# Current Case Studies

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# Clinical Research & Informatics

Current Studies

## Study to Determine the Safety and Efficacy of TANOVEA™ (Rabacfosadine for Injection) in Cats with Lymphoma, Lymphoid Leukemia or Multiple Myeloma/Plasma Cell Tumor

The primary objective of this study is to determine the maximum tolerated dose, dose-limiting toxicities, safe starting dose, and pharmacodynamic effect of TANOVEA™ (rabacfosadine for injection) in cats with lymphoma, lymphoid leukemia, or multiple myeloma/plasma cell tumor.

A secondary objective of this study is to assess the efficacy and determine progression-free survival in treated cats.

**INCLUSION CRITERIA:**

- Species: Feline
- Breed: No specification
- Initial age: At least 1 year old on Day 0
- Weight: No weight requirement
- Sex: Male or female, intact or neutered
- Origin: Client–owned cats

**DIAGNOSIS:**

Cats must have a diagnosis of low, intermediate, or high grade, lymphocytic or lymphoblastic lymphoma, cytologically or histologically confirmed in any anatomic site.

**PRIOR TREATMENT:**

Prior surgery, radiotherapy, and/or chemotherapy are acceptable. There must be a two-week washout period between prior chemotherapy and Day 0 and a six-week washout period between radiotherapy and Day 0.

General health: Cats must be free of severe underlying disease (including underlying pulmonary pathology), be FeLV, and FIV negative, and have an expected survival of at least 6 weeks.

**EXCLUSION CRITERIA:**

- Cats that have received chemotherapy within 2 weeks of Day 0.
- Cats that have received non-steroidal anti-inflammatory drugs (NSAIDS) within 72 hours of Day 0. While on study, treatment with prednisone (1 mg/kg every other day) is acceptable.
- Cats that have received radiation therapy within 6 weeks of Day 0.
- Concurrent malignancy or other serious systemic disorder incompatible with this study.

**OWNER INCENTIVES:**

- TANOVEA™ (Rabacfosadine for Injection) is provided at no cost for use in this study.
- $1,500 client incentive for each cat enrolled, to be used for treatment costs.
- In the event of AE-related hospitalization costs as a result of participation in the study, up to $3,000 per cat to cover clinical trial-related hospitalization costs. This will be addressed on a case-by-case basis.
- Client is responsible for all other charges.

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# Clinical Research & Informatics

Current Studies

## Pulmonic Stenosis (PS) Study: Cats & Dogs

Pulmonic stenosis is a birth defect in the heart. It is caused by an incomplete pulmonary valve on the right side of the heart. It can result in serious, life-threatening changes in the way that the heart pumps blood. This study will aim to collect data on procedural technique of the corrective surgery.

**OWNER INCENTIVES**

Discounted charges for the procedure are the incentive. A free initial screening echocardiogram is included with the first visit. The client is responsible for all other charges including the initial standard exam fee. The procedure will be discounted and capped at $3,500.00.

**CONTACT**

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# Clinical Research & Informatics

Current Studies

## Patent Ductus Arteriosus (PDA) Study: Cats & Dogs

Patent ductus arteriosus (also called PDA) is a birth defect in the heart. It is caused by incomplete changes in the heart's circulation when a dog or cat is born. This results in serious, life-threatening changes in heart function and size. This study will aim to collect data on procedural technique of the corrective surgery.

**OWNER INCENTIVES**

Discounted charges for the procedure are the incentive. A free initial screening echocardiogram is included with the first visit. The client is responsible for all other charges including the initial standard exam fee. The procedure is normally $7,000 but will be discounted and capped at $4,000.

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# Clinical Research & Informatics

Current Studies

## Mitral Valve Disease Study: Dogs

**PURPOSE**

To evaluate the relevance of history and presentation in the evaluation of chronic valve disease in small breed dogs.

**CASE SELECTION**

All dogs <20kg and older than 8 years with a significant systolic heart murmur. Study will cover a free echocardiogram.

**EXCLUSION CRITERIA**

- Dogs with other clinically relevant cardiac diseases (minor tricuspid valve disease will be included).
- Dogs receiving antitussive medications (including corticosteroids, bronchodilators, cough suppressants).
- Dogs receiving cardiac medications (pimobendan, enalapril, spironolactone).

**OWNER INCENTIVES**

Clients will be responsible for some of the evaluation but will be given a substantial discount.

