A clinical trial led by the National Cancer Institute (NCI), sponsored by the Morris Animal Foundation seeks to evaluate the safety and effectiveness of Standard of Care therapy, with or without adjuvant rapamycin administration, in canine osteosarcoma (OSA).

**Inclusion Criteria:**

- Histologically or cytologically (inclusive of alkaline phosphatase positivity) confirmed osteosarcoma
- Measurable disease that is amenable to surgical removal via amputation (No evidence of metastasis based upon physical exam, thoracic radiographs, and abdominal ultrasound).
- Favorable performance status: Grade 0 or 1 (modified ECOG criteria)
- ONLY newly diagnosed dogs are eligible with no prior therapy (conventional or metronomic chemotherapy, ionizing radiation, bisphosphonates) for osteosarcoma
- Dogs receiving analgesics including NSAIDs, gabapentin, tramadol, or other will be eligible for study inclusion
  - ALT and ALP ≤ 2.5x normal reference range if managed on NSAIDS
  - ALT ≤ 1.5x and ALP ≤ 5x normal reference range if no current usage of NSAIDS

**Exclusion Criteria:**

- Dogs < 25 kg in size
- Dogs without measurable disease (appendicular osteosarcoma) at presentation to the regional COTC site
- ANY prior therapy for osteosarcoma (conventional or metronomic chemotherapy, ionizing radiation, bisphosphonates)
- Concurrent medications deemed incongruent with this study. All pre-existing necessary medications should be recorded as concomitant medications.
- Significant co-morbid illness, which includes but is not limited to renal or hepatic failure, history of congestive heart failure or clinical coagulopathy
- Creatinine > 3.0 mg/dL
- Bilirubin > 2.0 mg/dL or elevated bile acids
- HCT < 25%, platelets < 150,000 cells/ul
- Any hematologic/biochemical abnormality > grade 1 (VCOG-CTCAE)

**Screening:** Physical Exam, Blood work, Urinalysis, Chest X-Rays, Abdominal Ultrasound and Fine Needle Aspirate of lesion must be completed to determine eligibility at NCSU. Screening is done at owner cost, if patient is deemed eligible $300 towards screening is provided.

**Study benefits and incentives:** Costs associated with this study will be provided as part of participation. $1000 towards canine limb amputation is provided. Funds may be available for adverse events management according to the institution.

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