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 solid tumors

Study Title: CHECKMATE-K9: A pilot study evaluating the safety and tolerability of combination VGS-011 (anti-CTLA4 mAb) and VGS-002 (anti-canine PD1 mAb) in dogs with solid tumors.

Purpose of Study/Background/Objectives: VGS-001 and VGS-002 are designed to stimulate the immune system. They have each undergone studies to evaluate safety and dosing when given individually, however the 2 drugs have not yet been used in combination. We are hopeful the combination of drugs will be better at stimulating the immune system against various cancer types. In this trial we will evaluate the combination for safety, tolerability and effectiveness.

Inclusion Criteria:

- Dogs with measurable solid tumors except hemangiosarcoma and lymphoma
- > 10kgs and < 50kgs
- Tumor tissue is available for testing (previously removed tissue is acceptable)
- No chemotherapy in the last 2 weeks, no radiation therapy in the last 6 weeks
- No previous check point blockade treatment or Apoquel/Zenrelia
- No steroids in the last 7 days
- Cytopoint and Librela are allowed
- Patients cannot have a history of autoimmune/ immune-mediated disease, colitis, IBD, endocrine disorders or liver disease.
- Adequate organ function for sedation
- No other significant illnesses or advanced metastatic disease

Eligibility Diagnostics: Within 14 days of starting trial

- CBC, Chemistry Panel, U/A, Total T4
- Cytology or histopathologic diagnosis of cancer
- 3 view chest x-rays
- Abdominal Ultrasound
- Tumor tissue must be available (either from initial surgery or biopsy sample can be collected)

Treatment/Protocol:

- Patients will receive 4 doses of VGS-001 and VGS-002 given at the same visit, every 3 weeks. Patients will have a total of 6 visits following enrollment.
- On visits for VGS-001 and VGS-002 treatment blood, feces and tumor tissue may be collected and patients will be closely monitored during and for 4 hours after administration.
- We will use complete bloodwork, chest x-rays, ultrasound and study lab samples to track patients' responses.
- Following completion of trial patients may go on to the therapy of their choice

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
- During the treatment phase the trial will cover the cost of visits, blood work, x-rays, ultrasounds, treatment with VGS-001 and VGS-002 and the associated charges at those visits
- In the event of side effects, the trial will cover up $1500 of care. The care must take place at the U of I.

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.