Vivesto doses first patient in its clinical Paccal Vet trial

Solna, Sweden, March 7, 2024 – Vivesto AB, an oncology-focused development company, today announced that the first patient has been dosed in the company's Paccal Vet open-label, pilot clinical trial in dogs with splenic hemangiosarcoma following splenectomy. An interim analysis is expected by the end of 2024.

"*It is great progress to have the first patient dosed in the Paccal Vet trial as this represents another important milestone towards demonstrating that Paccal Vet could be a suitable treatment option for dogs suffering from this severe cancer type where there are no approved drugs available. It is encouraging to see the great interest from study sites, and we anticipate that study enrollment will accelerate from now on,*" said Erik Kinnman, CEO of Vivesto.

The study will include four treatment cycles of Paccal Vet (paclitaxel micellar) and it is planned to investigate two cohorts. Each cohort is planned to include a maximum of 23 patients. The study will be conducted at six clinical sites in Washington and Oregon.

If promising results in either cohort are shown, the study will 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.

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 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.

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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 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.

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 2024-03-07 08:10 CET.

Attachments

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