Study Title: Evaluation of the procaspase-3 activator, PAC-1, in combination with doxorubicin in dogs with metastatic osteosarcoma

Purpose of the study: Procaspase-3 is a cell enzyme which can be activated to caspase-3, which subsequently promotes cell death. PAC-1 is a novel compound which sensitizes procaspase-3 for activation by conventional chemotherapeutic agents, thereby enhancing anticancer activities. The goal of the first phase of this trial is to identify a safe, relevant dose of PAC-1 for tumor bearing dogs when used in combination with intravenous doxorubicin, a commonly used chemotherapeutic agent. This will be achieved by treating dogs daily with oral PAC-1 and standard doses of doxorubicin then evaluating biologic effects by appropriate surrogate markers.

Inclusion Criteria:
• Dogs with histologically or cytologically confirmed metastatic osteosarcoma
• Dogs must have a measurable tumor burden
• Dogs must have a favorable performance status (survivability of 6 weeks)
• NO concurrent chemotherapy or radiation therapy. Dogs must be off of all such therapy for 1 week prior to study enrollment. (i.e. prednisone)
• Dogs with recurrent disease are eligible
• Signed informed owner consent; all treatment options for the pet will be presented and owner must decline all other options
• NO significant co-morbid illness, which includes renal or hepatic failure, history of congestive heart failure or clinical coagulopathy
• Dogs must weight > or = 20 kg

Diagnostics:
• Diagnostics include: 1) Screening bloodwork and urinalysis, 2) tumor confirmation, 3) chest x-rays.

Treatment:
• All dogs will be treated daily at home with oral PAC-1 and doxorubicin every 2 weeks for 3 treatments.

Compensation:
• The study will pay for doxorubicin drug and administration costs for 3 treatments. Estimated at $750-$1050 for total compensation.

Contact Information: Please feel free to call Rebecca Kamerer at (217)300-6453 to refer a patient or for any additional information. Referring veterinarian and client calls are welcome. Owners may schedule appointments by calling (217)333-5300.