A dog with allergic dermatitis was euthanized on Day 74 after physical examination revealed enlarged prescapular lymph nodes, bilateral orofacial swelling, and ascites. The dog was 32 weeks old and had been treated with oclacitinib maleate for 10 weeks before the physical examination. The dog had a history of distemper virus (CDV) and was negative for modified live virus vaccine. An adequate immune response (serology) to CDV was demonstrated on Day 74.

Vaccine Response Study

Clinical pathology findings considered to be oclacitinib maleate-related included increased reticulocyte count, neutrophil and monocyte counts, and decreased hemoglobin and hematocrit. Maleate-treated dogs had microscopic subcutaneous lumps (2.6% APOQUEL, 3.4% placebo), vomiting (3.9% APOQUEL, 0% placebo), and anorexia (1.4% APOQUEL, 0% placebo). These findings were consistent with the expected side effects of oclacitinib maleate. Dogs in the high dose (3X and 5X) treatment groups had increased reticulocyte count and decreased hemoglobin and hematocrit compared to placebo-treated dogs. These findings were consistent with the expected side effects of oclacitinib maleate.

Vincent's disease was a common finding in dogs treated with oclacitinib maleate, and was also observed in placebo-treated dogs. The incidence of Vincent's disease was higher in dogs treated with oclacitinib maleate compared to placebo-treated dogs. This finding was consistent with previous studies that showed an increased risk of Vincent's disease in dogs treated with oclacitinib maleate.

For additional information about adverse drug effects reported in clinical trials, please refer to the Safety Data Sheet, contact Zoetis Inc. at 1-888-FDA-VETS or online at www.Zoetis.com. For additional information about adverse drug reactions in humans, please refer to the FDA website at www.FDA.gov.
A double-masked, 30-day, controlled study was conducted to determine the effect of oclacitinib maleate (APOQUEL) on the resolution of pruritus associated with allergic dermatitis in dogs. The study included two treatment groups: APOQUEL and placebo (vehicle control). Dogs were included if they were 6-12 months old, had at least one report of pruritus, and had at least one report of skin lesions. The study was conducted over 30 days, with APOQUEL administered twice daily at a dose of 0.4-0.6 mg/kg per dose. The primary endpoint was the mean change from baseline in owner-assessed pruritus Visual Analog Scale (VAS) scores. Secondary endpoints included changes in other skins signs, such as erythema, crusts, and alopecia. The study showed that dogs treated with APOQUEL had a significantly greater improvement in pruritus compared to the placebo group. The APOQUEL group had a mean reduction in VAS score of 4.9 cm (from a baseline value of 6.2 cm) compared with the placebo group (mean reduction of 0.6 cm). The results indicated that APOQUEL was effective in reducing signs of allergic dermatitis, including pruritus and skin lesions, in dogs.