Asian field efficacy studies for Porcilis PCV M Hyo

It's time for Porcilis® PCV M Hyo!

MSD Animal Health
The Science of Healthier Animals®

Porcilis® PCV M Hyo

Asian field efficacy studies

In three Asian countries, Porcilis® PCV M Hyo field efficacy was compared against competitor vaccines.

In this brochure we present you the main results and primary observations.

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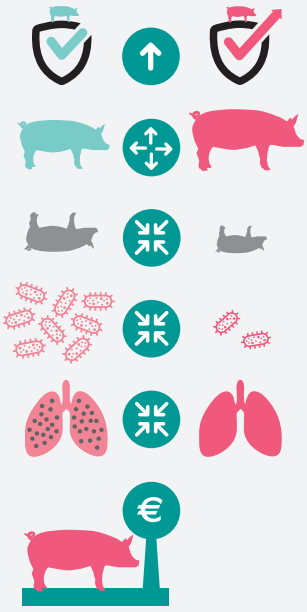
Results field efficacy studies

Primary observations from the field studies

Porcilis PCV M Hyo:

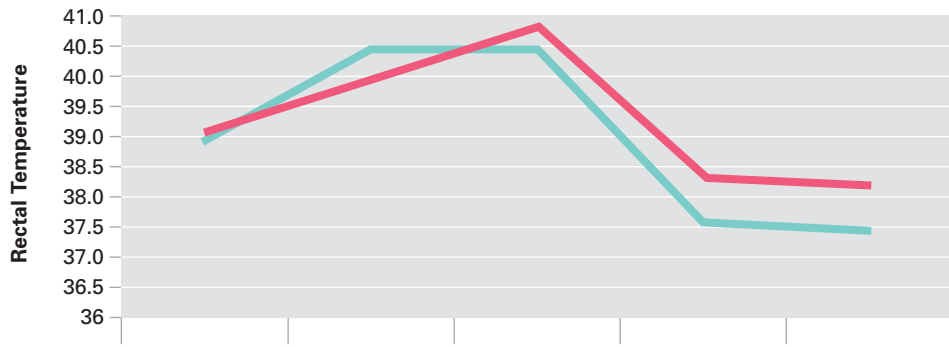
- demonstrated its safety in real farm conditions
- increased production efficacy through improved ADG
- reduced mortality
- reduced PCV2 viremia (showing a superior PCV2 control)
- reduced the severity of Lung Lesion Scores (showing a superior *Mycoplasma hyopnumoniae* protection)
- increased revenue per pig



Philippines *Thailand* *South Korea*

Porcilis® PCV M Hyo

Average Rectal Temperature



	0	4	8	24	48
	38.8	40.0	40.0	37.7	37.6
	38.9	39.5	40.3	38.3	38.2

Thailand

demonstrated safety in Thailand and Korea




	4 hrs	1 day	4 day	7 day	14 day
Farm 1	-	-	-	-	-
Farm 2	-	-	-	-	-

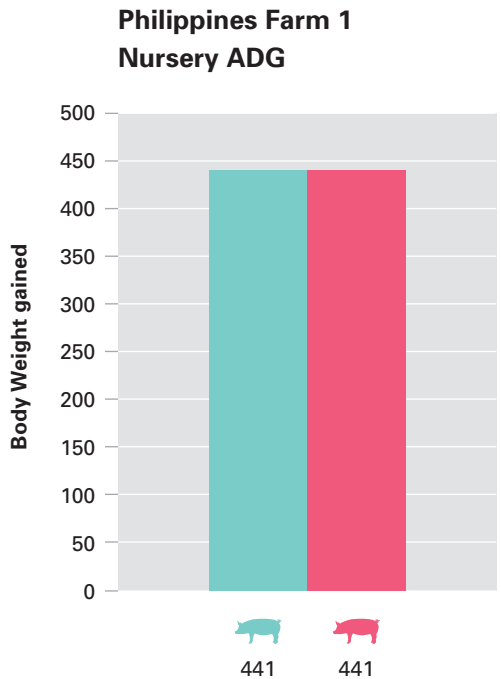
- No systemic reaction
- No local reaction
- No difference with competitors in reaction after vaccination

