CVM-ClinicalTrials@osu.edu

Novel Therapeutic for Inflammatory Bowel Disease in Dogs

This study aims to look further into the effectiveness and impact of a novel biologic treatment for treating mediators of inflammation in dogs with canine inflammatory chronic enteropathy. Chronic inflammatory enteropathy (CIE) is a collective term used to describe gastrointestinal (GI) disorders that have clinical signs lasting more than three weeks or recurring clinical signs. Clinical signs of CIE include vomiting, diarrhea, abdominal pain, weight loss, and/or changes in appetite. CIE is not caused by parasites, bacterial infections, or cancer. The exact cause of CIE is not known; however, it is thought that many factors such as genetics, food components, stomach barrier, gut health and immune response may all contribute to CIE. Current treatments that may be prescribed for the management of clinical signs of CIE include special diets, antibiotics, or immunosuppressive drugs.

VMB-C001a is an investigational new drug and is a canine-specific monoclonal antibody (mAb). VMB-C001a has not been demonstrated to be safe or effective for the treatment of CIE and has not been approved by the FDA for any use. The purpose of this study is to investigate the safety and efficacy of VMB-C001a in dogs with CIE with no guaranteed effect as a medical treatment to participating dogs. The safety and effectiveness of VMB-C001a will be evaluated by comparing it to a placebo (a solution containing no active ingredient).

To be eligible for enrollment in this study, your dog must have chronic diarrhea (small, mixed, or large bowel diarrhea +/- vomiting). Tests to ensure his/her general health will be performed at the initial evaluation must meet all eligibility criteria for enrollment and to confirm a diagnosis at enrollment.

This study occurs over a 4 to 5-month period and requires that your dog be brought to OSU Veterinary Medical Center for evaluation by the investigators for at least 6 separate study visits throughout the 4 to 5-month period. Additional visits may be required to evaluate your dog and the need for treatment.

Your dog will first be evaluated for inclusion into the study during a Screening Visit. If your dog has not had a food trial with a limited ingredient or hydrolyzed diet, your dog will be placed on one of these diets for two weeks. It is very important that you do not feed your dog anything except the food provided by the Study Site during the food trial as your dog may improve with the change in diet alone and no medication is needed. If your dog improves with diet alone, your dog will not need to move forward in the study.

If your dog has already had a food trial or still qualifies for the study following the food trial, your dog may be scheduled for endoscopy. Endoscopy with gastrointestinal biopsies is required to confirm the diagnosis of CIE and rule out other causes of your dog's illness. Your dog will come into the Study Site between the Screening Visit and Day 1 to have endoscopy with biopsies collected. The Study Veterinarian may recommend hospitalizing your dog the night prior to the procedure for preparation for endoscopy. Prior to the endoscopy procedure, your dog will not be able to eat for approximately 24 hours. Your dog will be given medications to anesthetize your dog for the endoscopy procedure. During the endoscopy, a camera will be used to visually evaluate your dog's gastrointestinal tract and biopsies will be collected and sent to a laboratory for analysis. Once the results of the biopsies are available, the Study Veterinarian will review the results and evaluate your dog for inclusion into the Study. Your dog will be brought back to the veterinary clinic for Visit 1 (Day 0) if the biopsies confirm a diagnosis of CIE. Dogs that do not have a diagnosis of CIE will not be eligible to continue in the Study.

Procedures during the Study:
If your dog qualifies for enrollment at Visit 1, your dog will be assigned to treatment with either VMB-C001a or placebo (VMB-C001a and placebo may be referred to herein as "Study Drug") using a process called randomization and will begin treatment at Visit 1 (Day 0). Your dog has a 66% chance of being assigned to VMB-C001a and a 33% chance of being assigned to placebo. You and your Study Veterinarian will not know which treatment your dog is receiving; however, in the event of an emergency, your Study Veterinarian can find out your dog's treatment assignment, if necessary.

Your dog will come back to see the veterinary clinic for additional visits at days: 14 ±2 (Visit 2), 45 ±2 (Visit 3), 75 ±2 (Visit 4) and 105 ±2 (Visit 5). At Day 105, your dog will complete the study. Additional visits may be required during the study as recommended by the Study Veterinarian and depending on your dog's condition. No additional study visits will occur after Day 105.

