Veterinary Health Center
AT KANSAS STATE UNIVERSITY
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Title: **Clinical trial evaluating the impact of oclacitinib maleate (Apoquel®) on T regulatory cells in dogs receiving standard-of-care (SOC) maximum-tolerated-dose (MTD) carboplatin chemotherapy for the treatment of naturally-occurring cancer.**

Purpose: The objective of this Phase 1 (pilot) study is to evaluate the impact on the T cell subpopulations in dogs receiving combination therapy with oclacitinib maleate (Apoquel®) and carboplatin chemotherapy, with all drugs intended to be administered at standard doses and intervals, for the treatment of naturally-occurring cancer. Recent laboratory work has suggested T cell populations in dogs are impacted by oclacitinib, and this could have positive therapeutic implications for dogs with cancer. This is because T regulatory cells can inhibit the body's immune response to diseases, such as cancer, so by decreasing the numbers of these cells we might enhance the body's immune response. The secondary objective of this study is to verify the safety of combination therapy with oclacitinib maleate (Apoquel®) and carboplatin chemotherapy, when administered at standard doses and intervals, in dogs with naturally-occurring cancer.

Clinical Protocol: All enrolled dogs will receive oclacitinib maleate (Apoquel®) throughout the study period, beginning on study day 0/1. All enrolled dogs will also receive standard carboplatin chemotherapy, administered intravenously on five occasions throughout the study period, on study days 14, 35, 56, 77 and 98. Blood and urine samples will be collected at baseline on study day 0/1, and immediately prior to each dose of chemotherapy on study days 14, 35, 56, 77 and 98, as well as two week after each dose, on study days 28, 49, 70, 91 and 112, and three weeks after the final dose of doxorubicin therapy, on study day 119. An additional blood sample will be collected simultaneously on each of these clinic visits, on study days 0/1, 14, 35, 56, 77, 98 and 119, for flow cytometric analysis of the T cell populations. Additionally, owners will complete a quality of life questionnaire at each of the study visits. The questionnaire specifically addresses the potential clinically observable side-effects of this combination therapeutic protocol, such as lethargy, weakness, inappetence, nausea, vomiting and/or diarrhea.

Eligibility:

- Dogs diagnosed with naturally-occurring cancer, and for which carboplatin is determined to be an appropriate therapy, will be considered for enrollment.
- Dogs of any breed, age, gender and weighing a minimum of 5.0kg, with satisfactory health scores are eligible to be considered for enrollment.
- Dogs receiving additional concurrent corticosteroids will be excluded from enrollment.

Client Compensation: Currently there are minimal funds to support client and pet involvement in this study. The Flow Cytometric analysis, blood and urine tests on specified study days (0/1, 14, 35, 56, 77, 98 and 119), and the oclacitinib are covered, at the hospital's discretion. Clients will be responsible for the costs associated with initial diagnostic work-up, ongoing diagnostic and monitoring tests (blood tests, urine tests, and imaging not covered by the study), and the prescribed carboplatin therapy, and any additional and/or ongoing therapy.

CONTROL GROUP*: This trial includes a subset of patients with naturally-occurring cancer to serve as a control group. Patients in the control group will receive standard carboplatin chemotherapy but will not receive oclacitinib maleate (Apoquel). The objective for the control group is to evaluate the impact of carboplatin chemotherapy alone, on the T cell subpopulations in dogs with naturally-occurring cancer.*

All enrolled dogs will receive standard carboplatin chemotherapy, administered intravenously on five occasions throughout the study period, on study days 0/1, 21, 42, 63 and 84. Blood and urine samples will be collected immediately prior to each dose of chemotherapy, on study days 0/1, 21, 42, 63 and 84, as well as a blood test two weeks after each dose, on study days 14, 35, 56, 77 and 98, and three weeks after the final dose, on study day 105, as is considered standard practice for monitoring throughout carboplatin chemotherapy. An additional blood sample will be collected on each of the clinic visits, on study days 0/1, 21, 42, 63, 84 and 105, for Flow Cytometric analysis of the T cell populations.

Similar to the primary study, the Flow Cytometric analysis and the blood and urine tests on specified study days (0/1, 21, 42, 63, 84 and 105) will be covered, at the hospital's discretion.

- ***Owners will be given a choice as to which group they wish to participate in.***

Contact Information:

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