



Funded Study: Treatment of canine bladder urothelial carcinoma

Study Title: Investigating the immune and cytoreductive activities of Gilvetmab alone and in combination with indoleamine 2,3-dioxygenase inhibition in canine urothelial carcinoma of the bladder.

Purpose of Study/Background/Objectives: The purpose of this study is to evaluate if immunotherapeutic strategies with Gilvetmab and epacadostat can improve immune recognition and cytoreduction of bladder transitional cell carcinoma in pet dogs.

Inclusion Criteria:

- Diagnosis of bladder transitional cell carcinoma by either cytology or BRAF positive molecular testing, in conjunction with a visible bladder mass on ultrasound examination.
- The patient must be in good overall condition and have no other serious illness.
- May not have received prior chemotherapy, radiation treatment, or immunotherapies.

Exclusion Criteria:

- Other significant comorbidities, unable to safely undergo multiple sedation events.
- Previous chemotherapy, radiation therapy or immunotherapy.

Eligibility Diagnostics:

- CBC, Chemistry Panel, U/A
- Cytology consistent with transitional cell carcinoma or BRAF
- Bladder ultrasound

Treatment/Protocol: The patient will have whole blood and urine collected at various time points following initial clinical presentation and have serial focal bladder ultrasound under light sedation. Pet dogs will be treated with standardized palliative therapies including oral piroxicam and gabapentin and be randomized to being treated with Gilvetmab alone or in combination with oral epacadostat. On scheduled revisits, dogs will have their blood and urine analyzed, and have their bladder tumors measured using urinary catheter placement and focal ultrasound. Tumors may be biopsied under sedation or anesthesia via cystoscopy. Pet dogs will be followed throughout the course of their natural disease progression following treatment with Gilvetmab alone or in combination for a maximum time duration of 1 year (6 months of therapy + 6 months of follow-up observation).

Compensation:

Clients are responsible for all costs associated with eligibility testing for enrollment. Once the patient has been enrolled into the clinical trial, clients will be responsible for exam charges, chemistry panels and associated venipuncture along with abdominal ultrasounds. The trial will fund the treatment and other diagnostics. The clinical trial will provide up to \$500 of support for adverse events due to the clinical trial protocol. You will be responsible for the treatment of any complications that may arise if above \$500, and unrelated medical conditions.

Contact Information: Please feel free to contact our Clinical Trials Coordinator, Rebecca Kameron, at (217) 300-6453 or rmoss81@illinois.edu to refer a patient or for any additional information. Referring veterinarian and client calls are welcome.

