

Vivesto initiates clinical development of Paccal Vet in veterinary oncology

Solna, March 20, 2023 - Vivesto AB, an oncology-focused research and development company, today announced that the company has decided to initiate clinical development of the veterinary oncology drug candidate Paccal Vet (paclitaxel micellar). A clinical efficacy study with Paccal Vet in dogs in hemangiosarcoma and malignant melanoma is planned to start in the second half of 2023.

The need for safe and effective cancer treatment in dogs is vast and increasing as the number of pets grows. There are 90 million dogs in the US and 93 million dogs in the EU in 2021, with approximately 1.5 million dogs developing cancer in each market per year. There are currently few approved drugs for the treatment of cancer in dogs and current paclitaxel formulations are not tolerated by dogs and therefore cannot be used.

Vivesto's drug candidate Paccal Vet is paclitaxel formulated with the company's XR-17 technology, which enables good solubility without the undesirable effects of traditional formulations containing solvents. A first limited clinical efficacy study is planned to, as a first step, evaluate Paccal Vet in the indications of hemangiosarcoma and malignant melanoma. There are no approved chemotherapy treatments for these diagnoses in dogs.

"The veterinary oncology drugs available today are not always developed for use in pets and may be associated with side effects and lack of efficacy. With Paccal Vet, we address an area with great medical need for better treatment options and a rapidly growing market. A thorough review of previous clinical studies with Paccal Vet have demonstrated favorable efficacy and safety. By changing the treatment strategy and moving into indications with great medical need, we have overall an attractive development situation and hopefully a relatively quick route to market. We are now looking forward to starting the clinical development with the goal of being able to include the first patient during the fall," said Erik Kinnman, CEO of Vivesto.

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, reduces the risk of serious side effects and death caused by 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% 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 adjuvant chemotherapy. The median survival time for dogs with hemangiosarcoma of the spleen undergoing surgery alone is approximately 3 months. Chemotherapeutic agents are used to manage residual metastatic disease after surgery. The most common chemotherapy programs in use today can extend survival with hemangiosarcoma of the spleen by an average of 6.5 months.

About malignant melanoma in dogs

The number of dogs diagnosed with malignant melanoma annually in the US and Europe is approximately 60,000 per market. The most common primary site is the oral cavity (80%), but other primary sites include the skin, skin-mucosal areas, nail beds, and the footpad. Oral and digital melanomas are more aggressive than at other anatomical sites, with a median survival time of 65 days (oral cancer) in dogs left untreated.

Malignant melanomas are highly proliferative, spreading primarily to local lymph nodes and lungs. Surgery and/or radiotherapy are the main treatment options today and target local disease, therefore metastatic disease is still the main cause of death for dogs with malignant melanoma. Consequently, chemotherapy is also considered for the treatment of metastatic and non-operable melanoma. Between 20-30% respond to currently available treatment.

For More Information:

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About Vivesto AB

Vivesto is a research and development company focused on the development of new therapeutic options for patients suffering from hard-to-treat cancers. It has a growing pipeline of clinical-stage assets targeting late-stage cancers. Apealea® (paclitaxel micellar) is being made available to ovarian cancer patients through a partnership with Elevar Therapeutics, Inc. Development programs include Cantrixil, in clinical development for late-stage ovarian cancer, and docetaxel micellar, in development for advanced prostate cancer. Vivesto has proprietary drug delivery technology designed to improve solubility, efficacy and safety. Vivesto's shares are traded on Nasdaq Stockholm (VIVE). To find out more about Vivesto please visit www.vivesto.com.

Attachments

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