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Overview of the Current Oncology Trials at UT

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Oncology Clinical Trials

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WE CURRENTLY HAVE TRIALS RECRUITING THE FOLLOWING TUMOR TYPES (alphabetical list):

DOGS- anal sac adenocarcinomas, histiocytic sarcoma (malignant histiocytosis), lymphoma, mast cell tumors, melanoma, multiple myeloma, osteosarcoma, squamous cell carcinoma (oral), thyroid carcinoma, transitional cell carcinoma (bladder)

CATS- lymphoma, squamous cell carcinoma (oral)

NEW TUMOR TYPES! Tumor type: **CANINE B AND T CELL LYMPHOMA (HIGH GRADE), OSTEOSARCOMA, and MULTIPLE MYELOMA**

Trial: **Evaluation of oncolytic viruses in canine cancer.**

The goal of this trial is to evaluate the response of various tumor types to an oncolytic virus designed to infect cancer cells but not normal cells. This project is a collaboration with the Mayo clinic and funded by the Morris Animal Foundation (B cell lymphoma) and the UT Center of Excellence (T cell lymphoma, Osteosarcoma, Multiple Myeloma) evaluating a new and exciting approach to cancer treatment! This trial is **fully funded**. (PI- Dr. Sara Allstadt Frazier; contact Oncology at (865) 974-8387 or Gina Galyon at 865-755-8151 or Dr. Frazier at sarafrazier@utk.edu). Patients ideally should be off other therapies (including steroids) for 2 weeks prior to enrollment. Trial period is for 30 days (~4 visits to UT).

Tumor type: **FELINE ORAL SQUAMOUS CELL CARCINOMAS**.

Trial: **Phase I trial of nanoencapsulated antisense CK2.**

This trial aims to evaluate the tolerability of a novel gene therapy against CK2 in a targeted nanocapsule that homes specifically to cancer cells. Cats with oral squamous cell carcinoma confined to the oral cavity +- regional lymph nodes may be eligible. The trial period is 3 weeks, with two treatments per week. Pre- and post-treatment biopsies are required to assess CK2 expression. The trial includes **financial incentives,** with **drug supplied at no cost and cost of pre- and post-treatment biopsies and labwork is covered during treatment**. PI – Dr. Claire Cannon, clairecannon@utk.edu or 865-974-8387.

Tumor type: **CANINE HISTIOCYTIC SARCOMA.**

Trial: **Phase II, Open Label Trial of Paccal Vet® (water-soluble micellar paclitaxel) in Dogs with Histiocytic Sarcoma.**

The trial will evaluate a new canine chemotherapy agent, Paccal Vet, for canine histiocytic sarcoma. Paccal Vet has been studied in other canine tumors. This trial includes **financial incentives** to the client (Paccal vet provided at no cost, additional staging tests are covered to determine response). Trial period is a minimum of 6 weeks (3 required visits to UT), but additional Paccal Vet provided if dog responds to treatment. PI- Dr. Sara Allstadt Frazier, contact at sarafrazier@utk.edu or Gina Galyon at 865-755-8151. Patients need to be off other therapies (including steroids) for 2 weeks prior to enrollment.

Tumor type: **CANINE LYMPHOMA.**

Trial: **Preclinical Comparison of Three Indenoisoquinolines Candidates in Tumor-Bearing Dogs.**

The goal of this trial is to evaluate 3 new drugs in tumor-bearing dogs and define the pharmacokinetics, pharmacodynamics, and toxicity profile of each agent. Dogs must have confirmed lymphoma to be eligible for the trial. For more information contact investigators: Claire Cannon or research technician Gina Galyon at 865-755-8151. This trial is **fully funded** and clients will receive a **$1000 incentive** at the end of the study period (29 days) to use for future therapy.

NEW! Tumor type: **FELINE HIGH GRADE LYMPHOMA**.

Trial: **Efficacy of High-dose L-asparaginase and Impact on Ammonia and Amino Acid Levels in Cats with High Grade Lymphoma.**

The trial will evaluate the response of cats with lymphoma to a single treatment with L-asparaginase. The trial period is one week and includes three visits to UT for blood sampling and re-staging tests. This trial is **funded** and includes a **free dose of Elspar and imaging studies**. PIs-Drs. Jeanne Larson and Sara Allstadt Frazier, contact at jlarson8@utk.edu or sarafrazier@utk.edu or 865-974-8387. Patients need to be newly diagnosed within 7 days of enrollment and not on other therapy. After the study period ends, they may go on to receive other chemotherapy treatments.

