

Vivesto reports positive interim results for Paccal Vet pilot study in dogs

Solna, Sweden, November 7, 2025 – Vivesto AB, an oncology-focused development company, today announced positive interim results obtained in Vivesto's open label, clinical pilot study with Paccal Vet in dogs with splenic hemangiosarcoma following splenectomy. Full results are expected during the first half of 2026.

The interim results indicate that treatment with Paccal Vet (paclitaxel micellar) leads to longer overall survival in dogs with Stage I-II splenic hemangiosarcoma following splenectomy, as compared to surgically treated historical controls.

"We are thrilled about the highly promising interim results for Paccal Vet in the treatment of hemangiosarcoma, one of the most common malignant cancers in dogs with a very poor prognosis. The data reinforces our commitment to advancing a therapeutic option that improves the quality of life and survival of dogs diagnosed with this severe type of cancer. We look forward to the full results and the next phase of development with great optimism," said Erik Kinnman, CEO of Vivesto.

The ongoing pilot study is an open label, exploratory indication-finding study in dogs with different stages of splenic hemangiosarcoma (HSA) following splenectomy. A total of 11 dogs were included in the interim analysis. Dogs were eligible if they either completed treatment through the first follow-up visit or experienced disease progression during or after the treatment phase.

The study is being conducted at eight clinical sites in Washington, Oregon, Colorado and California. The study requires a total of 18 evaluable dogs, of which 13 have been enrolled so far.

Treatment options for dogs suffering from severe cancers are limited, and for many indications, there are no approved drugs available. For splenic hemangiosarcoma there are no approved drugs to follow splenectomy, which is the standard of care. Instead, human drugs that are not approved or adapted for veterinary use are commonly used.

If the positive results observed in the interim analysis are confirmed after completion of the study, a pivotal study will be conducted to gather further evidence on the efficacy and safety of Paccal Vet in dogs with splenic hemangiosarcoma with the aim of achieving full marketing approval. Positive results also open up the possibility to file for a conditional approval and marketing well in advance of completion of the pivotal study.

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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, which is being developed for blood cancer, 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 and in a dose-finding study in cats with solid tumors.

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

About Paccal Vet

Vivesto's drug candidate Paccal Vet consists of paclitaxel formulated with the company's proprietary XR-17 technology, which enables good solubility without the undesirable effects of traditional formulations containing solvents. The absence of the solvent cremophor, to which cats and dogs 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 cats and 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. Vivesto is also conducting a Paccal Vet dose-finding study in cats with solid tumors.

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. No cancer medicines have been developed for the treatment of hemangiosarcoma in dogs. However, chemotherapeutic agents developed for human use are used off-label in dogs to manage residual metastatic disease after surgery. The most common such chemotherapy program in use today can extend survival with hemangiosarcoma of the spleen by 2-4 months.

This information is information that Vivesto AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-11-07 15:15 CET.

Attachments

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