

A Funded Clinical Trial for Dogs with Soft Tissue Sarcoma

Announcing a clinical trial to evaluate a novel form of antiangiogenic therapy in dogs with measurable soft tissue sarcoma.

Trial Summary

An estimated 86 client-owned pet dogs will be enrolled in this Phase II study. The study is a randomized, investigator-masked, placebo-controlled study in dogs with measurable soft tissue sarcoma. The randomization of active Test Article to placebo will be 1:1 with a crossover option for dogs in the placebo arm that have disease progression.

The first eight (8) dogs enrolled in the study will be assigned to receive active Test Article in an open label manner and will have blood samples collected over a period of 24 hours post treatment.

Once enrolled, study patients will be evaluated at Days 14, 28 and every 28 days thereafter until tumor progression occurs.

Trial Support and Funding

Study drug, diagnostic tests, and follow-up exams will be paid for by the study sponsor. In the event that side effects are noted and attributed to the study drug, the study will pay for medical management of the side effects.

Trial Eligibility

Inclusion Criteria:

- Client-owned pet dogs;
- Informed owner consent prior to initiation of screening/treatment;
- Measurable soft tissue sarcoma (must have at least 1 target lesion \geq 1cm longest diameter based on physical exam or \geq 2cm if measured via thoracic radiographs);
- Histological diagnosis of a Grade II or III soft tissue sarcoma (historical biopsies are accepted), excluding hemangiosarcoma;
- Favorable Performance Score 0-1 (based on Modified Eastern Cooperative Oncology Group Performance Score);

Exclusion Criteria:

- Dogs with a concurrent medical disorder likely to result in death or euthanasia within 4 months or a condition which may be disruptive to the intent and objectives of the study;

- Anticipated poor owner compliance;
- Dogs that are pregnant or likely to become pregnant;
- Dogs that are participating in another clinical trial;
- Dogs that will be unavailable for the duration of the trial or that are felt to be unsuitable by the Investigator for any other reason;
- Chemotherapy within 21 days of the enrollment visit;
- Prednisone treatment within 7 days of the enrollment visit;
- Treatment with hormonal, immunotherapy, biological therapy, and/or small molecule inhibitors within 21 days of the enrollment visit;
- Treatment with radiation therapy within 30 days of the enrollment visit;
- Surgery within 14 days of the enrollment visit (with the exception of incisional biopsy if necessary at screening);
- Treatment with Non-steroidal Anti-inflammatory Drugs (NSAIDs) within 14 days of enrollment.