The following is provided by the Study at NO CHARGE to clients:

- Echocardiogram
- ECG

(A value of $794.33)

**CLIENT RESPONSIBILITIES**

Client is responsible for all other charges including, but not limited to:

- Exam fee
- Thoracic radiography (will not be repeated if adequate films already acquired)

**FOR MORE INFORMATION**

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# Clinical Research & Informatics

Current Studies

## Study to Determine the Efficacy and Safety of Alternating Rabacfosadine and Doxorubicin Treatments Against Multicentric Lymphoma in Previously Untreated Dogs

**OBJECTIVE:**

Lymphoma is one of the most common cancers in dogs. Current treatment options include various types of chemotherapy, including TANOVEA®-CA1 (rabacfosadine for injection), the first FDA conditionally approved drug to treat canine lymphoma. It is an intravenous chemotherapy agent that has been used both in normal dogs and in more than 600 dogs with cancer. The goal of this study is to evaluate the effectiveness and safety of rabacfosadine given once every 42 days alternating with doxorubicin given every 42 days.

**ELIGIBILITY REQUIREMENTS:**

- Patient must be at least 1 year old
- Histologic or cytologic diagnosis of lymphomas confirmed
- Documentation of immunophenotype
- Peripherally accessible and measurable disease
- No prior antineoplastic therapy, including corticosteroids
- Adequate organ function as indicated by:
    - Absolute neutrophil count > 2,000 cells/uL; Hematocrit > 25%; Platelet count > 75,000/uL: Serum creatinine <2.5 mg/dL; Bilirubin ≤ the upper normal limit; Transaminases ≤ 3 times the upper normal limit or if > 3 times the upper normal limit then serum bile acids must be ≤ the upper normal limit
- General performance score of 0 or 1 on Day 0 (VCOG-CTCAE v1.1)

**EXCLUSION CRITERIA:**

- Received chemotherapy
- Received radiation therapy
- Received long-acting corticosteroids within 4 weeks, or short acting corticosteroids within 1 week of Day 0
- General performance score of > 2 on Day 0.
- Pulmonary fibrosis or a history of chronic pulmonary disease that could lead to fibrosis, such as chronic bronchitis
- West Highland White Terrier Breed
- Concurrent malignancy or other serious systemic disorder which, in the Investigator's opinion, could results in a life expectancy of less than 3 months.
- Pregnant, lactating or intended for breeding.
- Any other reason which according to the Investigator, would affect the safety of the dog or severely interfere with study procedures.
- Currently enrolled in another clinical study
- Owned by an Investigator or his/her staff or family
- Any other reason which according to the Investigator, would affect the safety of the dog or interfere with study procedures

**OWNER INCENTIVE:**

Rabacfosadine will be provided at no cost. You will be responsible for the costs of the initial examination and tests to determine eligibility to participate, the recheck examinations, blood tests, and ancillary medications.

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# Clinical Research & Informatics

Current Studies

## Efficacy and Field Safety of Once Daily Oral Administration of LY3411067 for Control of Atopic Dermatitis in Client-Owned Dogs

**OBJECTIVE:**

The objectives of this pivotal field study are to confirm the effectiveness and safety of once daily oral administration of LY3411067 tablets in dogs with atopic dermatitis for the control of pruritus and/or skin lesions under field conditions. This is a blinded- placebo controlled study with a novel Janus kinase (JAK) inhibitor.

**ELIGIBILITY REQUIREMENTS:**

- Client-owned dog of any breed or sex, at least 12 months of age, weighing ≥ 3.0 kg.
- Diagnosis of atopic dermatitis (AD) for dog having compatible history and clinical signs. Diagnostic regimen should rule-out diseases resembling atopic dermatitis (food allergies, flea allergy dermatitis, primary bacterial or fungal dermatitides and/or otitis, internal and external parasitism, metabolic disease and others, as appropriate).
- Dog must have at least moderate pruritus (moderate itching as assessed by Owners).
- Dog must be physically healthy; serious or systemic disease must be well-controlled.
- Dogs that have recently discontinued NSAID therapy must meet a 6-week washout period.
- Dog must have no evidence of fleas at the baseline physical examination and have received a flea treatment at least 7 days prior to enrollment.
- Allergen-specific immunotherapy must have been ongoing for at least 6 months prior to enrollment and the same treatment schedule must be maintained throughout the study.
- Any nutritional products intended to alleviate signs of atopic dermatitis must have been on the therapy for at least 12 weeks prior to enrollment (use to remain consistent during the study).
- Any grooming aids, bathing products, or skin cleansers/topical antimicrobials must not contain glucocorticoids or topical anesthetics and must have been in use for at least 4 weeks prior to enrollment.
- Topical ear or eye treatments must not contain glucocorticoids.
- If the eye/ear product contains tacrolimus or cyclosporine, the treatment must have been given for at least 6 weeks prior to enrollment or a 2-week washout will be required.
- Dog must have a 4-week washout prior to Day 0 if treated with:
- Systemic cyclosporine, tacrolimus, oclacitinib, or other JAK inhibitors (e.g. Apoquel)
- Dog must have an 8-week washout prior to Day 0 if treated with:
    - Mid- to long-acting injectable glucocorticoids
    - Anti-IL31 monoclonal antibody injections (e.g. Cytopoint)

