

## Vivesto announces positive Paccal Vet FDA pre-submission meeting

Solna, June 16, 2023 - Vivesto AB, an oncology-focused research and development company, today announced that the company had a successful and encouraging pre-submission conference (PSC) with the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) regarding development of Paccal Vet.

Vivesto requested the meeting to get the FDA's feedback on the planned clinical development program for the company's veterinary oncology drug candidate Paccal Vet (paclitaxel micellar) with the intention to pursue full approval in the US. On a high level, the FDA agreed to Vivesto's development strategies. The strategy is to perform a pilot study, to evaluate Paccal Vet in dogs with hemangiosarcoma and malignant melanoma, which is to be followed by a pivotal study. Vivesto plans to start the pilot study in the second half of 2023.

*"We are encouraged by this successful pre-submission meeting with the FDA regarding Paccal Vet," said Erik Kinnman, CEO of Vivesto. "There are millions of dogs in the US and EU developing cancer each year and few approved drugs for treatment. Our plan to start clinical development of Paccal Vet is a critical first step to advancing this drug and expanding treatment options in this rapidly growing market."*

The company received advice on major technical sections Chemistry Manufacturing and Controls (CMC), Target Animal Safety (TAS), Environmental Impact (EI) and Effectiveness. Vivesto also received advice regarding MUMS (Minor Use/Minor Species) application and designation.

### *About hemangiosarcoma in dogs*

Hemangiosarcoma is one of the most common malignant cancers in dogs and is associated with a poor prognosis, with less than 10% of dogs surviving 12 months. The number of dogs diagnosed with hemangiosarcoma annually in the US and Europe is approximately 75,000 per market. Dogs with hemangiosarcoma rarely show clinical symptoms until the tumor has grown very large and spread. Treatment options for hemangiosarcoma include surgery and adjuvant chemotherapy.

### *About malignant melanoma in dogs*

The number of dogs diagnosed with malignant melanoma annually in the US and Europe is approximately 60,000 per market. The most common primary site is the oral cavity (80%), with a median survival time of 65 days (oral cancer) in dogs left untreated. Malignant melanomas are highly proliferative, spreading primarily to local lymph nodes and lungs. Surgery and/or radiotherapy are the main treatment options today and target local disease, therefore metastatic disease is still the main cause of death for dogs with malignant melanoma. Consequently, chemotherapy is also considered for the treatment of metastatic and non-operable melanoma. Between 20-30% respond to currently available treatment.

**For More Information:**

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**About Vivesto AB**

Vivesto is a research and development company that develops new treatment options for patients suffering from difficult-to-treat cancer. The company has a portfolio of projects with the potential of offering cancer patients with unmet medical needs new treatment alternatives. Vivesto has a track-record of developing drugs from the preclinical stage, through clinical development to regulatory approval. Vivesto's most advanced program Apealea® (paclitaxel micellar) has been granted market approval in the EU as a treatment for adult patients suffering from the first relapse of platinum sensitive epithelial ovarian cancer, or primary peritoneal cancer or fallopian tube cancer. Other clinical development programs include Cantrixil for late-stage ovarian cancer, and Docetaxel micellar, in development for advanced prostate cancer. Vivesto has developed proprietary drug delivery technologies designed to improve solubility of various active pharmaceutical ingredients.

Vivesto's shares are traded on Nasdaq Stockholm (ticker: VIVE). Visit [www.vivesto.com](http://www.vivesto.com) for more information about Vivesto.

**Attachments**

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