

## REPORT ON SAFETY TESTING OF SUVAXYN® PCV2 ONE DOSE

Fort Dodge Animal Health's Single-Dose Porcine Circovirus Vaccine Type 1-Type 2 Chimera (Killed Virus) Under Field Conditions

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### KEY POINTS

- The safety of Suvaxyn PCV2 One Dose, a single-dose porcine circovirus vaccine Type 1-Type 2 chimera killed virus vaccine from Fort Dodge Animal Health, was evaluated in commercial pigs at sites in Illinois, Iowa, North Carolina and Texas.
- Pigs were observed for local and systemic reactions for 2 weeks following vaccination.
- No local or systemic adverse reactions were observed following vaccination, giving Suvaxyn PCV2 One Dose a virtually reaction-free rating.

### EXPERIMENTAL DESIGN AND PROTOCOL

Four locations with commercial pigs were selected for the study. Only pigs evaluated as "healthy" by a veterinarian were enrolled in the study, and only 1 group of pigs per site was enrolled. Vaccinated pigs were about 4 weeks of age. Suvaxyn PCV2 One Dose was administered in a single 2-mL dose intramuscularly (IM).

Test animals were not randomized and no control groups were used in this study. The test vaccine was labeled with USDA-approved labels; thus, trial site personnel were not blinded to treatment.

The investigating veterinarian observed vaccinated pigs for 30 minutes, watching for immediate reactions such as salivation, labored or irregular breathing, shaking, or anaphylaxis. For 2 weeks following vaccination, pigs

were observed daily by the owner or site employees for any delayed reactions such as lethargy, anorexia or unusual swelling at the injection site. All reactions observed by or reported to the field investigator were recorded and classified as vaccine-related or nonrelated.

### RESULTS AND DISCUSSION

Results from the 4 test sites are summarized in Table 1.

#### Illinois Site

A total of 250 pigs (239 female and 11 male) were vaccinated. One pig died 8 days post-vaccination; mulberry heart disease was the cause of death. The investigating veterinarian reported no vaccine-related reactions.

#### Iowa Site

A total of 310 pigs (151 female and 159 male) were vaccinated. Four test group pigs died due to causes unrelated to vaccination and did not complete the study; *Streptococcus suis* was determined as the cause of death. The investigating veterinarian reported mild lethargy in several pigs immediately post-vaccination but attributed this to handling and ear tagging. No vaccine-related reactions were reported.

#### North Carolina Site

A group of 250 mixed-sex pigs was vaccinated. The investigating veterinarian reported no vaccine-related reactions.

#### Texas Site

A total of 300 pigs (140 male and 160 female) were vaccinated. The investigating veterinarian reported no vaccine-related reactions.

**TABLE 1: SAFETY RESULTS FOR SUVAXYN PCV2 ONE DOSE AT 4 TEST SITES**

LOCATION	NO. PIGS VACCINATED	NO. PIGS WITH ADVERSE REACTIONS	% REACTION-FREE RATING
Illinois	250	0*	100
Iowa	310	0**	100
North Carolina	250	0	100
Texas	300	0	100

\*One pig died 8 days post-vaccination due to mulberry heart disease.

\*\*Several pigs were lethargic 2 to 3 hours post-vaccination; behavior was associated with ear tagging. Four pigs died before the end of the trial; deaths were due to *Streptococcus suis*.

### CONCLUSION

None of the 1,110 pigs enrolled in this study exhibited post-vaccination reactions. All 4 investigating veterinarians reported satisfactory safety with Suvaxyn PCV2 One Dose.

Results from this study demonstrate the safety of Suvaxyn PCV2 One Dose under field conditions to be satisfactory when administered by IM injection to pigs 4 weeks of age.