Tumor type: **CANINE MAST CELL TUMOR.**
Trial: **Use of Kinavet (masitinib) for non-resectable canine mast cell tumors.**
This is a double-blinded placebo-control trial that evaluates Kinavet in dogs with non-resectable mast cell tumors (2/3 of the dogs will receive Kinavet, 1/3 –placebo). Dogs cannot be on chemotherapy and should be off steroids for at least 3 weeks. A screening visit to determine eligibility is required. The trial is **fully funded**. PI- Dr. Olya Smrkovski, contact: (865) 974-8387 or email: opuretsk@utk.edu.

Tumor Type: **CANINE THYROID CARCINOMA**.
Trial: **Evaluation of a novel hand held device to monitor response of canine thyroid carcinomas to radiation therapy.** The trial period is 3 weeks. This trial includes a financial incentive of $500. PI: Dr. Nathan Lee, contact at nlee9@utk.edu or 865-755-8571.

Tumor type: **CANINE TRANSITIONAL CELL CARCINOMA.**
Trial: **Pilot study, Neurotransmitter levels in blood samples of dogs with and without transitional cell carcinoma.**
Research by Dr. Schuller's lab has shown that high blood levels of cancer stimulating stress neurotransmitters can stimulate certain cancer types in vitro and in rodent animal models. The current pilot study will explore blood samples in dogs with transitional cell carcinoma to determine if they have increased stress neurotransmitter levels and/or decreased GABA levels. Patients must be untreated (NSAIDs are not allowed). Patients can present to UT or referring practitioners may submit blood for use in this study. A 5ml blood sample is needed for study- no cost to client for participation. (PI- Dr. Hildegard M. Schuller; Co-investigators: Drs. Joe Bartges and Sara Allstadt Frazier)

COMING SOON: Tumor Type: **OSTEOSARCOMA**
Trial: **Evaluation of Orally Administered mTOR inhibitor Rapamycin in Dogs with Osteosarcoma.**
Several lines of evidence suggest that blockade of the mTOR pathway may be an effective strategy to prevent metastatic cancer progression. This study seeks to identify an optimal dose of the mTOR inhibitor, rapamycin, to be advanced to a canine clinical trial that will assess the role of rapamycin as an antimetastatic agent in dogs with osteosarcoma. An open label, prospective preclinical trial of orally administered rapamycin will be conducted in dogs with osteosarcoma. This is a fixed schedule, dose escalation study in dogs with measurable tumors. Data from the initial pilot PK analysis will help determine the doses to be evaluated in the dose escalation study. The primary objective of this study is to identify a tolerable chronic exposure of oral rapamycin in tumor-bearing dogs that is achievable in human patients and has been demonstrated to inhibit metastatic progression in murine models. Toxicity will be evaluated via dose escalation and assessment of dose limiting toxicities (DLT) and parallel assessment of pharmacokinetic exposures. The study is FULLY FUNDED and will provide rapamycin for dogs that respond for up to 6 months of treatment. (PI-Dr. Sara Allstadt Frazier, sarafrazier@utk.edu)

COMING SOON: Tumor type: **CANINE BLADDER TRANSITIONAL CELL CARCINOMA**
Trial: **Evaluating a novel optical imaging agent, fluorocoxib A, to detect cyclooxygenase-2 (COX-2) expressing cancers of bladder in dogs.** COX-2 enzyme is highly present in cancer cells, but not in normal cells that makes an attractive target for detection of cancer. This study using fluorocoxib A in dogs with naturally occurring cancers will assist to identify tumors that would benefit from COX-2 targeted NSAIDs. In addition, this study will assist to translate this novel imaging agent into clinical applications for detection of cancer, as well for monitoring the early responses to therapy not only in dogs, but also in human patients. This trial includes **financial incentives** to the client. Patients may be enrolled undiagnosed and the trial will pay for biopsy for diagnosis. Patients must be off NSAIDs for 2 weeks before enrollment or biopsy. Trial period is approximately 24 hours. (PIs- Drs. Maria Cekanova and Joe Bartges; please contact Amanda Callens at (865) 974-8387).

Contact information listed is for the convenience of referring veterinarians to contact with any questions prior to referral. Please don't share contact information of specialists with clients.

Please note: For all trials, patients must be examined at UTCVM to determine eligibility. Clients are often responsible for the initial examination fee for the first visit (currently $129) and any tests required by that trial to determine eligibility (many trials require some staging tests performed to determine eligibility but some may cover the cost of some tests). Each trial has different funding and an explanation of covered costs and non-covered costs will be reviewed with each case.