

## OWNER INFORMED CONSENT FORM



UW Veterinary Care  
UNIVERSITY OF WISCONSIN-MADISON

2015 Linden Drive  
Madison, WI

**Name of Study:** *A multi-center pivotal field study to confirm the effectiveness and safety of verdinexor for the treatment of lymphoma in dogs*

You may be invited to include your dog in an investigational clinical study to evaluate the safety and effectiveness of a new treatment for lymphoma in dogs.

### **Information about Canine Lymphoma:**

Your dog is a possible candidate for the study because he/she was diagnosed with lymphoma or is suspected to have lymphoma.

### **Information about the Investigational Drug:**

The investigational formulation contains a novel ingredient that binds transport molecules within cells, including cancer cells. The safety of the investigational drug has not yet been fully demonstrated. While receiving the investigational treatment, your dog may experience side effects that may include but are not limited to, decrease in appetite, vomiting, increase in liver values, diarrhea, weight loss, lethargy, changes to blood cell counts, and death.

Handling of verdinexor tablets, and handling and cleanup of dogs treated with verdinexor including but not limited to vomit, feces, urine, saliva and blood samples may lead to exposure to verdinexor.

### **Precautions for use of verdinexor tablets in dogs:**

- Verdinexor can potentially cause birth defects and affect female and male fertility based on animal studies. While tablets are coated for protection, wear protective gloves when handling the tablets and to prevent contact with feces, urine, vomit and saliva for 3 days after the dog has received treatment. Place all waste material in a plastic bag and seal before disposal. Pregnant and breast-feeding women should not administer the product, or handle urine or feces from dogs receiving the product.
- Verdinexor should be administered under the supervision of a veterinarian experienced in the use of cancer therapeutic agents.
- Use standard measures for the safe handling of all drugs.
- Do not eat, drink or smoke while handling the product.
- Do not store near food in or near a food preparation area.

### **In case of accidental exposure:**

Accidental skin contact: Tablets are coated and intact tablets should be considered safe for handling and minimal contact. In case of accidental skin contact with broken or crushed tablets, wash the affected area immediately and thoroughly with soap and water.

Accidental eye exposure: In case of accidental eye exposure:

- Remove contact lenses.
- Rinse the eyes with large amounts of tap water (use eyewash station if present) for 10 minutes while holding back the eyelid.
- Seek medical advice immediately and, if available, show the package insert or label to the physician.

Accidental oral exposure or ingestion: Seek medical advice immediately and show the client information sheet to your physician.

**Study Requirements:**

This pivotal field study (clinical trial) is a randomized, masked, placebo-controlled, pivotal effectiveness study that will enroll at least 125 dogs in several veterinary clinics in the US. The study will test the investigational drug compared to a placebo (a tablet that does not contain the investigational drug). There is a 1 in 5 chance that your dog will receive the placebo tablets. The investigational drug tablets or the placebo tablets will be administered in accordance to an established dose, orally twice per week with at least 72 hours between doses. Depending on how your dog tolerates the investigational treatment or the placebo after two weeks, the dose may be increased or decreased. Your participation in the study will be for 56 days during which time you will need to bring your dog to the veterinary clinic for scheduled or unscheduled follow up visits.

**Owner Requirements:**

If you elect to enroll your dog in this study your participation is important and needed. You will be required to perform the following tasks and record data on specific forms:

- ✓ Your dog's living environment and feeding habits during the duration of the study are up to you – at your discretion except that you must give the investigational treatment with food or just after feeding your dog a meal or a “snack”.
- ✓ Study Visits: You or a person designated by you will need to bring your dog in to the veterinary clinic for the Day 0, 7 ( $\pm 2$ ), 14 ( $\pm 2$ ), 28 ( $\pm 3$ ), 42 ( $\pm 3$ ) and 56 ( $\pm 3$ ) visits. Depending on how your dog is feeling, you may also be required to bring him/her for unscheduled visits. You will receive a phone call on Day 4 to determine if your dog should be re-evaluated before the scheduled Day 7 visit
- ✓ Dosing: You or a person designated by you will dose your dog at home orally twice per week with at least 72 hours between doses, at approximately the same time each day and record this information on CRF 15: Owner Records – Daily Dosing and Observations. You can discuss any problems or issues directly with Treatment Coordinator.
  - o Forms you or a person designated by you will need to complete: CRF 15: Owner Records – Daily Dosing and Observations
- ✓ You or a person designated by you should monitor your dog for any abnormal health observation during the study and record this information on the “Owner Observations” form. You or a person designated by you must contact the veterinarian as soon as possible should you have any concern.
  - o Forms you or a person designated by you will need to complete: CRF 15: Owner Records – Daily Dosing and Observations

**Funding:**

Since your dog has been identified as a candidate for enrollment he or she may already be showing signs (symptoms) of lymphoma. If you elect to enroll your dog in the study, the study sponsor will provide the investigational treatment to be used during the study and pay for the cost of the examinations and tests. If your dog has any adverse events that are study related and require treatment, the sponsor will cover the costs of reasonable treatment. In return for your dog's enrollment and your participation in the study, you will be eligible to receive a \$1,000 credit to be applied to your account at the veterinary clinic, provided your dog is not withdrawn due to non-compliance and you successfully complete the study and associated paperwork. If your dog is withdrawn due to other factors, your veterinarian will be compensated for the portion of the study your dog did complete.

**Withdrawal from the Study:**

You have the right to withdraw your dog from the study at any time and this will not affect future care of your dog. It is requested that any dog that is withdrawn early is brought into the veterinary clinic for examinations and tests.

**Other Options:**

Your dog's participation in this study is entirely voluntary. If your dog is determined eligible and you decline participation, there will not be any detrimental effect on the professional care and treatment of your pet(s).

**Confidentiality:**

Your name and information about your dog will be used strictly to relay information related to your pet's care and well-being. This information will not be shared or sold for any commercial purposes. It may be viewed by the sponsor of the study and/or their designee(s) for research purposes only.

**Additional Information:**

After you leave today, if you have any questions, please call the veterinary clinic for information. Since the investigational medication is a treatment for dogs only, always store it in a secure location, out of reach of children. To be eligible for study enrollment, the dog's medical history during the preceding 30 days must be known and documented accurately.

**Owner Consent:**

1. I have been informed of the possible benefits and risks associated with this investigational drug.
2. I have been informed of other conventional treatments available for treating my dog and have elected to pursue this clinical study.
3. I understand that there is a control treatment (placebo treatment) in this study.
4. I understand the financial responsibilities for my pet's medical care while in this study. The study is fully funded with respect to study diagnostics, administration, and management of investigational drug- related side effects during the study period.
5. I have been informed of the follow-up visits necessary for participation in this study.
6. I understand that part of my commitment to this study is completing a quality of life questionnaire on certain days during the study.
7. I acknowledge that no guarantees have been made to me concerning the expected results from my dog participating in this study.
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 any social media such as blogs, Twitter, Instagram 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, and that I would have an option to accept or decline such procedure.
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.

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.

<b>Owner First and Last Name:</b> (Print)	<b>Dog Name:</b> (Print)	
<b>Owner Signature:</b>	<b>Owner Initials:</b>	<b>Date:</b> (DD/MMM/YYYY)

<b>Study Case Number Assigned by Study Investigator or Designee:</b>	_____ - _____	
<b>Investigator Name:</b> (Print)	<b>Investigator Signature:</b>	<b>Date:</b> (DD/MMM/YYYY)