Title:  Efficacy of Alternating Rabacfosadine and Doxorubicin Treatments Against Multicentric Lymphoma in Dogs

Investigator:
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If interested, please have your primary veterinarian request additional information through the UGA Oncology service by calling the small animal referral coordinator at 706-542-5362.

Study description:
The purpose of this study is to evaluate the safety and efficacy of rabacfosadine (TANOVEA®-CA1) and doxorubicin in dogs with previously untreated spontaneous multicentric lymphoma. Lymphoma is one of the most common cancers encountered in veterinary oncology, and multi-drug chemotherapy protocols (e.g. CHOP-based protocols) have long been considered standard of care. However, with CHOP-based protocols, chemotherapy treatments are administered weekly, which is a major time commitment for owners. Rabacfosadine and doxorubicin are anti-cancer agents that have demonstrated efficacy in dogs with multicentric lymphoma and are given every 3 weeks. Dogs must have a confirmed diagnosis of treatment naïve lymphoma to be eligible for participation in this study. In addition the following conditions must be met:

Inclusion criteria:
1. Dogs must be otherwise healthy, have adequate bone marrow and organ function, and weigh ≥ 5.0 kg.
2. Only treatment naive dogs are eligible for inclusion.
3. Owners must sign a consent form.

Exclusion criteria:
1. Dogs with lymphoma previously treated with anti-cancer therapy, including prednisone are excluded.
2. Dogs on homeopathic/alternative therapies are excluded. Exceptions include chondroitin sulphate, vitamins, essential fatty acids and glucosamine.
3. Dogs of the West Highland white terrier breed are excluded due to a genetic predisposition toward pulmonary fibrosis, a rare, but potentially unique toxicity of TANOVEA®-CA1.

Dogs will undergo preliminary staging tests including initial consultation and physical examination, tumor measurements, complete blood count (CBC), serum biochemical profile, urinalysis, chest x-rays, and documentation of immunophenotype (if not previously performed) to determine trial eligibility. Once accepted into the study, the intent will be to administer TANOVEA®-CA1, alternated with doxorubicin, every 3 weeks for approximately 6 total treatments. Dogs will be rechecked one week after the first TANOVEA®-CA1 and one week after the first doxorubicin treatment for assessment of adverse events. Thereafter, they will be seen every 3 weeks for administration of chemotherapy. Owners will be asked to complete a quality of life assessment at each visit, and lab work will be rechecked prior to each treatment. Trial participation will continue as long as the treatment is well tolerated and response to treatment is favorable. Once off study, the dog will be eligible for other treatment as deemed appropriate.
TANOVEA®-CA1 will be provided at no cost as part of this trial. Owners will otherwise be responsible for costs of doxorubicin and all associated monitoring, treatment and possible adverse events.

**Duration of study:**
The study is currently OPEN and expected to continue through 2020.

**Potential benefits to veterinary medicine:**
Lymphoma is one of the most commonly diagnosed cancers in dogs. While conventional chemotherapy induces remission in the majority of dogs with multicentric lymphoma, relapses are common. Successful demonstration of efficacy and safety of alternating TANOVEA®-CA1 and doxorubicin will provide an important drug in the veterinarian’s armamentarium and a valuable option for pet owners seeking cancer treatment for their pets.