At all Study Visits (Screening Visit and Visit 1-5), your Study Veterinarian will perform a complete physical examination, measure body weight, and ask you details about your dog's health history. Your Study Veterinarian will also ask you about medications your dog has received, if there have been any changes to your dog's diet, or changes in behavior or your dog's condition. You will complete a questionnaire about your dog's attitude/activity, appetite, vomiting, stool consistency, and stool frequency. A small amount of blood and urine will be collected at Study Visits: Screening, 1, and 5, and at the Endoscopy Visit and Visit 3 if needed. At Visits 2 (Day 14), 3 (Day 45) and Visit 4 (Day 75), your dog will receive additional study drug treatments.

Client Compensation:
The Sponsor is conducting this Study to investigate the efficacy of VMB-C001a for managing CIE in dogs. There is no guarantee that your dog will benefit, directly or indirectly, from participation in this Study. The results of this Study will impact the knowledge of the Study Drug and may be of benefit to other dogs in the future with CIE.

If your dog is deemed eligible for screening and enrollment, the costs of all Study-related procedures and dog food will be paid for entirely by the Sponsor. The Study Drug will be provided free of charge during the Study. You will not receive any additional Study Drug once your dog exits the Study. You will receive compensation for your dog's participation if enrolled in this Study. However, any travel expenses you may incur as a result of your participation in this Study will not be reimbursed.

If your dog experiences any adverse event during the Study that the Sponsor determines could be related to the Study Drug, the Sponsor will pay for reasonable and necessary veterinary fees and expenses related to the adverse event. You will resume responsibility for any veterinary care and costs for your dog after your dog has exited the Study.

Potential Medical Benefits:
The Sponsor is conducting this Study to investigate the efficacy of VMB-C001a for managing CIE in dogs. There is no guarantee that your dog will benefit, directly or indirectly, from participation in this Study. The results of this Study will impact the knowledge of the Study Drug and may be of benefit to other dogs in the future with CIE.

Potential Medical Risks:

- **General risks:** Because VMB-C001a is an investigational new animal drug, there is a chance your dog may not benefit from this drug. There is also a chance your dog will be placed in the placebo group and will not receive the investigational veterinary product.
- **General statement about Safety:** Since VMB-C001a is an investigational drug, there is limited information available about the risks of using VMB-C001 in dogs. The Sponsor has evaluated 3 dose levels of VMB-C001a in 20 healthy laboratory dogs. The highest monthly dose administered to 4 dogs was 18 mg/kg given monthly for 3 months, which is more than 1.5 times greater than the highest dose proposed in this Study. There were no significant adverse reactions.

There may be other risks that are unknown when taken alone or in combination with other medications. As with all drugs or medications that are the subject of research like VMB-C001a, there is a risk of an allergic reaction, which, if not treated promptly, could become life-threatening.

Although not expected in this study, there is a chance for discomfort or reaction related to collection of blood or urine samples (such as pain, bruising or infection at the site of sample collection). Urine sample collection by cystocentesis (as described above, using a needle through the abdominal wall) is usually not painful. There is a very small chance of bladder injury during cystocentesis or bladder expression.

Additionally, if your dog needs to have an endoscopy with gastrointestinal biopsies performed during the screening process, the risks associated with this procedure are complications of anesthesia and/or the endoscopy. Less <0.5% of endoscopy procedures have resulted in death.

While your dog is enrolled in the Study, it will not receive any of the current treatments such as special diets (other than the diet specified by the Study Veterinarian during the Study), antibiotics, or immunosuppressant drugs.

What qualifies my pet for enrollment?

Inclusion Criteria:

- Dogs of any age, sex, breed, or weight are eligible
- Dogs must have had chronic, intermittent vomiting, diarrhea, inappetence/anorexia, and/or weight loss for at least 3 weeks prior to the Screening Visit.

Exclusion Criteria:

- Dogs must not have any other serious concurrent illness.

Diagnosis/Condition Being Studied: Inflammatory Bowel Disease

Intervention to Be Studied: Clinical Effect of Novel Drug

Contact:

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If you believe your pet may be eligible for this study, please fill out a pre-screening questionnaire.