Pfizer Animal Health

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FluSure® Pandemic: Challenge study[1]

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FluSure® Pandemic is for use in healthy swine, including pregnant sows and gilts, 3 weeks of age or older as an aid in preventing nasal shedding and reducing lung lesions caused by the pandemic H1N1 (pH1N1) strain of Swine Influenza Virus (SIV).

In 2009, the USDA provided Master Seed viruses of pH1N1 strains to multiple manufacturers in anticipation of potential transmission to swine herds. Pfizer Animal Health became the first U.S. biologics manufacturer to receive a USDA conditional license in 2009. The product gained full licensure from the U.S. Department of Agriculture in 2010.

The American Association of Swine Veterinarians (AASV) recommends vaccination for swine influenza to control clinical signs of disease due to SIV. Additionally, AASV recommends vaccination for pH1N1 if scientific evidence demonstrates that vaccination reduces viral shedding and the risk of transmission to pork-production personnel.

Pfizer Animal Health conducted a challenge study to demonstrate efficacy.

Trial Design

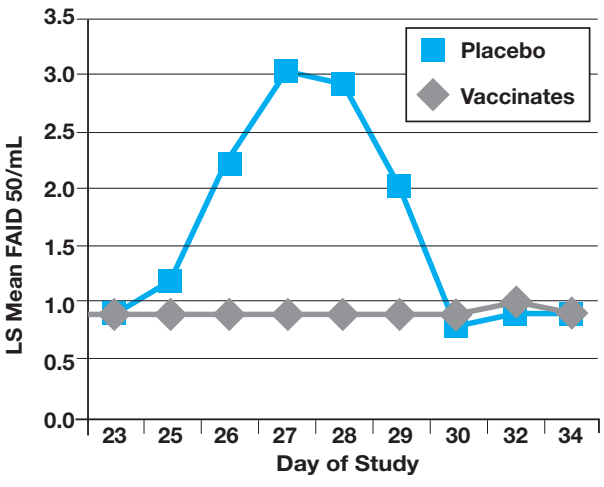
In this study, SIV-negative pigs, 3 to 4 weeks of age, were blocked by litter and randomized to treatment and pen using a generalized randomized block design.

Pigs were assigned to a placebo group (n=20), vaccinate group (n=20) or a non-vaccinated, non-challenged group (n=4). Treated pigs received two doses of vaccine at a two-week interval. Serum was collected on Day-1 and Day 21 (Table 1 on reverse side). Pigs were challenged intratracheally on Day 24. Half of the pigs from each treatment group were necropsied on Day 29 (five days post-challenge) and the remaining pigs were necropsied on Day 34 (10 days post-challenge). Researchers scored lung lesions and collected bronchioalveolar lavage (BAL) fluids for virus isolation.

Results

- Virus isolation found significantly less detectable virus in nasal swabs for pigs in the vaccinate group when compared to the placebo group at Day 25 (P=0.0098) and Days 26-29 (P≤0.0001) (Figure1).

Figure 1. Virus isolation from nasal swabs



Lung lesion scores in pigs in the vaccinate group were significantly lower (P≤0.0001) than the placebo group.

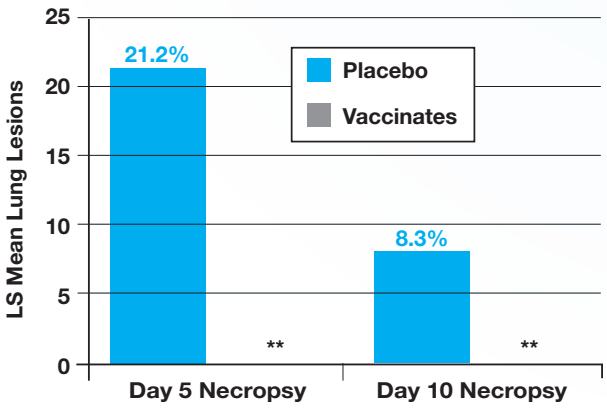
Table 1. HI antibody titers to A/CA/04/2009[a] and A/MX/4108/2009[b]

		GMT HI titer / virus			
		Day -1		Day 21	
Group	No. of pigs	CA/04	MX/4108	CA/04	MX/4108
Non-vaccinated, non-challenged	4	5	5	7.1	7.1
Placebo	20	5	5	10.0	7.6
Vaccinates	20	5	5	331.3	197.0

a. Pigs were vaccinated on Days 0 and 14 with vaccine prepared from A/CA/04/2009.

b. Pigs were challenged with A/MX/4108/2009.

Figure 2. Lung lesions in pigs vaccinated and challenge with a heterologous pH1N1 SIV



** P ≤ 0.0001, compared to placebo; 2-tailed t test

- Lung lesion scores in pigs in the vaccinate group were significantly lower (P≤0.0001) than the placebo group (Figure 2). LS mean lung lesion scores were 21.2 for pigs necropsied on Day 29 (five days post-challenge) and 8.3 for pigs necropsied at Day 34 (10 days post-challenge). LS mean score for the vaccinates was zero at both time points.
- Geometric mean virus titer in BAL fluids was significantly less for the vaccinate group (P=0.0001) than the placebo group at Day 29 (five days post-challenge) necropsy.
- No pigs showed clinical signs or respiratory disease post-challenge.

Discussion

Based on results of this study, FluSure Pandemic reduces viral shedding and lung lesions. Producers are advised to consult with their veterinarian, as well as continue to follow AASV recommendations for routine swine flu preventive measures and pH1N1 prevention.

References:

1. Data on file, Study Report No. 3121R-60-09-792, Pfizer Inc.

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