A randomized, masked, placebo-controlled field study to determine efficacy and safety of Paccal Vet® in dogs with non-resectable mammary carcinoma of stage III-V

Purpose

To test the safety and efficacy of the mammary cancer drug Paccal Vet®.

Background

The chemotherapy drug paclitaxel is used for the treatment of breast cancer in humans. Breast cancer tumors in humans resemble mammary cancer tumors in dogs; therefore, it is hoped that paclitaxel will have similar efficacy in the dog. However, certain properties of the human drug make it unsuitable for treating dogs.

Paccal Vet® is a version of paclitaxel that has been modified for use in dogs, and it has already shown promising results against canine mammary carcinoma. This study will further test the safety and efficacy of Paccal Vet® in client-owned dogs with mammary carcinoma.

Eligibility

- Female dogs of any age, weight or breed
- Dogs with measurable disease of mammary carcinoma (at least one target lesion with a longest diameter (LD) of ≥ 10 mm) of stage III-V, and in whom curative intent surgery cannot be performed or has been declined by the owner
- Life expectancy due to the studied disease, in the Investigator's opinion, of more than 1 month with treatment
- Performance Status Score (constitutional signs) 0, 1 and 2 on a scale of 0 – 5 (VCOG-CTCAE v1.1)

Exclusion Criteria

- Previous or current chemotherapy treatment
- Prior radiation therapy to the target tumor
- Prior hormonal or biological therapy directed at the tumor
- Presence of an active systemic infection with a potential risk to severely harm the dog
- Pregnant, lactating or intended for breeding during the study period
- Any concurrent disease state that would require additional therapy which could result in a life expectancy of less than 3 months
- Current enrollment in another clinical trial

Trial Support and Funding

Dogs will be randomized 2:1 to receive the new investigational drug or placebo, i.e. there is a 33% chance that a dog will receive inactive treatment. Dogs will be treated with up to 4 cycles of Paccal Vet® or placebo. Check-up visits will take place at 4 and 11 days after each treatment. Owners must fill in an owner’s diary and a quality of life questionnaire at each visit. All dogs whose disease has not progressed at Visit 14 will continue into a follow-up period with monthly visits to the veterinarian, a period that may last for an additional 9 months. Dogs that are randomized to placebo and progress during the 4-cycle treatment period will be offered rescue treatment as decided by the study responsible veterinarian, the investigator.

All diagnostic tests, study drug, chosen rescue medication, and follow-up exams will be paid for by the Study Sponsor.

Dog owners will be reimbursed for traveling expenses for study visits completed on schedule.

Contact

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If your query is urgent, please call the Small Animal Hospital (540) 231-4621 and ask for the oncologist on duty.