

## Vivesto's US clinical Paccal Vet trial receives approval to start patient recruitment

Solna, Sweden, December 28, 2023 – Vivesto AB, an oncology-focused research and development company, today announced that the US Veterinary Review Board Clinical Studies Committee approved the company's planned Paccal Vet open label, pilot clinical study in dogs with splenic hemangiosarcoma following splenectomy. Clinical sites have been chosen and will be ready to start activities after supply of Paccal Vet (investigational veterinary product, IVP) in January. A planned interim analysis is expected in the second half of 2024.

*"It is encouraging to obtain the ethical approval needed to initiate Paccal Vet's pilot study. The clinical centers participating in the study will be receiving Paccal Vet IVP after the holidays and will then be able to enroll and treat the first patients,"* said Erik Kinnman, CEO of Vivesto. *"We are really looking forward to starting this clinical study in dogs suffering from this severe cancer type, where there are no approved drugs available, and the dogs typically only live for a couple of months after diagnosis."*

The Paccal Vet development program was discussed with FDA earlier this year. No further Agency approval is required prior to study start.

The study is an open label, exploratory indication finding study in dogs with different stages of splenic hemangiosarcoma (HSA) following splenectomy. The study will include 4 treatment cycles of Paccal Vet (paclitaxel micellar) and it is planned to investigate 2 cohorts. Each cohort is planned to include a maximum of 23 patients. The study will be conducted at 6 clinical sites in Washington and Oregon. First patients are expected to be dosed in early 2024 and a planned interim analysis is expected in the second half of 2024.

If promising activity in either cohort is shown, the study shall be followed by a pivotal study designed to confirm the initial findings of this pilot study and to gather further evidence on the safety and efficacy of Paccal Vet in dogs with splenic hemangiosarcoma.

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.

### **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 percent 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. Hemangiosarcoma usually affects older dogs (>8 years) of all breeds. The tumor normally appears on the spleen, right heart base or liver, but can also be found on the skin and other sites such as the bones, kidneys, bladder, muscles, mouth and central nervous system.

Treatment options for hemangiosarcoma include surgery and, for some of the dogs, an unapproved adjuvant chemotherapy. The median survival time for dogs with hemangiosarcoma of the spleen undergoing surgery alone is approximately 1-3 months, depending on the stage/seriousness of the disease. Chemotherapeutic agents are used to manage residual metastatic disease after surgery. The most common chemotherapy program in use today can extend survival with hemangiosarcoma of the spleen by 2-4 months.

**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 hard-to-treat cancer. The company develops projects with the potential to offer new treatment options for cancer patients with high medical needs. Vivesto has the capacity and expertise to develop drugs from early preclinical development to clinical phase. Late clinical-phase and commercial development is intended to take place through partnerships with other pharmaceutical companies.

Vivesto is developing the cancer programs Cantrixil and Docetaxel micellar, and the veterinary oncology program Paccal Vet (paclitaxel micellar) which is being developed for the treatment of malignant melanoma and hemangiosarcoma in dogs.

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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