Vivesto's Paccal Vet granted FDA MUMS designation

Solna, Sweden, December 22, 2023 – Vivesto AB, an oncology-focused research and development company, today announced that the drug candidate Paccal Vet was granted MUMS (Minor Use/Minor Species) designation by the U.S. Food and Drug Administration (FDA) for treatment of splenic hemangiosarcoma (HSA) following splenectomy in dogs. With the MUMS designation, Paccal Vet can get 7 years market exclusivity in the HSA indication following an FDA approval of the product.

Minor Use designation applies for drugs treating animal diseases that occur infrequently or in a small number of animals annually in the US. Designated new animal drugs that first receive FDA approval in a specific indication are granted seven years of marketing exclusivity, which means that Paccal Vet would be protected from generic competition for the approved use during that time. Further incentives such as regulatory support and fee reductions are provided.

The development program for Paccal Vet was discussed with the FDA earlier this year. No further FDA approval will be necessary prior to the start of the planned clinical pilot study in dogs with splenic hemangiosarcoma following splenectomy, and the first patient in the study is expected to be treated early 2024.

"*It is very encouraging to get the MUMS designation for our oncology veterinary product Paccal Vet. Not only will the designation provide several advantages and potentially reduce the cost and time to market authorization and launch, it is also a positive signal from the FDA that Paccal Vet potentially has an important role to play in the treatment of this severe cancer type*," said Erik Kinnman, CEO of Vivesto. "*We are now looking forward to get the pilot study going and to start treating the first patients in the beginning of next year*".

The MUMS Act was modeled on the Orphan Drug Act for humans, which encourages pharmaceutical sponsors to develop drugs for rare diseases in people, by providing incentives for approval. Incentives include market exclusivity for the specific intended use. Moreover, a sponsor of a designated new animal drug is also eligible to apply for grants to cover the cost of related clinical studies.

About splenic 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 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'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. In addition, 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 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 2023-12-22 17:26 CET.

Attachments

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