Title: Study to Determine the Safety and Efficacy of TANOVEA™ (Rabacfosadine for Injection) in Cats with Lymphoma Using a Dose Escalation Model

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 a new anti-cancer agent in the treatment of cats with lymphoma. Lymphoma is one of the most commonly diagnosed cancers in cats. Chemotherapy is the treatment of choice, and multi-agent doxorubicin-containing protocols are often recommended. While this approach has proven successful in inducing clinical remission in dogs, evidence to support its use as “standard of care” in cats is lacking. TANOVEA™ is a novel targeted anti-cancer therapy that has demonstrated significant efficacy in dogs with lymphoid neoplasia. For the most part, it has been well tolerated, with potential side effects including bone marrow suppression, skin toxicity, and gastrointestinal upset. TANOVEA™ has not been studied in cats with lymphoma. Cats must have a confirmed diagnosis of lymphoma (any grade, any anatomic site) to be eligible for participation in this study. In addition the following conditions must be met:

Inclusion criteria:
1. Cats must be FeLV/FIV negative, otherwise healthy, and have adequate bone marrow and organ function.
2. Prior treatment is acceptable (although not required), but there must be an appropriate lapse between other cytotoxic treatment(s) and trial entry.
3. Owners must sign a consent form.

Cats will undergo preliminary staging tests including initial consultation and physical examination, tumor measurements, complete blood count (CBC), serum biochemical profile, urinalysis, and chest x-rays to determine trial eligibility. Once accepted into the study, the intent will be to administer escalating dosages of TANOVEA™ to each cat every 3 weeks for approximately 5 treatments. Cats will be rechecked one week after first treatment for assessment of adverse events; after the second treatment, they will be seen every 3 weeks for administration of drug. Lab work will be rechecked prior to each treatment. Tumor measurement and disease restaging will be strongly encouraged at the time of every other treatment to determine drug efficacy. Trial participation will continue as long as the treatment is well tolerated and response to treatment is favorable. Once off study, the cat will be eligible for other treatment as deemed appropriate.

TANOVEA™ will be provided at no cost as part of this trial. In addition, costs of recheck lab work including CBCs (up to 6 total), serum biochemical profiles (up to 2 total), and urinalysis (up to 2 total) will be covered by study funds. An imaging allowance of $300 will also be allowed to offset the cost of re-staging. Owners will otherwise be responsible for costs associated with monitoring and treatment. Complications of chemotherapy will NOT be covered by the study. Note: TANOVEA™ (rabacfosadine for injection) is not FDA approved for use in cats.
**Duration of study:**

The study is currently OPEN.

**Potential benefits to veterinary medicine:**

Successful demonstration of efficacy and safety of TANOVEA™ will provide an important drug in the veterinarian’s armamentarium and a valuable option for pet owners seeking cancer treatment for their pets.