Vivesto's Paccal Vet receives Limited Market classification in EU

Solna, Sweden, November 11, 2024 – Vivesto AB, an oncology-focused development company, today announced that the drug candidate Paccal Vet was confirmed as intended for a Limited Market by the European Medicines Agency, for treatment of splenic hemangiosarcoma (HSA) following splenectomy in dogs. The classification may give the opportunity for a faster regulatory route to approval in the EU. If approved, Paccal Vet would be protected from generic competition for 10 years in EU.

Limited Market classification is the EU equivalent to the US MUMS classification, which Vivesto received for Paccal Vet in 2023, and is designated for products for the treatment or prevention of diseases that occur infrequently in the EU. The benefits comprise potentially reduced data requirements and enhanced regulatory assistance. Limited Market classification and the eligibility to be authorized with a reduced clinical data package is similar to the US conditional approval, i.e. a file based on safety data and reasonable expectation of efficacy (possibly no requirement for pivotal study). The authorization is valid for five years and is renewable every five years after that.

"We are very happy to have gained the Limited Market classification, aiming to increase the availability of treatments for serious or life-threatening animal diseases and unmet veterinary medical needs. This brings Vivesto one step closer to our goal of bringing Paccal Vet to the market to help the 75,000 dogs diagnosed with hemangiosarcoma annually in Europe," said Erik Kinnman, CEO of Vivesto.

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About Paccal Vet
Vivesto's drug candidate Paccal Vet consists of paclitaxel formulated with the company's proprietary XR-17 technology. Vivesto has previously shown good safety of Paccal Vet in the treatment of various types of cancer in dogs. The absence of the solvent cremophor, to which dogs are particularly sensitive, may reduce the risk of serious side effects and death associated to the treatment. Paccal Vet also does not require the addition of human albumin, which when used in dogs can cause hypersensitivity reactions and reduced treatment effectiveness.

Previous clinical studies performed by Vivesto has demonstrated safety in more than 300 dogs. Also, anti-tumor activity has been shown in squamous cell carcinoma and non-resectable mammary carcinoma of stage III-V.

About Vivesto AB
Vivesto is a Swedish development company that aims to offer new treatment options for hard-to-treat cancers where there are major medical needs and significant market potential. The project portfolio consists of Cantrixil and Docetaxel micellar, which are being developed for blood cancer

and prostate cancer, respectively, and the veterinary oncology program Paccal Vet (paclitaxel micellar), which is being evaluated in a pilot clinical trial in dogs with splenic hemangiosarcoma following splenectomy.
Vivesto's shares are traded on Nasdaq Stockholm (ticker: VIVE). Visit www.vivesto.com for more information about Vivesto.

Attachments

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