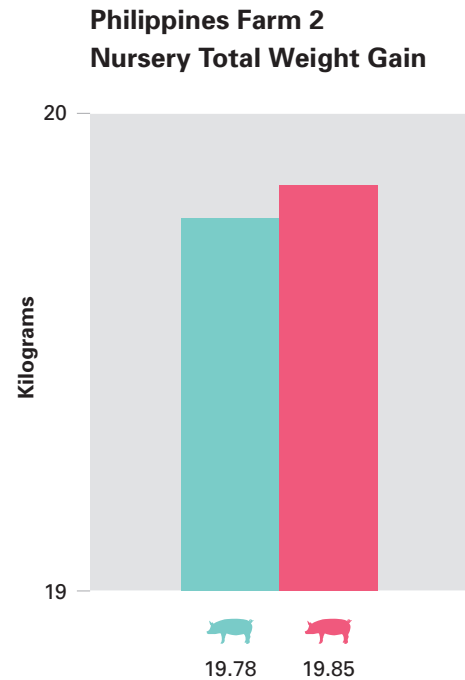
South Korea

Competitor

Porcilis PCV M Hyo

Porcilis® PCV M Hyo





Philippines

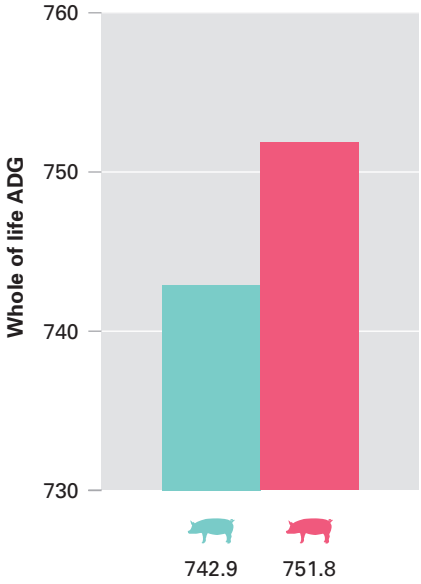
Impact on Average Daily Gain through nursery

Porcilis PCV M Hyo
demonstrated its safety in real farm conditions

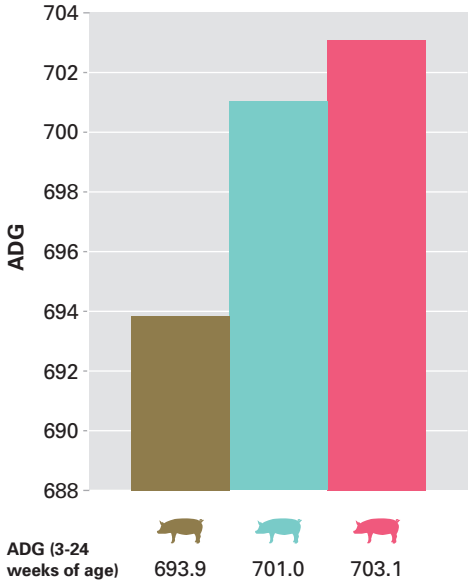
- No statistical difference in nursery ADG in Philippines.
- No difference to other products with regard to reaction after vaccination in South Korea.
- No statistical difference in rectal temperatures post vaccination in Thailand.

