Oral presentations

Randomized, blinded European field studies to evaluate the efficacy and safety of a novel oral ectoparasiticide, Simparica™ Chewable Tablets (sarolaner), in dogs naturally infested with fleas and ticks

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The efficacy and safety of a novel oral ectoparasiticide, sarolaner (Simparica™ Chewable Tablets) at the intended commercial dose (2 to 4 mg/kg) against natural infestations of fleas and ticks in dogs was evaluated in two randomised, single blinded, multi-centred field studies in Europe. The efficacy of sarolaner to reduce the clinical signs associated with flea allergy dermatitis (FAD) and the palatability of Simparica™ chewable tablets were also evaluated. Spinosad (Comfortis® Chewable Tablets) and fipronil (Frontline® Spot On Dog) were used as comparators in the flea and tick study, respectively.

Dogs were treated on Days 0, 30 and 60. Efficacy was based on the mean percent reduction of live parasite counts

on Days 14, 30, 60 and 90 versus the pre-treatment count (Day 0). Non-inferiority of sarolaner to the comparators was assessed at each time point at a margin of 15%, one-sided $\alpha = 0.025$.

In total, 285 flea- and 181 tick-infested dogs were included for efficacy and safety assessment. Additionally, 137 and 48 dogs were assessed only for safety, respectively, in the flea and tick studies. There were no treatment related adverse events reported.

On Days 14, 30, 60 and 90, efficacy of sarolaner against fleas was 98.8%, 99.4%, 99.9% and 99.9% and that of spinosad was 98.9%, 93.7%, 96.8% and 95.1%, respectively. Simparica™ was non-inferior to Comfortis® at all time points and superior on Day 30. In the 42 dogs that were identified with FAD, the clinical signs of FAD improved following treatment administration in both groups.

In the tick study, efficacy of sarolaner was 97.4%, 97.6%, 99.8% and 100% and for fipronil it was 94.1%, 88.5%, 89.9% and 98.1% on Days 14, 30, 60 and 90, respectively. Simparica™ was non-inferior to Frontline® at all time points and superior on Days 30 and 60.

Sarolaner in Simparica™ chewable tablets was voluntarily and fully consumed within one minute on 93% of all 1280 offerings.

Sarolaner administered orally at monthly intervals at 2 to 4 mg/kg was safe and highly effective against natural infestations of fleas and ticks on dogs, and was at least as effective if not superior to commercial comparator products. Treatment with sarolaner improved the clinical signs of FAD and the Simparica™ chewable tablets were highly palatable.

The efficacy of sarolaner (Simparica™ Chewable Tablets) for the treatment of induced tick and flea infestations compared to fluralaner (Bravecto® Chewable Tablets) in dogs.

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Two randomised, placebo-controlled, double blinded, studies were conducted to compare the speed of kill of Simparica™ Chewable Tablets (sarolaner) to Bravecto® Chewable Tablets (fluralaner) against ticks and fleas in dogs.

In both studies, dogs received placebo, sarolaner or fluralaner orally on Day 0 (n=8/group; 3 groups/study). Dogs in the sarolaner groups were re-treated on Days 30 and 60, while the placebo and fluralaner groups received placebo on these days. Dogs were infested with 50 *Rhipicephalus sanguineus* ticks on days -2, 14, 28, 44, 58, 74, 90 and 95 and in the flea study with 100 *Ctenocephalides felis* fleas on days -1, 14, 29, 44, 59, 74 and 90.

Efficacy was calculated based on the percent reduction of mean live parasite counts in each treatment group at 8, 12 and 24 hours after treatment and each post-treatment infestation versus placebo. A mixed linear model for repeated measures was used to compare treatments.

Both products had >90% efficacy against ticks 12 hours after treatment and 100% by 24 hours after treatment. Tick counts were significantly lower for the fluralaner-treated dogs at 8 hours after treatment. For sarolaner, tick counts were significantly lower than fluralaner at the 24 hour time points on Days 44, 58, 74, 90 and 95.

Both products cleared the flea infestations completely within 8 hours (100% efficacy) after treatment (one single flea was found on one sarolaner-treated dog 24 hours after treatment). No fleas were found on any sarolaner-treated dogs at 12 and 24 hours after the post-treatment infestations or on any of the fluralaner-treated dogs at 24 hours. For sarolaner-treated dogs, flea counts were significantly lower than fluralaner at 8 hours on Days 74 and 90.

Both products evaluated demonstrated efficacy against ticks and fleas. Sarolaner had significantly greater efficacy from 6 weeks on at the 24 hours counts against ticks and in the last month at 8 hours against fleas than fluralaner. Fluralaner reduced tick counts significantly more than sarolaner 8 hours after treatment, likely due to the high dose needed to provide 3 months residual effectiveness. The significantly higher efficacy of sarolaner and more rapid speed of kill from 6–10 weeks after initial treatment reflects the consistent efficacy of sarolaner over the full monthly treatment period while effectiveness of fluralaner may be declining.