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 oral malignant melanoma

Study Title: Evaluating CD 45-binding interleukin-12 and interleukin-15 fusion peptide in tumor-bearing dogs.

Purpose of Study/Background/Objectives: We will be evaluating the safety and immune activating effects of injecting the combination of IL-12/IL-15 fusion peptide into oral melanoma tumors. IL-12 and IL-15 have separately been shown to work reasonably well to stimulate the immune system against canine melanoma and safety has been proven in mice. Previous trials in pet dogs with IL-12 have been successful. In this trial, canine patients with oral melanoma will be evaluated to determine if administration of the IL-12/IL-15 fusion protein can exert clinical benefit.

Inclusion Criteria:

- Dogs at least 1 yr old and 8kgs
- Confirmed oral melanoma by cytology or histopathology
- Tumors must be 1-5 cm in diameter
- No previous radiation, chemotherapy or immunotherapy.
- While on study, no immunosuppressive/homeopathic/alternative therapy including prednisone, cyclosporine or other immune modulatory agents.
- Adequate organ function for sedation and contrast

Eligibility Diagnostics: (Within 28 days of starting therapy)

- CBC, Chemistry panel, U/A
- Confirmation of oral melanoma by cytology or histopathology.
- Cytology of the draining lymph node

Treatment/Protocol:

- Patients will receive 4 doses of IL-12/IL-15 intratumorally. Injections are given 2 weeks in a row, with a 3-week break, then 2 additional weeks of treatment.
- At each treatment, blood samples 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 4 weeks for 3 visits, then once every 8 weeks for 3 visits, then every 12 weeks for a total of 1.5yrs, then study is complete.
- We will use complete bloodwork, lymph nodes samples, 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.