A Multicenter, Randomized, Placebo-Controlled Study of AT-005 in Combination with CCNU Chemotherapy in the Treatment of Canine Intermediate and High Grade, Peripheral T-cell Lymphoma

Thank you for your interest in participating in this clinical study. The study has been developed by the study Sponsor in close communication with veterinary oncology specialists. The goal of this study is to evaluate the safety and effectiveness of a USDA conditionally licensed antibody, AT-005, when given in combination with a chemotherapy protocol in dogs with high grade peripheral T-cell lymphoma. Please review the following information related to participation in this study. Please discuss with your veterinarian if you have questions about this information.

**STUDY DESIGN:** This clinical study is being conducted at multiple veterinary hospitals throughout the United States. For participation, your dog must meet the eligibility requirements listed in the study protocol. Your veterinarian will confirm eligibility by reviewing your dog’s medical history, performing a physical exam, collecting biopsy samples, fine needle aspirates, chest radiographs, and submitting routine blood and urine testing (clinical chemistry, CBC, and urinalysis). Biopsy sample collection may include local or brief general anesthesia. Your veterinarian will discuss the risks of general anesthesia if necessary.

Once trial eligibility is confirmed, your dog will be treated with conventional chemotherapy (CCNU). All dogs enrolled in the study will receive CCNU chemotherapy. After two doses of CCNU, eligibility for randomization will be determined. If eligible, your dog will be randomized to receive the antibody or a placebo. There is a 50:50 chance that your dog will receive placebo in addition to chemotherapy. Your veterinarian will be blinded or “masked” (unaware of which study treatment your dog is receiving) and it is important that this blinding be maintained. In the event that your dog’s lymphoma progresses past a threshold designated by the protocol, your dog will be removed from the study and will be eligible to receive treatment as recommended by your veterinarian. The placebo and study compound are given as intravenous infusions by the veterinary staff.

You will be required to come in for regularly scheduled study visits during the course of the study. As is common when receiving chemotherapeutic agents, blood and urine testing will be conducted at many study visits.

There is a possibility that blood and tissue samples may be collected during various time points throughout the study. These samples are collected to further evaluate the study compound in your dog and are not considered standard care for veterinary cancer patients.

**POSSIBLE SIDE EFFECTS:** Although no side effects have been seen in dogs treated previously with AT-005, it is possible that side effects may be seen in your pet. These may include, but are not limited to, injection allergic reactions, decrease in appetite, nausea, diarrhea, and death. Separately, CCNU chemotherapy has the potential to cause a variety of side effects, some of which may be life-threatening. These side effects will be discussed with you by your veterinary oncologist prior to study enrollment.

**COMPENSATION:** Once informed consent is obtained and the patient is enrolled, this study provides partial funding for screening and full funding during the study period for all study-related costs including study visit evaluations while on study and all necessary diagnostics and treatment. The study will provide a maximum of $1,200 in compensation for management of adverse events and supportive medications during the study. Additional adverse event or medication costs will be owner financial responsibility once $1,200 is surpassed. In the event that the $1,200 is not surpassed and your dog experiences progressive disease during the course of the study, the remainder of the $1,200 may be applied towards additional oncology care for your dog.

Investigator signature and date: ___________________________
Before enrolling in the study, it is imperative that the following conditions are understood:

1. I have been informed of the possible benefits and risks associated with this treatment.
2. I have been informed of other conventional treatments available for treating my dog, including but not limited to surgery, chemotherapy, and radiation therapy, and have elected to pursue this clinical study.
3. I have been informed that the antibody is a conditionally licensed product meant strictly for veterinary use only.
4. I understand that there is a 50:50 chance that a placebo, not the antibody, will supplement my dog’s CCNU treatment.
5. I understand the financial responsibilities for my pet’s medical care while in this study. The study is fully funded with respect to study-mandated examinations, diagnostics, treatment, and management of treatment related side effects during the study period.
6. I have been informed of the follow-up visits necessary for participation in this study. I understand that specific blood tests, biopsy samples, and fine needle aspirates may be required as part of this study and that these blood tests and aspirates may not be considered to be part of the conventional care.
7. I acknowledge that no guarantees have been made to me concerning the expected results of the treatment.
8. I understand that information collected in this clinical study, including case history, diagnostic tests and images, and photographs may be used in future scientific publications and scientific seminars.
9. I understand that I am not permitted to reference this clinical trial, clinical trial sponsor, or drug name on media outlets, including social media such as blogs, Twitter, or Facebook.
10. I understand that no holistic medications or treatments may be administered to my pet during this study without prior approval.
11. I understand that permission for a post mortem examination may be requested in the event of my pet’s death. This post mortem examination may be limited to the collection of tumor tissue from a single location.
12. I understand that, under the discretion of the Investigator, Sponsor or designee on behalf of the Sponsor, my pet’s involvement in this study can be terminated at any time. Failure to adhere to the study visit schedule may cause my dog to be removed from the study.
13. I understand that I can withdraw my dog from the study at any time for any reason.
14. By my signature below, I agree to permit my pet to participate in this clinical investigation and I acknowledge that I have read and understood the information provided herein. I understand that a copy of this document will be provided to me.

Owner Name

Owner Signature

Date

Investigator signature and date:

KEEP ORIGINAL IN CLINIC | GIVE COPY TO OWNER