Porcilis® PCV M Hyo

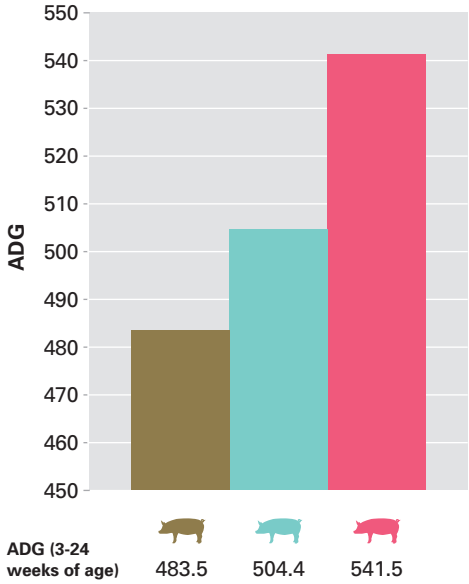
Thailand Farm 1
Wean to Finish ADG



Korean Farm 1
Wean to Finish ADG



Korean Farm 2
Wean to Finish ADG



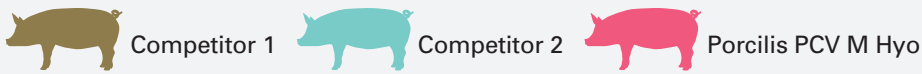
Thailand

South Korea

Impact on Average Daily Gain from wean to finish

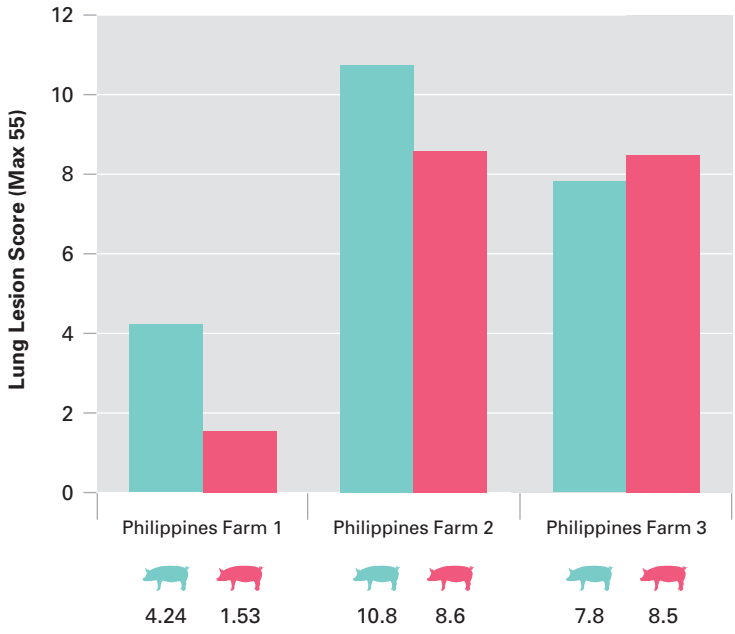
Porcilis PCV M Hyo
demonstrated its efficacy in real farm conditions

- Showed numerically and statistically higher ADG compared to competitor vaccines in different situations.



