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: Canine Recurrent Soft Tissue Sarcoma.

Study Title: Evaluating aluminum hydroxide-anchored recombinant interleukin-12 (JEN-101) in dog with recurrent soft tissue sarcoma.

Purpose of Study/Background/Objectives: JEN-101 has been proven to work reasonably well to stimulate the immune system against canine melanoma. In this trial we will be using the same idea to treat dogs with recurrent soft tissue sarcoma. In other studies, it has been shown that using immunotherapy prior to surgery has supported good long-term outcomes for the patient. These results could be related to the specific type of immunotherapy and the type of tumor treated. In this trial patients will have tumor regrowth, and we will evaluate if administration of JEN-101 to residual disease can exert clinical benefit.

Inclusion Criteria:

- Dogs with previously excised and recurrent soft tissue sarcoma that have a histologic or cytologic confirmation of recurrence
- Tumors must be $\geq$ 2cm in one dimension
- No radiation or chemotherapy within 6 weeks
- No previous immunotherapy, check point blockade treatment, Apoquel, steroids, or other immune modulators such as cyclosporine
- Adequate organ function for sedation and contrast

Eligibility Diagnostic:

- CBC, Chemistry panel, U/A (within 28 days of starting therapy)
- Confirmation of tumor recurrence with cytology

Treatment/Protocol:

- Patients will receive 4 doses of IL12 intratumorally once every 2 weeks.
- On treatments #1 and #4 blood will be collected over 24hrs. Patients can either stay in hospital or return the next day for a blood draw.
- After treatment, rechecks will be once every 3 weeks for 2 visits, then one recheck 6 weeks later, followed by two more rechecks once every 3 months, then study is complete.
- We will use complete bloodwork, CT scans and biopsies of the tumor to track patients' response.

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 once your pet is deemed eligible

Contact Us: Our trials team recommends you schedule an on-site appointment to assess your pet's eligibility. We do not require a referral. The professional fee for the consultation is approximately $200 and does not include tests, medications or treatments that may be recommended at your appointment. **To schedule please call 217-333-5300.**

We would like the opportunity to review your pet's 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 veterinarians and client calls are welcome.