UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN

College of Veterinary Medicine
Veterinary Teaching Hospital
240 Small Animal Clinic, MC-004
1008 W. Hazelwood Drive
Urbana, IL 61802-4714

Funded Study: Treatment of canine appendicular osteosarcoma.

Study Title: Investigating a new-generation extracellular vesicle (EV) therapeutic cancer vaccine in dogs

Purpose of Study/Background/Objectives: The purpose of this investigation is to establish intra-dermal dosing and demonstrate immunological activity of imiquimod-tagged EVs derived from the patient's primary tumor cells.

Inclusion Criteria:

- Dog must weigh≥ 15kg and have a histologic diagnosis or cytologic diagnosis of alkaline phosphatase positive sarcoma, consistent with osteosarcoma.
- Dogs must have adequate organ function for sedation
- Dogs must be off Apoquel for 1 week and no Apoquel is allowed during trial treatment period

Exclusion Criteria:

- Previous chemotherapy, immunotherapy, or radiation therapy
- Any metastatic disease
- Health conditions that preclude multiple sedation events
- Apoquel within 7 days

Eligibility Diagnostics:

- CBC, Chemistry Panel, U/A
- Cytologic (with alk phos stain) or histopathologic diagnosis
- 3 view chest x-rays
- Abdominal ultrasound

Treatment/Protocol: Dogs will have their tumor excised by limb amputation. Primary tumor cells will be cultured from the removed tumor in our research laboratory to develop patient-specific vaccines. The therapeutic EV vaccine will be administered back to the dog in a three-dose series starting around 14 days after surgery.

Dogs will receive the therapeutic cancer vaccine once weekly for the first three weeks. Blood samples will be collected over 24hrs at the first 3 visits (week 1,2, and 3), after each vaccine. Dogs may stay in hospital overnight or go home and return the next day. Dogs will receive a physical exam and blood collection weekly for 3 weeks following a three-dose series (week 4, 5, and 6).

Compensation: Once a dog is deemed eligible and owner consents to trial, the pet owners will receive $2,500 credit towards their dog's amputation. The dog will be deemed eligible to

continue in the clinical trial once the production of the vaccine has been achieved. The cost of all trial related diagnostics (serial lab tests) and treatments (personalized cancer vaccine manufacturing and administration, treatment of potential side effects) are fully covered in the 6-week total trial period. The pet owner will be responsible for all visit-related costs after the trial period. The pet owner will be responsible for all costs associated with unrelated medical conditions during the clinical trial.

Contact Information: Please feel free to contact our Clinical Trials Coordinator, Rebecca Kamerer, at (217) 300-6453 or rmoss81@illinois.edu to refer a patient or for any additional information. Referring veterinarian and client calls are welcome.