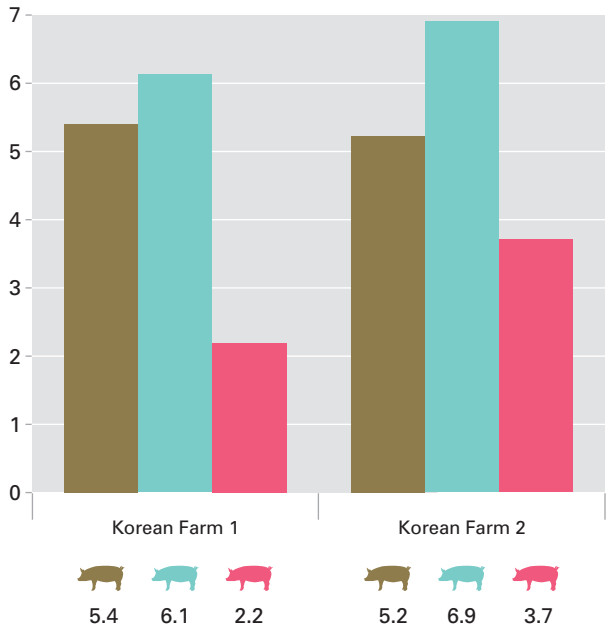
Porcilis® PCV M Hyo

Philippines Average Lung Lesion Scores



**Goodwin Scoring System (55)*

Korean Average Lung Lesion Score



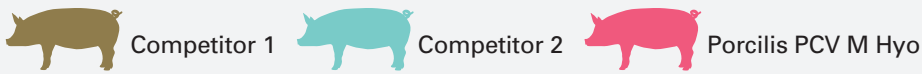
Philippines

South Korea

Impact on Lung Lesion Scores

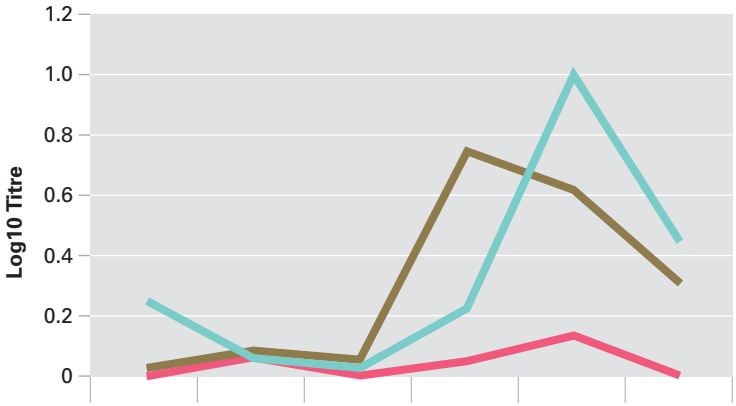
Porcilis PCV M Hyo
demonstrated its efficacy in real farm conditions

- Vaccination reduced the severity of Lung Lesion Scores at slaughter.
- In majority of countries/trials, Lung Lesion Scores were less severe in Porcilis PCV M Hyo pigs than in competitor pigs, as indicated by the higher percentage of pigs without (or with lower score) lesions.
- Porcilis PCV M Hyo provided superior protection against *Mycoplasma hyopneumoniae* as demonstrated by Lung Lesion Scoring.



Porcilis® PCV M Hyo

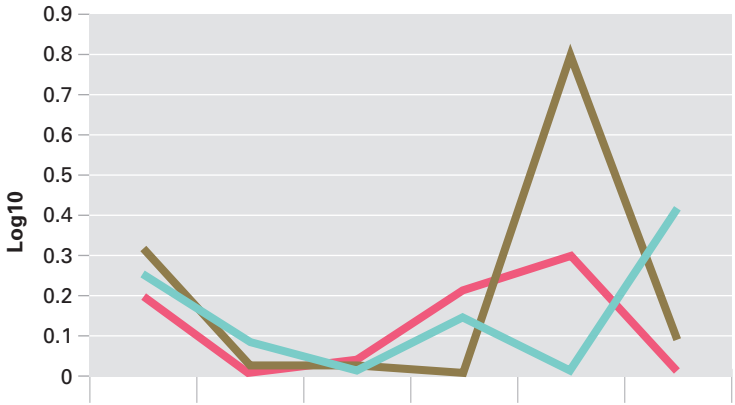
Korean Farm 1 PCV2 qPCR



	3 wks	7 wks	11 wks	15 wks	19 wks	26 wks
	0.03	0.08	0.06	0.75	0.62	0.31
	0.25	0.06	0.03	0.22	1.00	0.45
	-	0.06	-	0.05	0.13	-

Area under the Curve	
Competitor 1 [b]	12.15
Competitor 2 [b]	14.67
Porcilis PCV M Hyo [a]	1.16

