**Title:**
Evaluation of progression free survival and immunological response to a vaccine administered to dogs receiving definitive surgery and adjuvant carboplatin chemotherapy for spontaneous appendicular osteosarcoma

**Investigator:**
Corey Saba, DVM, DACVIM (Oncology faculty)

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:**
Osteosarcoma is the most common primary bone tumor in dogs. Surgery (usually amputation) followed by carboplatin chemotherapy is considered the standard of care treatment, with the median survival time approaching 1 year. The objectives of this study are to evaluate the safety and efficacy of a novel immunomodulator in dogs as an adjunct treatment for osteosarcoma.

The following conditions must be met:

**Inclusion criteria:**
1. Dogs must be at least 2 years of age.
2. Dogs must weigh ≥25 kg with histologically confirmed, HER2 positive osteosarcoma of the appendicular skeleton.
3. Dogs must have measurable disease amenable to limb amputation with no evidence of distant metastasis (tumor spread).
4. Dogs may not have received long-acting steroids within 30 days prior to enrollment, or other forms of immunotherapy previously.
5. Dogs with any serious underlying diseases (tumor metastases, heart disease, renal disease, liver disease, autoimmune disease, chronic infectious diseases and/or other cancers) are not eligible to participate.
6. Dogs must reside with their owners within driving distance of UGA.
7. Owners must sign a consent form including consent for necropsy if unexpected death occurs during the study.

**Dogs that have received previous treatment for osteosarcoma are not eligible for this trial.

Specific questions about potential cases should be directed to the study investigator.**

Dogs will undergo preliminary staging tests including initial consultation, physical examination, lab work, thoracic radiographs, and tumor biopsy to determine trial eligibility. All eligible dogs will undergo amputation of the affected limb followed by carboplatin chemotherapy every 3 weeks for up to 4 doses. Dogs will also be randomized to receive either immunotherapy or placebo in conjunction with carboplatin therapy. The initial immunotherapy treatment series or placebo (4 injections) will be administered every 2 weeks. Boosters will occur one month following completion of the initial series and then every 3 months thereafter until removal from the study. Preliminary staging tests, amputation, carboplatin treatments, immunotherapy (or placebo) treatments and follow-up visits after completion must be performed at the University of Georgia Veterinary Teaching Hospital. Dogs will remain on the study until osteosarcoma metastasis is documented.

This study is partially funded by the Sponsor to help offset the costs of carboplatin and immunotherapy (or placebo) treatments (including administration costs), in addition to repeat labwork (up to 4 CBCs, 2 biochemistry profiles, 2 urinalyses) and chest x-rays for re-staging. Owners are responsible for the costs of all office visits, tests required for enrollment eligibility screening, amputation surgery, lab work and chest x-rays in excess of those covered by the study, and treatment of any adverse events.
**Duration of study:**
The study is currently OPEN. Enrollment opportunities are limited and will terminate when the target enrollment is filled.

**Potential benefits to veterinary medicine:**
We expect standard of care treatment in addition to immunotherapy will significantly improve disease-free interval and overall survival time in dogs with osteosarcoma over standard of care treatment alone.