Title:
COTC028: Preclinical assessment of an oral p97 inhibitor, CB-5339, in tumor-bearing dogs

Investigators:
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If interested, please have your primary veterinarian request additional information through the UGA Oncology service by calling the small animal referral coordinator at 706-542-5362.

Study description:
The purpose of this study is to evaluate the safety and efficacy of CB-5339, a novel anticancer agent, in dogs with cancer. CB-5339 has been evaluated in normal research dogs; however, this agent has not been previously used in dogs with cancer. Dogs must have a confirmed diagnosis of a malignant solid tumor (excluding mast cell tumor and hemangiosarcoma), lymphoma or multiple myeloma to be eligible for participation in this study. In addition the following conditions must be met:

Inclusion criteria:
1. Dogs must be otherwise healthy and have adequate organ function.
2. Dogs must weigh ≥ 15.0 kg.
3. Tumors must be ≥ 3 cm and amenable to repeated incisional biopsies.
4. Dogs must be off all prior anti-cancer treatments for ≥ 14 days prior to study enrollment.
5. Owners must sign a consent form including consent for necropsy if unexpected death occurs during the study.

Dogs will undergo physical examination, tumor measurements and biopsy, and routine laboratory testing to determine eligibility. To complete enrollment dogs will also have chest x-rays and additional blood and tumor biopsy samples collected for analysis. Abdominal ultrasound may be recommended at the discretion of the attending clinician. Participation in the study will include ~5 appointments over 22 days from the start date (not including pre-enrollment visit). Dogs will be required to return to UGA for each scheduled appointment during the study. Appointments will include pre-treatment evaluation, Days 1, 2, 8, 15 and 22. A physical examination, blood collection, tumor measurements and biopsies will occur during rechecks according to the study schedule. CB-5339 will be given by mouth over two 4-day increments (days 1-4 and 8-11) followed by one week without drug over the course of the study. Owners will be asked to complete a quality of life assessment at each recheck.

Owners are responsible for the costs of initial evaluation and staging. Once a dog is enrolled, the study will cover all routine costs associated with the study including office exams, hospitalization (for sample collection), lab work, biopsies, radiographs, and CB-5339 treatments. If adverse events or complications arise during the study that are directly related to treatment, up to $1250 of their management per dog per event will be paid for by study funds.

Duration of study:
The study is ongoing and expected to be completed by Aug 2019.

Potential benefits to veterinary medicine:
It is hoped that dogs with tumors will show an improved response to this novel treatment. In addition, studies of this new drug in dogs with cancer will complement currently planned human trials designed to test new doses and effects of this agent.