Serologic Response to and Duration of Immunity of a New Vaccine for Porcine Parvovirus, Erysipelas and Leptospirosis

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This abstract summarizes data supporting efficacy of a porcine parvovirus, *Erysipelothrix rhusiopathiae*, *Leptospira interrogans* serovars bratislava, canicola, grippotyphosa, hardjo, icterohaemorrhagiae, and pomona vaccine (FarrowSure® Plus B). The vaccine was designed to overcome inadequacies in currently available, similar products, including poor duration of immunity of the *E. rhusiopathiae* component. Three studies will be summarized: A serologic study, demonstrating superiority of the serologic response to FarrowSure Plus B compare to FarrowSure® B; an efficacy study demonstrating a 20 week duration of immunity for the *E. rhusiopathiae* component; and an efficacy study demonstrating a 26 week duration of immunity for the *E. rhusiopathiae* component.

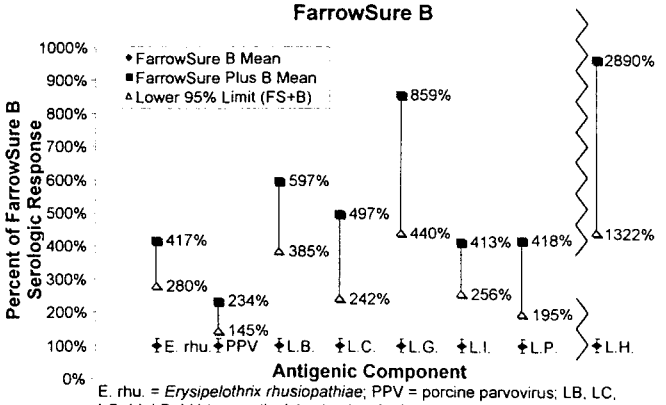
Serologic Study: A bioequivalence assay was conducted as a test of non-interference rather than a traditional interference study to evaluate the response of swine vaccinated with FarrowSure Plus B. FarrowSure B (adjuvanted with aluminum hydroxide gel) and FarrowSure Plus B (adjuvanted with Amphigen®) were prepared at comparable antigenic level with similar antigens, except that the *E. rhusiopathiae* of the FarrowSure Plus B was a clarified preparation. A 'zone of equivalence' to the control (FarrowSure B) was established as ±20% of the mean serologic response for a given antigen. To be non-inferior, the lower limit of the 95% confidence interval of the difference in response to the same antigen in FarrowSure Plus B must have been at least equal to the lower limit of the 'zone of equivalence'. In fact, the response to all antigens in FarrowSure Plus B were superior to FarrowSure B (Figure 1).

Efficacy/Duration of Immunity (20 weeks): Pigs were vaccinated with one of 4 vaccines, including a saline control; a 1/4X immunogenicity dosage of the *E. rhusiopathiae* component; the immunogenicity dosage (1X); and a 2X immunogenicity dosage. All other antigen dosages across the test vaccines were constant. Pigs were given 2 doses (5 mL each) about 3 weeks apart. Sera were collected prior to each vaccination and at regular intervals after vaccination. Pigs were challenged with a virulent culture of *E. rhusiopathiae* 20 weeks after the second vaccination. Animals were considered diseased if they had two consecutive days of elevated rectal temperatures (≥105.6°F for controls or ≥104.6°F for vaccinates) or *E. rhusiopathiae* was isolated from pigs with signs consistent with erysipelas. Saline vaccinated pigs were not protected (80% diseased) from challenge. Only 60% of the pigs vaccinated with the 1/4X dosage were protected. In contrast, 90% of the pigs vaccinated with the 1X or with the 2X dosage were protected from challenge.

Efficacy/Duration of Immunity (26 weeks): Pigs were similarly vaccinated, but the 1/4X immunogenicity group was not included. The pigs were challenged with *E. rhusiopathiae* 26 weeks after the second vaccination. Seventy percent of the saline vaccinated pigs were susceptible to challenge. Pigs vaccinated with the 1X or the 2X dosage were protected (85% and 90% respectively) from challenge.

Serologic Response: A profile of the serologic response after vaccination during the duration of immunity studies demonstrated a similar phenomenon: Saline controls did not respond serologically; the 1/4X dosage group responded weakly; the 1X and 2X dosage groups responded strongly and were not significantly different from each other in either duration of immunity study.

Figure 1. Difference between FarrowSure Plus B and FarrowSure B as a Percent of Response to FarrowSure B



E. rhu. = *Erysipelothrix rhusiopathiae*; PPV = porcine parvovirus; LB, LC, LG, LI, LP; LH (respectively) = *Leptospira interrogans* serovars bratilsava, canicola, grippotyphosa, icterohaemorrhagiae, pomona, and hardjo. Note that the LH scale is modified to fit in the same chart as the other antigens.