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

Patient Disease: Appendicular osteosarcoma with pulmonary metastatic disease in dogs

Study Title: Treating osteosarcoma lung lesions with intravenous small molecule immunotherapy

Purpose of Study/Background/Objectives: Osteosarcoma (OS) is the most common primary bone tumor diagnosed in large and giant breed dogs. Conventional therapies for OS include surgical amputation of the affected limb followed by chemotherapy. Despite the use of systemic treatments, most dogs will have disease spread to the lungs (pulmonary metastases). Once OS lung lesions develop, treatments are not very effective. As such, there is a great and unmet clinical need for the discovery of novel treatment strategies that are more effective for managing OS lung lesions. Evidence supports OS to be a tumor that might respond to immunotherapy and improve long-term outcomes for patients at various stages of disease.

Inclusion Criteria:

- Historical or active diagnosis of appendicular osteosarcoma diagnosed via histopathology or cytology
- If not previously amputated, primary tumor pain must be controlled
- Nodules must be at least 5mm in diameter on CT scan
- Must be in good overall condition, no other serious uncontrolled illness and have an expected survival time of at least 9 weeks.
- Must not have had radiation within 1 week or chemotherapy/immunotherapy within 3 weeks.
- Concurrent use of immunosuppressive drugs is not allowed (cyclosporine, Apoquel, immunosuppressive doses of steroids)

Exclusion Criteria:

- Pleural effusion
- Hypoxia or signs of respiratory distress

Eligibility Diagnostics:

- CBC/Chem/Urinalysis
- Thoracic radiographs
- Abdominal ultrasound

Treatment/Protocol: The patient will receive up to 8 IV doses of Z-007 once weekly. During treatment (treatment #1, #4 and #8) patients will be required to stay in hospital or return the next day for a blood draw. Patients will receive a thoracic computed tomography (CT) scan at the first visit along with complete bloodwork at every visit. Patients will return to the hospital 1 week after their last treatment for a recheck CT scan. If there is an objective response (shrinkage of pulmonary nodules by greater than 30%) at week 9, continued compassionate use of Z-007

might be offered at the discretion of the attending clinician(s), otherwise the patient is off trial and will be offered other options.

Owner Responsibilities:

- You are responsible for the initial exam and diagnostics to determine eligibility
- You are expected to make and keep all appointments associated with the study
- You are responsible for all costs associated with unrelated medical conditions

Compensation: This is a fully funded trial. Owners are responsible for all charges to deem their pet eligible for the clinical trial. After eligibility the clinical trial will cover the cost of exam fees, bloodwork, Z-007 administration and CT's.

Contact Us: Our trials team will need to have an appointment with both the owner and pet to assess eligibility. To make an appointment please call 217-333-5300.

They will also need records from your veterinarian. After the appointment has been made the records can be emailed to medrec@illinois.edu or faxed to 217-244-2554.

If you have further questions please feel free to contact our Clinical Trials Coordinator, Rebecca Kamerer, at (217) 300-6453 or rmoss81@illinois.edu

Referring veterinarian and client calls are welcome.