

## **NOVEL INFLUENZA VACCINE EFFICACY AND SAFETY ESTABLISHED FOR NEWBORN PIGS**

T. Kaiser 1, R. Smiley 1, B. Fergen 1, M. Eichmeyer 1, W. Johnson 1, M. Genzow 2, C. Goodell 1.

*1 Boehringer Ingelheim Vetmedica, Duluth, United States; 2 Boehringer Ingelheim Vetmedica GmbH, Ingelheim, Germany.*

### **Introduction**

Economic losses due to swine influenza (IAV-S) are substantial and a global problem, ranking among the top three major health challenges in the swine industry. Historic control strategies include the use of killed virus (KV) vaccines in breeding females to confer passive immunity to offspring, however effective protection requires KV vaccine and challenge virus to be closely related. Live attenuated influenza virus (LAIV) vaccines present an important platform with advantages to stimulate both cell-mediated and mucosal immunity. Boehringer Ingelheim has licensed a bivalent IAV-S (H1N1 and H3N2) LAIV vaccine (Ingelvac Provenza™).

### **Materials & Methods**

The vaccine strains have been attenuated by NS1 gene modification. When a host cell is infected with wild-type influenza virus, the intact NS1 protein suppresses the host cell interferon response. The vaccine's truncated NS1 gene encodes for a carboxy-truncated proteins which in turn does not diminish the host cell's interferon response. Licensing studies included: 10-times overdose safety (newborn pigs), non-target species safety (ferret, rat, chicken), dissemination/shed (dissemination within the body and shed from vaccinated pigs to sentinels), laboratory efficacy (challenge with heterologous viruses at 3 weeks post-vaccination), and field safety (997 pigs at 3 locations).

### **Results**

The laboratory safety studies in host animals and in non-target species showed no adverse observations during each 14-day trial. The dissemination/shed study detected virus in nasal secretions for up to 7 days post-vaccination with limited transmission to sentinels. Efficacy studies with pigs vaccinated at 1- to 5-days-old demonstrated protection against heterologous H3N2 and H1N2 viruses measured by lung lesions, clinical signs, and nasal virus shedding. Finally,

Investigators at field locations rated the product satisfactory after evaluating pigs daily for 14 days post-vaccination.

### **Discussion & Conclusion**

Ingelvac Provenza™ is the first commercial LAIV vaccine to demonstrate cross-protection efficacy and safety in pigs as young as 1 day of age.