

Funded Study: Funded study for canine patients with oral melanoma.

Study Title: Evaluating the safety and immune activation properties of cANK-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. Specific proteins called cytokines are necessary to amplify the immune response, including interleukin-12. While interleukin-12 is important for robust immune activities, when systemically released, this inflammatory protein can lead to toxicity, sometimes severe and life-threatening. Locally depositing and retaining interleukin-12 within the tumor mass would have the potential of harnessing the benefits of the immune system yet reduce the chances for untoward systemic toxicities. Recent studies have shown that anchoring interleukin-12 within tumor masses is highly effective in fighting cancer and minimizing toxicity in mouse models of cancer, and our preclinical studies have demonstrated that this immune stimulating strategy can also be safely administered to healthy beagle dogs. The intent of this study is 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 with measurable (1-5 cm), confirmed (cytology or histopathology) oral malignant melanoma
- Must be in good overall condition and have no other serious illness.
- No prior immunotherapy, must not have received chemotherapy or radiation therapy within 4 weeks of starting trial.
- > 1yr old, > 8 kgs
- While on study-no immunosuppressive therapy/homeopathic/alternative treatment including prednisone, cyclosporine or other immunomodulatory agents.

Exclusion Criteria:

- Poor prognosis/ill
- Previous immunotherapy

Eligibility Diagnostics: Prior to study entry, pet owners will be charged an initial consultation fee and be financially responsible and required to have the following diagnostics performed in their dog:

- 1) Diagnosis of melanoma with histopathology or cytology, if not already documented
- 2) Screening blood work and urinalysis, if not performed within 7 days
- 3) CT scan of the head and chest

Treatment/Protocol: Your dog will receive intratumoral injections of cANK-101 a total of 8 treatments every 21 days. Correlative study end points will include hematologic and biochemical tolerability, pharmacokinetic/pharmacodynamic relationships, radiologic changes, and immune surrogate markers.

Owner Commitments: Qualified dogs will receive intra-tumoral injections every 3 weeks for 8 treatments. Dogs and Owners will be required to visit study site for regularly scheduled appointments over a 6-month period and document study associated observations and questionnaires as appropriate. Visit frequency changes to every 3 months long term until progressive disease is seen.

Compensation: This is a funded study. Pet owners are financially responsible for all diagnostics such as blood work and cytology required for their pets to be deemed eligible for study recruitment. Pet owners will be responsible for any costs associated with unrelated medical conditions. After eligibility requirements have been met, patients will receive intratumoral injection of cANK-101 free of cost and administration fees will also be waived. The patient must present to U of I for adverse event management, the clinical trial will pay for up to \$1,000 of management (if needed) at the U of I.

Contact Information: We would be happy to provide you with additional information regarding the study. Please reach out to Rebecca Kamerer at rmoss81@illinois.edu or 217-300-6453.

