

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).

Owner Commitments:

- 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. The clinical trial will provide up to \$500 in support for adverse events due to the clinical trial protocol when treated at the U of I VTH.

Contact Information: 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

Please check our up-to-date website to see if this trial is still active and enrolling.

<https://vetmed.illinois.edu/research/clinical-trials/>

