ANIMAL CLINICAL INVESTIGATION NETWORK TRIALS

Animal Clinical Investigation (ACI) bridges the veterinary community with the pharmaceutical and biotechnology industries, working together to develop treatments for pets with cancer and other complex medical conditions.

Our success is based on collaboration with our network veterinarians that are cutting-edge 'thought leaders'. Together we help drug companies bring the safest and most effective therapies to market and help animal health companies develop new products for this market. To this end, ACI designs, conducts and reports clinical field studies in compliance with FDA regulations and industry standards.

For more information on the novel therapeutic agent for the treatment of solid tumors in dogs, and the Animal Clinical Investigation, visit our website, www.animalci.com

E-trial updates are available through our website, www.animalci.com

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FUNDED CLINICAL STUDY: Novel Therapeutic Agent for the Treatment of Solid Tumors in Dogs

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MELANOMA, OSTEOSARCOMA, SOFT TISSUE SARCOMA, OR SQUAMOUS CELL CARCINOMA

ACI is currently enrolling dogs for a nationwide clinical trial to evaluate a novel cancer treatment for measurable melanoma, osteosarcoma, soft tissue sarcoma, or squamous cell carcinoma. The goal of this therapy is to specifically target the tumor and induce an inflammatory response. The proposed benefit of such a response is to shrink existing tumors and reduce or eliminate microscopic cancer cells that may not be visible by standard (or any) means. The purpose of this study is to assess the safety and potential effectiveness of this therapeutic agent in dogs.

CLINICAL STUDY DETAILS

Therapeutic Agent Background

The therapeutic agent is a modified anaerobic bacterium. In previous trials, it has been shown to target the necrotic center of malignant tumors, leading to tumor regression or stable disease in many of the small mammals tested. Common side effects include fever, nausea and inflammation.

Trial Summary

A minimum of 100 dogs with spontaneous measurable melanoma, osteosarcoma, soft tissue sarcoma, or squamous cell carcinoma. “Measurable” may be a primary tumor or a metastatic lesion. Dogs that meet the eligibility criteria will be treated with a single intravenous infusion of the therapeutic agent. Treated dogs will require close monitoring for 6 hours after treatment with follow-up visits required 2, 4, 7 and 14 days post-treatment. While the patient remains on study, there will also be rechecks at 1 and 2 months. In some study dogs, medications in addition to the therapeutic agent will be used.

Trial Support and Funding

The study sponsor will pay for therapeutic agent, diagnostic tests, and follow-up evaluations. In the event that side effects are noted and attributed to the therapeutic agent, the study will pay for medical management of the side effects.

Trial Eligibility

Dogs are eligible if they meet the following inclusion criteria:

- Histologic or cytologic diagnosis of cancer (biopsy or needle aspirate)
- There is at least 1 tumor (melanoma, osteosarcoma, soft tissue sarcoma, or squamous cell carcinoma) which can be measured (minimum 1 cm in diameter)
- Generally feeling well (i.e. eating, drinking, ambulating on their own, etc.)
- No evidence of an active bacterial infection requiring antibiotics (other than topical medications) in the past 7 days
- No anti-cancer therapy within the past 21 days. This includes chemotherapy, radiation therapy, prednisone (or other forms of corticosteroids), and immunotherapy
- No tumors where abscess (infection) would result in major symptoms

The following animal hospitals are offering this clinical trial

For more information, please visit animalci.com and click on “Trials”