Avecho said “It is important to note that the observed toxicity was not caused by the TPM®. Pilot toxicology studies in this larger program demonstrated that TPM® was safe for injection at amounts exceeding those currently used in all other injectable formulation programs utilizing TPM®.”

Dr Greg Collier, Executive Chairman of Avecho commented “The partnership with Terumo has provided considerable expertise and funding towards multiple TPM® projects. While it is obviously disappointing to see it draw to a close, it is important to recognize how our technology and programs have advanced through our partnership with Terumo.”

Although significant commercial interest regarding a reformulated propofol remains, the company has yet to determine if it will continue to develop the existing TPM®/Propofol for acute use only or further optimize the formulation for the resumption of toxicology studies.

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About Avecho
Avecho Biotechnology Limited (ASX:AVE) develops and commercialises innovative Human Health, Animal Health and Personal Care products using its proprietary drug delivery system called TPM® (Targeted Penetration Matrix). 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 patches, gels and injectable products for the human health market and is also developing TPM® to enhance the feed efficiency and health of livestock.

Inherent Risks of Investment in Biotechnology Companies
There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology.

Forward-looking Statements
Certain statements in this announcement may contain forward-looking statements regarding the Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing the Company's goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services.

See more here - avecho.com.au