**Titles:**
COTC021: Evaluation of Orally Administered mTOR inhibitor Rapamycin in Dogs in the Adjuvant Setting with Osteosarcoma
COTC022: A Contemporaneous Controlled Study of the Standard of Care (SOC) in dogs with Appendicular Osteosarcoma

**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 contemporaneously compare the standard of care (SOC) treatment (defined as surgery followed by carboplatin chemotherapy) to SOC followed by rapamycin, an mTOR inhibitor, in dogs with appendicular osteosarcoma (OSA). Dogs enrolled in this trial will be randomized into one of these treatment arms. Dogs must have a cytology or biopsy confirmed diagnosis of appendicular osteosarcoma to be eligible for participation in this study. In addition the following conditions must be met:

### Inclusion criteria:

1. Dogs must be otherwise healthy and have adequate organ function.
2. Dogs must weigh ≥ 25.0 kg.
3. At the time of screening, dogs must have measurable disease amenable to limb amputation with no evidence of distant metastasis.
4. Dogs must be off all NSAIDs and steroids for ≥ 7 days prior to study enrollment.
5. Owners must sign a consent form including consent for necropsy if unexpected death occurs during the study.

**Dogs receiving any previous surgery (for osteosarcoma), previous or concurrent chemotherapy (including bisphosphonates), immunotherapy and/or radiation therapy are not eligible for this trial.**

Dogs will undergo physical examination, routine laboratory testing and imaging, and tumor biopsies to determine eligibility. All dogs will undergo limb amputation followed by 4 doses of carboplatin administered at 3-week intervals. Dogs assigned to receive rapamycin following carboplatin will begin this treatment at home 3 weeks following the final treatment with carboplatin. Additional follow-up visits will be required for all dogs regardless of treatment arm assignment. **These visits are required for inclusion in the study.**

Owners are responsible for the costs of initial evaluation and staging. Once a dog is enrolled, the study will provide a $1000 UGA hospital credit toward the cost of amputation. Thereafter, all routine costs associated with the study including office exams, lab work, imaging, and chemotherapy treatments will be covered by the study.

**Duration of study:**
The study is ongoing and expected to be completed by December 2016.

**Potential benefits to veterinary medicine:**
Collectively these data will be integrated within the development consideration of rapamycin and rapalogs for both canine and human pediatric sarcoma patients.