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 the safety and immune activation properties of JEN-101, a novel intratumoral interleukin-12 cytokine therapy in pet dogs with macroscopic malignant melanoma

Purpose of Study/Background/Objectives: Stimulating the immune system to fight cancer is a well-described and accepted treatment option for controlling cancer growth and metastases in people. Interleukin-12 has been proven to work reasonably well to stimulate the immune system against canine melanoma. In this trial we will use intratumoral injection with JEN-101 therapy to evaluate a novel intratumoral cytokine anchoring technology in pet dogs with measurable malignant melanoma. The findings from the current investigation will be helpful to further the evaluation of anchored cytokine strategies as a safe and novel anticancer immune therapeutic strategy for treatment of human cancer patients.

Inclusion Criteria:

- Dogs > 1yr of age and at least 8kg
- Must have a histologic or cytologic confirmation of malignant melanoma.
- Tumors must be between 1-5 cm in one dimension
- Dogs must be naïve to previous treatment-no previous chemotherapy, radiation therapy, immunotherapy, check point blockade treatment, steroids, or other immune modulators such as cyclosporine
- Adequate organ function for sedation and contrast

Eligibility Diagnostics:

- CBC, Chemistry panel, AST, C-reactive protein, U/A (within 28 days of starting therapy)
- Confirmation of tumor with cytology or histopathology

Treatment/Protocol:

- Patients will receive 4 doses of JEN 101 intratumorally once every 3 weeks.
- Patients will have a CT scan at day 1, day 90 and day 180.
- Blood will be collected over 24hrs on treatment days. 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 4 visits. The study is completed on day 180.
- 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.