04/11/24

OWNER INFORMED CONSENT

SCHOOL OF VETERINARY MEDICINE
University of Wisconsin-Madison
Advancing animal and human health with science and compassion

UW Veterinary Care
2015 Linden Drive, Madison, WI 53706

COTC031: EVALUATING THE SAFETY AND EFFECTIVENESS OF 45H1, A NOVEL ANTI CANCER AGENT, WHEN GIVEN TO DOGS WITH CANCER

This clinical trial led by the National Cancer Institute (NCI) assesses the safety and effectiveness of ch45H1, a novel anticancer agent, when given to dogs with cancer. This medication is designed to help your dog's immune system fight their cancer. The data from this study will be used to assist in the development of additional novel cancer agents in humans.

ch45H1 will be given by intravenous (IV, injection into the vein) infusion to your dog on Days 1, 22, 43, and 64 (once every 3 weeks) for a total of 4 doses.

In order to better understand your dog's participation in this study, the potential clinical adverse events that may be associated with either progression of the tumor and/or the study drug are listed below.

Cancer Progression: inappetence, pain, lameness/reluctance to walk or exercise, lethargy, coughing, respiratory impairment, gastrointestinal upset (vomiting, diarrhea, inappetence), evidence of metastatic spread of cancer cells to other parts of the body and subsequent organ failure.

Drug toxicities: fever, lethargy, gastrointestinal upset (vomiting, diarrhea, inappetence), allergic reaction, abnormal heartbeat, high or low blood pressure, low platelet counts (blood clotting cells), high or low white blood cell counts, anemia (low red blood cells), worsening liver or kidney function, low thyroid or adrenal hormone levels, diabetes mellitus, hives and/or rash, sepsis, fatality.

Research protocol: bruising, infection, bleeding at catheter site (if one is placed by the COTC site investigator); biopsy site infection, seroma (sterile fluid filled swelling), pain, bruising, dehiscence.

It is hopeful that minimal adverse events will be seen and that they will be transient in nature. However, these are experimental therapies, so all potential adverse events are not known. Any sign of illness in your dog should be reported to your oncologist immediately and may require return to the Veterinary Teaching Hospital for evaluation.

Within this study, we ask that you permit serial biopsies of your dog's tumor. A biopsy will be collected prior to the first dose of drug (pre-treatment), on Day 8, Day 29 and possibly on Day 85, depending on

how your dog has responded to therapy. Each of these biopsy sessions will occur under anesthesia, either local (sedation with anesthetic) or general. Your dog will return to the Veterinary Teaching Hospital on Days 8, 21 and 22, 29, 42 and 43, 63 and 64, and 85. Serial blood collections will occur on Days 1, 21-22, 42-43, and 63-64 of the study. Single time point collections will occur on Days 8 and 29.

If your dog's cancer responds well to the treatment they have been assigned, you will be asked to participate in an additional follow-up period of up to one (1) year's time. During that time, you will need to continue to regularly visit the Veterinary Teaching Hospital for examination, tumor evaluation, and blood collection. At the conclusion of the study, your dog will undergo a final tumor biopsy. Please carefully discuss the full study calendar with your clinician.

Future studies conducted in humans with cancer will be informed in part based on the information gathered in this study. The benefit to your dog associated with these treatmens are not known and toxicity is possible. Prior to entry into this study, your dog must have a confirmed diagnosis of cancer and staging tests to ensure his/her general health and to evaluate how advanced the disease is prior to treatment.

Most costs associated with this study will be provided as part of your participation. In the event, any complications arise from study drug administration, their management will be covered by study funds up to $2000/per event. This would include any unanticipated hospitalizations. Please discuss the study costs with your clinician.

Additionally, support will be provided after your dog's completion of this study, in the form of a $1000 gift towards additional treatment for your dog's cancer at this VTH.

Please read the following and sign below:

☐ I have been informed of the possible benefits and risks associated with this treatment. I understand that side effects of ch45H1 are not fully understood**.**

☐ I understand the risks of general anesthesia needed for surgery for my pet (including death).

☐ I have been informed of the study costs provided through participation in this study.

☐ I understand the need to return for all appropriate follow up care at the Veterinary Teaching Hospital as scheduled including:

- Day 8
- Days 21-22
- Day 29
- Days 42-43
- Days 63-64
- Day 85

☐ I will contact my COTC institution right away if my dog experiences any (even one episode) of vomiting, diarrhea, decreased appetite, or lethargy.

☐ I agree to return to my COTC institution for evaluation if directed by my veterinary oncologist if my dog experiences any illness.

☐ I acknowledge that in the event of acute medical complications associated with the study drug administration study funds will cover their management (up to $2000 per adverse event).

☐ I acknowledge that $1000 will be provided for additional treatment for my dog's cancer at the VTH after their completion of this study.

☐ I understand that I retain the right to remove my dog from this study at any time, however if I do prior to the study's conclusion then I forego further financial support.

☐ I understand that information; case materials, photos and patient information gathered in this study may be used for scientific presentations and publications.

☐ I understand that the study sponors can terminate this study at any time.

☐ I have disclosed all medications my dog is taking, and I will not administer any new (not prescribed) medications during the course of this study (including vitamins, supplements, pain medications, novel NSAIDS, aspirin, etc.).

☐ I understand that in the unexpected event of my pet's death while on study a post-mortem examination will be required.

☐ By signing below, I agree to permit my dog _____ (insert name) to participate in this clinical study and understand the information provided herein. I understand that a copy of this document will be provided to me.

_____	_____
Pet's name	COTC ID Number
_____	_____
Signature of Owner	Attending Clinician
_____	_____
Date	Date