Korean Farm 2 PCV2 qPCR



	3 wks	7 wks	11 wks	15 wks	19 wks	26 wks
	0.32	0.02	0.02	-	0.82	0.09
	0.25	0.08	-	0.14	-	0.42
	0.20	-	0.03	0.21	0.30	-

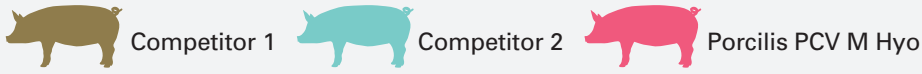
Area under the Curve	
Competitor 1 [a]	6.8
Competitor 2 [a]	8.31
Porcilis PCV M Hyo [a]	3.01

South Korea

PCV2 viremia by qPCR

Porcilis PCV M Hyo
demonstrated its efficacy in real farm conditions

- Area Under Curve (AUC) correlates to overall level of virus during the production phase.
- Statistically superior AUC in Korean Farm 1.
- Numerically superior AUC in Korean Farm 2.
- Lower AUC = lower levels of virus = reduced negative effects of PCV2 on production.
- Porcilis PCV M Hyo provided superior protection against Porcine Circovirus 2 infection as demonstrated by AUC measurement.



Porcilis® PCV M Hyo

Farm	PCV2 qPCR	Lung Lesion	ADG
Philippines 1	Not Tested	4.2 vs 1.5	612 vs 613
Philippines 2	Not Tested	10.8 vs 8.6	582.87 vs 585.99
Philippines 3	Not Tested	7.8 vs 8.5	Not Tested
Thailand 1	Not Tested	Not Tested	742.9 vs 751.8
Korea 1	12.15 vs 14.67 vs 1.15	5.4 vs 6.1 vs 2.2	693.9g vs 701.0g vs 703.1g
Korea 2	6.8 vs 8.31 vs 3.01	5.2 vs 6.9 vs 3.7	483g vs 504g vs 541g

Statistically or numerically superior for Porcilis PCV M Hyo

At least as good as competitor product

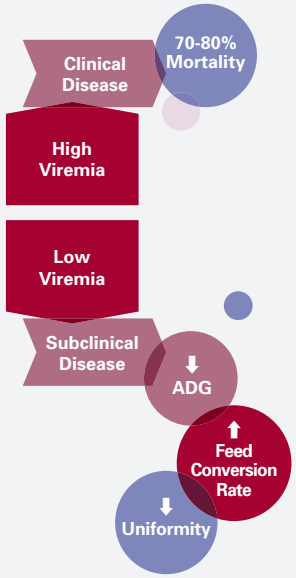
Philippines

Thailand

South Korea

Together they are stronger

PCV2 infection impacts the immune system, resulting in:

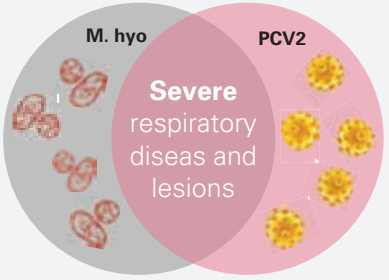


By themselves, PCV2 and Mycoplasma hyopneumoniae induce **mild** respiratory disease and lesions

Mycoplasma hyopneumoniae

- Initiator of Enzootic pneumonia
- A common agent in PRDC
- In PRDC, *Mycoplasma hyopneumoniae* potentiates disease caused by viral infections, such as PCV2
- Significantly reduces Average Daily Gain (ADG) in growing pigs
- Increases use of antibiotics

Concurrent infection



In concurrent infection, they induce **severe respiratory disease** and lesions consistent with PRDC

 Competitor 1

 Competitor 2

 Porcilis PCV M Hyo

Porcilis® PCV M Hyo
improved the paid revenue by at least USD 4.78

- 16 g/d ADG improvement  = $ 6.0 of revenue 
- 4.5% mortality reduction  = $ 9.0 of revenue 

Total result trials:
Improved income of $ 15.0 per finisher!

