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

Funded Study: Treatment of dogs with metastatic cancer to lung, with hypo-fractionated radiation and anti-PD-1 canine monoclonal antibody.

Study Title: Optimizing hypo-fractionated radiation to maximally harness the immunogenic potential of anti-PD-1 canine monoclonal antibody for oligometastatic cancer.

Purpose of Study: Dogs who develop lung metastasis from cancer elsewhere in the body often have few to no effective treatment options. Recent clinical research in people supports better outcomes when radiation is combined with systemic chemotherapy or immunotherapy. The purpose of this clinical trial is to treat dogs with oligometastasis (5 or fewer lung masses) with radiation to those lesions plus a new immunotherapy designed for dogs that will allow the immune system to "see" the cancer cells after radiation, hopefully enhancing the effect of the radiation treatment. All dogs receive both radiation and immunotherapy. Dogs will be randomized to one of two different schedules of radiation to learn whether one provides a stronger signal to the immune system than the other.

Inclusion Criteria:

- Canine patients with a prior diagnosis of cancer that metastasizes to lung and a finding of 1-5 lung masses on 3 view chest xrays.
- Dogs must be older than 1 year and weigh at least 8 kgs.
- No current chemotherapy, immunosuppressive/homeopathic/alternative therapy/ steroids/NSAIDs or cyclosporine.
    - Cytopoint for allergy treatment is allowed but Apoquel is not.
- Cytologic or histologic diagnosis of primary tumor
- If the diagnosis of the primary tumor is confirmed only by cytology and the primary tumor is still present, a small biopsy will be performed to obtain histopathology.
- Dogs must have adequate organ function.
- Respiratory rate < 60 breaths per minute at rest, no abdominal effort.

Exclusion Criteria:

- **>** 5 pulmonary metastatic lesions.
- Dogs < 8 kg in size and < 1 yr. of age.
- Patients lacking a confirmed cancer diagnosis or lack of slide availability.
- ANY prior immunotherapy or any radiation therapy within the last 6 mo. prior to enrollment.
- Chemotherapy within the last 3 weeks prior to enrollment.
- Patients taking NSAIDs or steroids. Patients can washout for 7 days prior to trial enrollment.
- Significant uncontrolled co-morbid illness, which includes but is not limited to renal or hepatic failure, history of congestive heart failure or DCM.
- Tachypnea (>60 breaths per minute and/or consistent abdominal effort) at rest.
- Pleural effusion
- Previous radiation to lung
- Known aminoglycoside allergy.

Eligibility Diagnostics:

- Physical examination
- CBC, serum biochemistry, urinalysis
- 3 view chest x-rays
- Histology or cytology of primary tumor

Treatment/Protocol: Dogs will be treated with one of two radiation protocols (10 Gy per fraction/dose). Either radiation every other day for 3 doses or radiation every other week for 3 doses. Additionally, they will receive an infusion of immunotherapy every other week for 3 doses, then once monthly for a total of 8 doses. Monitoring will occur with chest x-rays at 1, 3, and 6 months and then every 3 months thereafter. Blood will be collected to test the immune system during the treatment phase. At the time of death, a necropsy will be performed at the U of I or tissue will be collected from the primary tumor and from the metastatic lung lesion (this can be done with rDVM at owners' cost).

Compensation:
Clients will be financially responsible for enrollment diagnostics, the normal course of treatment for unrelated medical conditions and any complications that may arise. Once enrolled the trial will pay for CT scan, chest x-rays, blood work, radiation therapy and immunotherapy (Gilvetmab).

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