

Vivesto's positive dog topline results support continued development and strengthen partnering prospects for Paccal Vet

Solna, Sweden, September 15, 2026 – Vivesto AB, an oncology-focused development company, today announced positive topline results from its open label clinical pilot study evaluating Paccal Vet in dogs with splenic hemangiosarcoma following splenectomy. The results confirm the previously reported interim data and support continued clinical development towards regulatory approval, while bolstering ongoing business development activities.

The topline analysis of 26 dogs confirms the positive survival trend observed in the interim analysis from the first 11 dogs, previously reported in November 2025. Treatment with Paccal Vet (paclitaxel micellar) resulted in a median overall survival of 135 days in dogs with Stage I-II splenic hemangiosarcoma following splenectomy, representing prolonged survival compared to surgically treated historical controls and supporting continued development towards a pivotal registration study.

"These positive topline results confirm the encouraging efficacy signal we observed in the interim analysis and represent an important value inflection point for the Paccal Vet program," said Erik Kinnman, CEO of Vivesto. "The data support continued development toward registration and strengthen the commercial attractiveness of the program. Together with Liberi Group, we will now intensify our partnering activities and broaden our outreach to potential commercial partners."

A total of 26 dogs (Stage I-II) were included in the survival analysis. Of these, four dogs remain in active follow-up and continue to contribute to the survival analysis. Final results from the study are expected by the end of the year, but could be received later depending upon how long the remaining dogs are progression free or alive. As these dogs remain in the study, the final study results may demonstrate an even greater treatment benefit than reflected in the current topline analysis.

Overall, the safety findings were considered tolerable with proactive monitoring and supportive care when necessary. Most dogs experienced side effects commonly associated with chemotherapy, including decreased appetite, neutropenia (a temporary reduction in white blood cells) and diarrhea. Most side effects were temporary, resolved before the next treatment cycle and could be managed with supportive medication. A small number of dogs experienced serious side effects requiring urgent medical attention, particularly at higher doses. No hypersensitivity reactions were observed.

The confirmation of the positive interim results supports the initiation of a pivotal study aimed at obtaining full marketing approval for Paccal Vet in dogs with splenic hemangiosarcoma. Positive final results may also open the path to conditional approval and early market entry ahead of pivotal study completion.

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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 solubility without the undesirable effects of traditional formulations containing solvents. The absence of the solvent cremophor, to which cats and dogs are particularly sensitive, may reduce the risk of serious side effects and death associated with 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 have demonstrated safety in more than 300 dogs. Anti-tumor activity has also 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 regulatory approved cancer medicines are used 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 2026-09-15 13:45 CEST.

Attachments

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