**This is based on average ADG and mortality reduction across the trials.*
Calculations are based on sale weight of 100kg, 600g ADG growth rate, $200/market hog and $0.5/kg of composite feed costs.

Research method

Farms - Philippines

- Philippines Farm 1 – 3600 sows Porcilis® PCV M Hyo vs Competitor
- Philippines Farm 2 – 800 sows Porcilis® PCV M Hyo vs Competitor
- Philippines Farm 3 – 1500 sows Porcilis® PCV M Hyo vs Competitor

Farms - Thailand

- Thailand Farm 1 – 2400 sows Porcilis® PCV M Hyo vs Competitor

Farms - South Korea

- South Korea Farm 1(G) – 500 sows Porcilis® PCV M Hyo vs Competitor 1 vs Competitor 2
- South Korea Farm 2(O) – 700 sows Porcilis® PCV M Hyo vs Competitor 1 vs Competitor 2

References
Lin HY, Merin K, Buyan M, Caraballe M (2017) COMPARATIVE FIELD STUDY OF PORCILIS PCV M HYO VERSUS OTHER PCV2 AND M HYO VACCINES IN A COMMERCIAL FARM IN THE PHILIPPINES The 8th Asian Pig Veterinary Society Congress Proceedings, pp 313 - Lee SY, Kim DW, Kim TY, Noh SH, Lin HY (2019) COMPARATIVE FIELD STUDY OF PORCILIS PCV M HYO VERSUS OTHER PCV2 AND M HYO VACCINES IN TWO COMMERCIAL FARMS IN SOUTH KOREA In Publication

Porcilis® PCV M Hyo succeeded where others couldn’t…

Following the procedure applied by Eggen et al., the inventors made a straightforward combination of an M.hyo bacterin and such a standard PCV2 VLP antigen with empty Emunade adjuvant. Unfortunately a vaccine was obtained that provided less than half the normal level of protection against a M.hyo challenge infection: lung lesions were only reduced by 30 %, as compared to reduction by 66 % when using a vaccine with only M.hyo antigen in Emunade (M+Pac™).

The inventors were therefore surprised to find the M.hyo vaccine efficacy in a ready-to-use.

PCV2/M.hyo combination vaccine for swine could only be brought to desired levels, by applying a special process to the preparation of the composition containing the vaccine antigens: by adding PCV2 antigen only after the complex of M.hyo antigen and Aluminium-hydroxide adjuvant had been formed.

Similarly, the inventors were surprised to find that a PCV2/M.hyo combination vaccine as described herein demonstrated such a significantly improved safety profile as compared to a PCV2 single-antigen vaccine.

Reference: patents.google.com/patent/WO2016091998A1/en

Comparative field study of Porcilis PCV M hyo versus other PCV2 and *M. hyo* vaccines in two commercial farms in South Korea

Lee Sengyoon[1], Kim Dongwook[1], Kim Taeyeon[1], Noh Sanghyun[3], Lin Hongyao[2],

[1]Han Byol Farm Tech, 216-1804, 34, Donong-ro, Namyangju-si, Gyeonggi-do, Korea 12251, [2]MSD Animal Health Innovation Pte Ltd, 1 Perahu Road Singapore 718847, [3]MSD Animal Health Korea Ltd, 22Fl., Seoul Square Building, 416 Hangang-daero, Jung-Gu, Seoul, Korea 04637

Introduction

Porcine Circovirus 2 (PCV2) and *Mycoplasma hyopneumoniae (M. hyo)* are among the most prevalent pathogens in finishing pigs, and are implicated in swine respiratory disease. Vaccination against PCV2 and *M. hyo* is standard practice in the Korean swine industry. The aim of this study was to compare and observe the field efficacy of Porcilis® PCV M Hyo against other frequently used combination or mixed PCV2 and *M. hyo* vaccines.

