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ILLINOIS
Veterinary Teaching Hospital
COLLEGE OF VETERINARY MEDICINE

Funded Study: Treatment of Canine Lymphoma,
Multiple Myeloma, and Solid Tumors
University of Illinois Cancer Care Clinic and
Comparative Oncology Research Laboratory

Study Title: Preclinical Assessment of an Oral p97 Inhibitor, CB-5339, in Tumor-Bearing Dogs

Purpose of Study: CB-5339 inhibits p97, which is an important cellular enzyme that chaperones subsets of proteins for degradation. Emerging evidence suggests that cancer cells can become over-dependent on these protein disposal pathways and therefore inhibition of p97 is expected to have meaningful anticancer activity by inducing fatal stress in cells via protein accumulation.

Inhibitors of p97 have been developed and assessed for advancement into human cancer patients. In laboratory experiments, p97 inhibitors rapidly disrupted protein degradation systems and activated cell death mechanisms. CB-5339 possesses several important characteristics that support its advancement to first-in-human (FIH) use.

The clinical trial in tumor-bearing dogs is intended to define the safety, pharmacokinetics, and pharmacodynamic modulation of this investigational agent, CB-5339. This is designed as a dose escalation trial wherein tolerability, clinical efficacy, and pharmacokinetic/pharmacodynamic data is collected in canine solid tumors, multiple myeloma, and high-grade lymphoma.

Inclusion Criteria:

- Histologically confirmed cancer (lymphoma may be confirmed by pre-treatment biopsy or cytology) with a minimum lesion size of 3 cm
- For lymphomas, nodal presentation (stage 2 or greater) with minimal nodes size for biopsy of 3 cm in the longest dimension, must have at least 2 nodes that meet these measurement criteria
- For multiple myeloma, dog must present with 2 of the 4 major criteria for diagnosis: radiographic evidence of osteolysis (bone destruction), >20% plasma cells in bone marrow aspiration or biopsies, monoclonal gammopathy on serum protein electrophoresis or the presence of Bence-Jones proteinuria.
- Expected survival time of greater than 3 weeks
- Both newly diagnosed dogs and those with recurrent/relapse disease are eligible
- >15 kg

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: by histopathology for solid tumors, by histology or cytology for lymphoma or multiple myeloma
- 2) Screening blood work and urinalysis, if not performed within 7 days

Treatment:

The canine patient will receive CB-5339 oral treatments over the course of eleven days. There will be a total of 4 visits to the hospital, however, most treatments with CB-5339 will be given by owners at home. At enrollment, dogs will have bone marrow aspiration, chest radiographs, and may have an abdominal ultrasound performed. Blood work and tumor biopsies will be performed at scheduled visits.

Compensation:

Owners are responsible for eligibility criteria (blood work, tumor diagnosis, chest radiographs). The costs associated with drug administration, tumor biopsy, diagnostic imaging, hospitalization, and blood work will be covered by the trial once the canine patient is enrolled. Owners will also be gifted a hospital credit for their participation once their dog has completed the trial.

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.