**OWNER INCENTIVE:**

The owner will be awarded up to $650 (combined cash/hospital credit) for their account if pet completes the study in its entirety.

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# Clinical Research & Informatics

Current Studies

## A Multi-Center, Pivotal, Clinical Effectiveness Study of a Canine-Specific Biologic (KIND-037) for the Treatment of Atopic Dermatitis in Dogs.

**OBJECTIVE:**
This is a pivotal, client-owned field study to evaluate the efficacy (with duration) and field safety of a single 1 mL/10 kg dose of final formulation Investigational Veterinary Product (IVP) in client-owned dogs with naturally acquired atopic dermatitis (not previously treated with any approved or unapproved monoclonal antibody (e.g. Cytopoint)). Safety will be assessed by collation of adverse events.

**ELIGIBILITY REQUIREMENTS:**

The dog:

1. Dog meets animal description outlined above
2. Has canine atopic dermatitis based on the dog's history (in the Investigator/Examining Veterinarian's opinion) and current clinical signs consistent with atopic dermatitis and fulfilling at least five of the following Favrot's Diagnostic Criteria:
    a. Age at onset < 3 years
    b. Dog living mostly indoors
    c. Corticosteroid-responsive pruritus
    d. Chronic or recurrent yeast infections
    e. Affected front feet
    f. Affected ear pinnae
    g. Non-affected ear margins
    h. Non-affected dorso-lumbar area
3. Has non-seasonal pruritus
4. Is free of fleas and other external parasites at Visit 1
5. Has been administered a long-lasting ectoparasiticide treatment a minimum of 14 days prior to Visit 1. All dogs must remain on ectoparasiticide treatment throughout the study.
6. Has a Pruritic Visual Analog Scale (PVAS) score ≥ 3.6 at Visit 1
7. Has a Canine Atopic Dermatitis Extent and Severity Index (CADESI) score ≥ 35 at Visit 1

**EXCLUSION CRITERIA:**

The dog:

1. Has clinical evidence of malignant neoplasia or immune suppression such as hyperadrenocorticism or generalized demodicosis

2. Has active superficial pyoderma or otitis externa (bacterial or fungal) or pyoderma that is resolving (e.g. resolving epidermal collarettes)

Note: Pre-existing superficial pyoderma and/or otitis externa may be treated as needed and the dog may be considered for study inclusion when the superficial pyoderma and/or otitis externa have fully resolved and applicable wash-out periods of any medications administered have been observed.

3. Is receiving concomitant marketed products or compounded products used for the control of pruritus associated with atopic or allergic dermatitis (including, but not limited to, oral cyclosporine (Atopica®), oclacitinib (Apoquel®), or glucocorticoids (prednisone, prednisolone, methylprednisolone acetate (Depomedrol®).

4. Is receiving concomitant prohibited medications and therapies except as indicated in the “Concomitant Medications” section below

5. Has been treated with any approved or unapproved monoclonal antibody intended to manage the clinical signs of atopic dermatitis (e.g. Cytopoint®)

6. Has undergone intradermal allergy testing within the previous 1 week of Visit 1

7. Has had a change in allergen specific immunotherapy within the previous 8 months (32 weeks) of Visit 1

8. Has had a diet change within 4 weeks of Visit 1

9. Has pruritic parasitic skin diseases (e.g. sarcoptic mange, cheyletiellosis)

10. Is pregnant or lactating

**OWNER INCENTIVE:**

The costs of all study-related procedures and administration of study drug or placebo will be paid for entirely by the Sponsor (no cost to owners).

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