Materials and Methods

This study was performed in two commercial farms in South Korea with 500 (Farm 1) and 700 (Farm 2) sows respectively. 14 day old pigs were randomly allocated within litter to one of 3 treatments – Competitor 1: 50,100 piglets vaccinated at 3 weeks of age, Competitor 2: 50,100 piglets vaccinated at 3 weeks of age, Porcilis PCV M Hyo: 50,100 piglets vaccinated at 3 weeks of age. Efficacy parameters observed were Lung Lesion Score at slaughter (LLS), rt-PCR for PCV2 and Average Daily Gain from weaning to finishing (ADG). Safety parameters observed were local and systemic reactions up to 14 days post vaccination. PCV2 titers were tested with Median Diagnostics VDPro PCV2 Blocking ELISA on serum samples from 25 pigs per group every 4 weeks. Pig weights were collected individually at vaccination, at transfer to the finishing unit and before slaughter. Results were analyzed using Microsoft Excel Data Analysis Toolkit. T-test was used to compare ADG and Fisher's exact test was used to compare mortality, Lung Lesion Scores and Area Under the Curve (AUC) values to look for significant differences.

Results

From 3-26 weeks, Farm 1 PCV2 AUC was numerically different (12.15 vs 14.67 vs 1.16, P = 0.08) in favour of Porcilis PCV M Hyo. Farm 2 PCV2 AUC was numerically different (6.8 vs 8.31 vs 3.01, P = 0.54) in favour of Porcilis PCV M Hyo.

Farm 1 LLS was statistically different in favour of Porcilis PCV M Hyo (AVG LLS 5.4 vs. 6.1 vs 2.2; P = 0.02). Farm 2 LLS was numerically different in favour of Porcilis PCV M Hyo (AVG LLS 5.2 vs. 6.9 vs 3.7; P = 0.10). Overall ADG from weaning to finish was numerically favourable to Porcilis PCV M Hyo in Farm 1 (703g vs 701g vs 694g, P = 0.57) and statistically favourable to Porcilis PCV M Hyo in Farm 2 (541.5g vs 504.4g vs 483.5g, P = 0.02).

No local or systemic reactions were observed in the 14 day post vaccination period, across all 3 different vaccines used in the study.

Conclusion

The post vaccination observations support the fact that all 3 vaccines observed had a high safety profile when used in commercial swine. In two commercial farms with PCV2 and *M.hyo* field challenge, pigs vaccinated with Porcilis® PCV M Hyo showed both numerical and significant reduction in 1: lung lesions associated with *M. hyo*, 2: average PCV2 viremia titres compared to pigs vaccinated with competitor vaccines. ADG was also numerically or significantly improved by the use of Porcilis® PCV M Hyo.

Comparative field study of Porcilis PCV M hyo versus other PCV2 and *M. hyo* vaccines in a commercial farm in the Philippines

Lin Hongyao[1], Merin Katherine[2], Buyan Michael[2], Caraballe Marla[2]

[1]MSD Animal Health Innovation Pte Ltd, 1 Perahu Road Singapore 718847, [2]MSD AH Phils. 28F Philam Life Tower 8767 Paseo de Roxas Makati City, 1226 Philippines

Introduction

Porcine Circovirus 2 (PCV2) and *Mycoplasma hyopneumoniae (M. hyo*) are among the most prevalent pathogens in finishing pigs, and are implicated in swine respiratory disease. Vaccination against PCV2 and *M. hyo* is a standard practice in the Philippine pig industry, but a convenient ready to use 1-dose combination vaccine has not been available until recently. The aim of this study was to compare and observe field efficacy of Porcilis® PCV M Hyo against the frequently used PCV2 and 2-shot *M. Hyo* vaccines.

