

Inclusion & Exclusion Criteria for Randomized, blinded, placebo-controlled field study to determine the efficacy and safety of TANOVEA®-CA1 (rabacfosadine for injection) in dogs

Inclusion

All of the following must be true for the dog to be included in the study:

- At least one (1) year old on Day 0.
- Confirmed histologic or cytologic diagnosis of lymphoma by a veterinary pathologist.
 - o May have been previously treated or untreated.
 - o Must have peripherally accessible and measurable disease
- Adequate organ function as demonstrated by:
 - o Absolute neutrophil count (ANC) > 2,000 cells/μL
 - o Hematocrit > 25%
 - o Platelet count> 75,000/μL
 - o Serum creatinine < 2.5 mg/dL
 - o Bilirubin : ≤ the upper normal limit
 - o Transaminases : \leq 3 times the upper normal limit or if > 3 times the upper normal limit then fasting and postprandial serum bile acids must be \leq the upper normal limit
- Constitutional Clinical Signs General Performance score of either 0 or 1 on Day 0, (VCOGCTCAE vl.1).
- Signed owner informed consent.

Exclusion

The presence of any one of the following would result in the dog being excluded from entry into the study:

- Received chemotherapy within 2 weeks of Day 0
- Received radiation therapy within 6 weeks of Day 0
- Received long-acting corticosteroids within 4 weeks, or short-acting corticosteroids within 1 week of Day 0
- Received immunotherapy to treat lymphoma
- Received bleomycin
- Constitutional Clinical Signs General Performance score ≥ 2 on Day 0 (VCOG-CTCAE vl.1).
- Pulmonary fibrosis or a history of chronic pulmonary disease that could lead to fibrosis, such as chronic bronchitis.
- West Highland White Terrier breed, which has a genetic predisposition towards idiopathic pulmonary fibrosis
- Concurrent malignancy or other serious systemic disorder or infection which, in the Investigator's opinion, could result in a life expectancy of less than 3 months.
- Pregnant, lactating or intended for breeding
- Currently enrolled in another clinical trial
- 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.

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