Fully Funded Clinical Trial for Canine Appendicular Osteosarcoma

**Study Title:** Evaluation of Orally Administered mTOR inhibitor Rapamycin in Dogs with Osteosarcoma

**Purpose of study:** The majority of dogs with osteosarcoma will die from the spread of cancer to their lungs. New drugs which can delay or stop the spread of cancer cells will improve the survival time of dogs with osteosarcoma. Cancer cells use certain pathways to survive, including a pathway called mTOR. Therefore, drugs that block the mTOR pathway, such as Rapamycin, hold promise for preventing the development of metastatic disease. The goal of this trial is to evaluate the safety and pharmacokinetic orally administered Rapamycin in dogs with osteosarcoma through a traditional dose escalation study.

**Inclusion Criteria:**

- Dogs greater than 15 kilograms in body weight
- Histologic or cytologic diagnosis consistent with osteosarcoma
- Dogs with measurable disease
- Dogs must have favorable performance status (survivability of 6 weeks)
- No radiation, chemotherapy, or bisphosphonates within 2 weeks of study entry
- No NSAIDS within 3 days of study entry
- No significant co-morbid illness (liver, kidney, heart)
- No history of inflammatory bowel disease or chronic gastroenteritis

**Diagnostics:**

- Screening blood work and urinalysis
- Osteosarcoma confirmation
- Imaging if necessary (radiographs and/or ultrasound)

**Treatment:** Dogs will be treated with oral rapamycin at home starting on Mondays. There will be two different dosing schemes: 5 days on/2 days off (M-F) or every other day (M, W, F) dosing for 26 study days.

**Compensation:** The study will cover costs associated with the trial, except for the initial appointment fee, blood work, urinalysis, and histology/cytology. The trial will also provide a hospital credit of $125.00 at each required visit to University of Illinois (total $500.00 in-hospital credit).

**Contact information:** Please feel free to call Rebecca Kamerer 217-300-6453 to refer a patient or for any additional information. Referring veterinarian and client calls are welcome. Owners may schedule appointments by calling 217-333-5300.