**Title:**
Safety and efficacy evaluation of an immunomodulator in cats as an adjunct treatment for fibrosarcoma under field conditions

**Investigator:**
Corey Saba, DVM, DACVIM (Oncology faculty)

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:**
Feline fibrosarcoma is well recognized in veterinary oncology. Although the reported metastatic rate is relatively low (0-28%), these tumors are extremely locally invasive, and recurrences are common despite aggressive local treatment. When treated with surgery alone, recurrence is likely despite apparent complete excision, and the median time to first recurrence is very short. Despite recent advancements in surgical, radiation, and medical therapies, control of this disease remains very challenging. The objectives of this study are to evaluate the safety of an immunomodulator in cats as an adjunct treatment for fibrosarcoma.

The following study criteria must be met:

**Inclusion criteria:**
1. Cats must be otherwise healthy and FeLV/FIV negative.
2. They must have measurable tumors (< 5 cm) amenable to surgical resection to participate.
3. Cats must reside with their owners within driving distance of UGA.
4. Owners must sign a consent form including consent for necropsy if unexpected death occurs during the study.

**Cats having received previous immunotherapy are not eligible for this trial.**

**Specific questions about potential cases should be directed to the study investigator.**

Cats will undergo preliminary staging tests including initial consultation, physical examination, and measurement and biopsy to determine trial eligibility. Additional staging tests (e.g. lab work, chest x-rays, etc) may be recommended at the discretion of the attending clinician. Once accepted into the study, the cat will be randomized into a treatment group. The intent will be to administer the immunomodulator at regular intervals across a two month treatment window. This will require weekly visits to UGA for the duration of the initial treatment and quarterly visits thereafter for up to two years. Cats in this study are required to come to UGA for all scheduled visits, and owners will be expected to complete daily quality of life assessments for their cats.

The immunomodulator will be provided as part of the study. Once enrolled in the study, clients will be awarded an initial $500 UGA hospital credit as participation incentive. Upon completion of the immunomodulator treatment series, an additional $1000 UGA hospital credit will be awarded. Once the cat has been removed from the study (i.e. due to tumor regrowth) a final $500 UGA hospital credit will be awarded. If complications associated with the immunotherapy occur, up to $800 will be provided to offset the costs of their treatment and management.

**Duration of study:**
The study is currently OPEN. Enrollment opportunities are limited and will terminate when the target enrollment is filled.

**Potential benefits to veterinary medicine:**
We expect this trial will provide valuable information about the safety of the immunomodulator in cats with fibrosarcoma.