AUBURN UNIVERSITY

COLLEGE OF VETERINARY MEDICINE

CLIENT INFORMED CONSENT FORM

Title: Efficacy of temozolomide in canine oral melanoma

1. **Why is the study being performed?**

Canine oral melanoma accounts for about 30-40% of all oral tumors in the dog. It is a highly aggressive tumor with an 80% risk of spreading to organs outside of the mouth (including lungs, lymph nodes, brain, liver). Effective therapies that combat its spread are needed. Carboplatin, an IV chemotherapy, is the only drug with a documented response rate for canine oral melanoma and its response rate is only 28% in one small study. Temozolomide (TMZ) has a documented response rate for the treatment of metastatic melanoma in humans and could represent an oral alternative for systemic treatment of canine melanoma. At this time there has been no investigation of the response rates of canine oral melanoma to TMZ when TMZ is dosed at its most recently published dose in dogs with cancer. The goal of this study is to establish a response rate for TMZ in dogs with oral melanoma at this dose.

2. **Which animals / patients can participate in the study?**

Dogs with confirmed oral melanoma from a biopsy or cytology and have one of the following: original tumor still present or spread to other organs present can participate in the study. Dogs that can participate in the study must have pre-study bloodwork that does not demonstrate any clinically significant change, must feel well, have no contraindication to receiving chemotherapy and must be expected to live for at least 60 days.

3. **Why might my animal NOT be able to participate in the study?**

Dogs cannot participate in the study if they are currently receiving any other chemotherapy or immunotherapy agent, have pre-study bloodwork that demonstrates clinically significant changes in organs that may not be conducive to the administration of chemotherapy, feel poorly due to their disease or due to a disease process are not expected to live for at least 60 days.

4. **What will be happening to my animal if we participate in the study?**

Once enrolled dogs will be prescribed 150mg/m2 of temozolomide (TMZ) to be given by mouth for 5 consecutive days every 4 weeks. Dogs will be required to be monitored with bloodwork and urinalysis 10 days after the first day of drug administration every dose. While receiving TMZ dogs will be monitored for disease progression with chest x-rays, tumor measurements and lymph node evaluation 4 weeks after the initial dose of TMZ and then every 8 weeks until disease progression is noted or until 6 doses are completed. All dogs with no gross disease after

6 doses will be monitored with chest x-rays and lymph node evaluation every 12 weeks until disease progression is noted.

5. **Are there any benefits from the study for my animal?**

The tumor with which your dog has been diagnosed, melanoma, may respond to temozolomide (being provided at no cost to you). This response may be measured as tumor stabilization, shrinkage, or decreased development of tumor recurrence or further spread.

6. **Are there any risks or discomforts for my animal?**

As with all chemotherapy treatments, there is a risk of side effects. Expected effects include nausea, diarrhea, changes in liver and kidney function, decreases in neutrophils (cells that fight infection) and platelets (cells that help in blood clotting). These side effects are similar to those seen with other chemotherapy drugs and are usually manageable with treatment when immediately reported. In some cases, side effects can result in death. There is also a chance your dog's tumor will not respond to this treatment, resulting in cancer progression.

7. **Unforeseen adverse events**

No unforeseen adverse events are expected, since this drug has been used in dogs previously. However, as with any chemotherapy drug, unforeseen events can occur, including illness and death.

8. **Are there treatment options other than participating in the study?**

All treatment options that are considered standard for the management of the diagnosed tumor type will be discussed, including surgery, radiation therapy, chemotherapy, immunotherapy, other clinical trials, monitoring, and/or palliative care. You may decline treatment or choose a different treatment regimen for your pet. Declining participation will not negatively affect any further care your pet receives at our hospital.

9. **Owner responsibilities**

Owners are responsible for making their dog available to obtain all required monitoring tests either at Auburn University or at their primary care veterinarian's office while their dog is on the clinical trial. Owners are financially responsible for all fees associated with the care and monitoring of their dog while on trial.

10. **Participant dismissa**l

Dogs will be dismissed from the study if at any time the side effects or the disease itself are considered unacceptable by the clinician or the owner. Dogs will be dismissed from the study if/when disease progression is noted while receiving temozolomide. Dogs can be dismissed from the study if owners fail to comply with recommended monitoring by the supervising clinician.

11. **Financial obligations of all parties**

The chemotherapy drug temozolomide will be provided free of charge by the AUVTH. All other financial obligations accrued during the course of the clinical trial and upon dismissal from the trial (examination fees, diagnostic tests, monitoring tests and side effect management fees) are the responsibility of the owner. These costs will be discussed prior to each visit and a signed consent form obtained. These costs usually range from $150-1200 per visit, depending on the tests and treatments performed.

12. **Access to study information**

Information from this study will not be distributed to you as an individual but may be available through scientific publications.

13. **Confidentiality**

Information, case materials, photos, and generic patient information gathered in this study may be used for scientific presentations and publications. Confidentiality of personal information (client and animal) will be maintained to the extent of the law.

14. **Contact persons regarding this study**

Participants may contact any of these individuals with questions about this study:

Stephanie Lindley DVM, CVA, DACVIM (Oncology)
ses0034@auburn.edu

Noelle Bergman DVM, MS, DACVIM (Oncology)
nsb0009@auburn.edu

Ashley Smith DVM, MS, DACVIM (Oncology)
aas0042@auburn.edu

15. **Hospital review contact person**

Participants with concerns about any research study at the AU College of Veterinary Medicine may also contact:

D. Michael Tillson, DVM, MS, DACVS. Acting Director, Veterinary Teaching Hospital, College of Veterinary Medicine, Auburn University. (334) 844-4690.

Frank F. "Skip" Bartol, PhD. Associate Dean of Research and Graduate Studies. College of Veterinary Medicine; Auburn University. (334) 844-3700.

16. **Owner acknowledgements**

As legal owner of (or agent for) this animal, I understand and acknowledge the following:

a. I am agreeing to participate in a research study at the AU College of Veterinary Medicine.
b. I am free to withdraw my consent and to discontinue participation in the study at any time.
c. The decision for my animal to participate in this study is mine alone and participation is voluntary.
d. The decision to withdraw from the study or to disregard the recommendations of the veterinarians involved in the study, relieves the investigators of current and future obligations (both medical and financial) to the pet and/or owner covered by this study.
e. Non-study treatment protocols have been discussed and I understand the relative benefits of those treatments.
f. I am responsible for decisions and financial obligations related to treatment(s) sought or required for my animal at AU-VTH or at any other veterinary facility that are NOT specified in this document. This would include treatment for disease progression or for medical complications - related or unrelated to the study.
g. If I withdraw my animal from the study, I may be responsible for medical, diagnostic and treatment costs incurred even if these were originally covered by the study.
h. Any decision to discontinue participation in this study, whether to pursue other therapies or to have my animal euthanized, does not entitle me to any financial reimbursement for costs incurred during participation.
i. I have discussed the procedures / benefits and risks of study participation and had the chance to have my questions about the study answered.

_____ _____

Owner signature Date

17. **Investigator assurances**

a. I have explained the study details and answered questions to the best of my ability.
b. If the animal is a patient in the Auburn University Veterinary Teaching Hospital, I have discussed enrolling the patient into this study with the senior faculty member responsible for this patient's care.

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Primary Investigator Date

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Witness

This study has been reviewed and approved by the Clinical Research Review Committee of the College of Veterinary Medicine (CRRC) and the Auburn University Institutional Animal Care and Use Committee (IACUC).