

**Title:**

Phase Ib study of GS-424044 in dogs with malignant neoplasia

**Investigators:**

Corey Saba, DVM, DACVIM (oncology faculty) - [csaba@uga.edu](mailto:csaba@uga.edu)

Nicole Northrup, DVM, DACVIM (oncology faculty) - [northrup@uga.edu](mailto:northrup@uga.edu)

**Study description:**

The purpose of this study is to investigate a new chemotherapy drug as treatment for dogs with malignant tumors. Dogs with advanced solid tumors (mainly carcinomas and sarcomas) are eligible for participation in this study. In addition the following conditions must be met:

**Inclusion criteria:**

- Dogs must be otherwise healthy and at least one year of age
- Dogs must weigh at least 10.0 kg
- Tumor type must be confirmed by histology (for solid tumors)
- Adequate organ function as specified by standard laboratory tests
- Signed owner consent

**Exclusion criteria:**

- Dogs receiving another type of chemotherapy within 3 weeks of enrollment
- Dogs receiving radiation therapy within 6 weeks of enrollment
- Dogs receiving corticosteroids within 72 hours of enrollment
- Dogs with serious concurrent systemic disorder
- Dogs that have received lomustine (CCNU) or bleomycin

Dogs will undergo physical examination, tumor measurements, and routine laboratory testing to determine eligibility. If enrolled dogs will also have chest radiographs, tumor biopsy, and additional blood collected for analysis. In addition, an ultrasound or CT scan may be needed depending on the type and location of the tumor. Once enrolled, dogs will receive chemotherapy treatment once every 2 weeks for approximately 8 treatments. At certain time intervals during the study blood will be collected for analysis and repeat imaging tests will be performed to determine response to the drug. Enrollment in the study will continue as long as dogs tolerate the treatment well and respond favorably to the drug. If the drug is not tolerated well or the disease progresses, participation in the study will end and the dog will be eligible for other treatment as deemed appropriate.

The owner is 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, lab work, biopsies, radiographs, ultrasound, CT scans, and chemotherapy treatments. If adverse events or complications arise during the study that are directly related to treatment, up to \$3,000 of their management will be paid for by study funds. In addition, if study compliance is maintained \$1,000 will be awarded to owners for use at UGA's teaching hospital for further treatment or testing.

This drug has been previously used in dogs and appears to be well-tolerated in a majority of patients. However, it is still an experimental therapy and side effects similar to those with other chemotherapy treatments could occur including hair loss, gastrointestinal upset, decreased

white blood cell and/or platelet counts, increased susceptibility to infection, skin reactions, and organ toxicity.