Materials and Methods

This study was performed under a controlled, randomized and blinded design in a commercial swine farm in the Philippines. One week old pigs were randomly allocated within litter to one of 2 treatments – 1: Positive Control: 236 piglets were given *M. hyo* (1st dose) on day 7 and given PCV and *M. hyo* (2nd dose) on day 21; 2: Treatment: 260 piglets were vaccinated with Porcilis® PCV M Hyo on day 21. Primary efficacy parameters observed were Lung Lesion Score at slaughter (LLS) and PCV2 serology. A total of 10% of the population underwent Lung Lesion Scoring. Secondary parameters observed were mortality and Average Daily Gain (ADG). Typical *M. hyo* lesions were scored at slaughter using the Goodwin Method. PCV2 titers were tested with quantitative Median Diagnostics VDPro PCV2 Ab ELISA Test Kit on serum samples from 10 pigs per group every 4 weeks. All animals included in the trial were weighed individually at vaccination, at transfer to the finishing unit and before slaughter. Results were analyzed using Microsoft Excel Data Analysis Toolkit. T-test was used to compare ADG and Fisher's exact test was used to compare mortality, Lung Lesion Scores and serological titres to look for significant differences.

Results

PCV2 serological response was not statistically different between the control and treatment groups across the production period (P =0.3833).

At slaughter, the treatment group had significantly more lungs with score 0 compared to control group (LLS 0 68% vs. 41%; P = 0.0420).

Mortality was numerically lower in the treatment group in nursery and overall (5.38 vs 5.93; P = 0.8682). In addition, overall ADG was comparable between groups at end of nursery (C=577g/day vs. T=564g/day), finisher (C=775g/day vs. T=779 g/day) and overall (C = 613g/day vs. T = 612 g/day; P = 0.9987)

Conclusion

In a commercial farm with a PCV2 and *M. hyo* field challenge, pigs vaccinated with Porcilis® PCV M Hyo significantly reduced *M.hyo* pneumonia lung lesions compared to pigs vaccinated with a competitor vaccine. Both vaccines were comparable with respected to PCV2 serological response, mortality and impact on ADG.

The results support that this 1-dose ready to use PCV/*M. hyo* vaccine has equal (ADG, mortality) or better performance (Lung Lesion Scores) as the 2-dose (3 injections) competitor vaccination program, and is, as such, more convenient. In summary, Porcilis® PCV M Hyo is a safe, efficacious and convenient vaccine to protect against PCV2 and *M. hyo* infections.

Porcilis PCV M Hyo:
Proven safe and sound

- One injection, double protection
- Ready to use; no mixing
- Safe, simple and proven
- Less stress, less labor

It's easy. It's safe. It works.

Porcilis® PCV M Hyo. Indications for use: For active immunization of clinically healthy pigs to reduce viremia, virus load in organs and lymphoid tissues, virus shedding caused by PCV2 infection, and severity of lung lesions caused by M. hyo infection. To reduce average daily weight gain loss during the finishing period in face of infections with M. Hyo and/or PCV2 (as observed in field studies). **PCV2:** Onset of immunity: 2 weeks after vaccination. **Duration of immunity**: 22 weeks after vaccination. **M. hyo**: Onset of immunity: 4 weeks after vaccination. **Duration of immunity:** 21 weeks after vaccination. **Administration:** Vaccinate pigs by the intramuscular route in the neck. A single dose of 2 mL in pigs starting at 3 weeks of age. Before using the vaccine, allow it to reach room temperature and shake well before use. Avoid introduction of contamination. **Precautions:** Vaccinate only healthy piglets. Do not mix Porcilis PCV M Hyo with any other veterinary medicinal product. Shelf life after first opening the immediate packaging is 8 hours. Store Porcilis PCV M Hyo in a refrigerator (2°C – 8°C). Do not freeze. Protect the vaccine from direct sunlight. **Composition:** Each dose of 2 mL (intramuscular application) contains: Active substances PCV2 ORF2 subunit antigen: ≥ 2828 AU[1] M. hyo J strain inactivated: ≥ 2.69 RPU[2] Adjuvant (Emunade) Light mineral oil: 0.268 mL Aluminium (as hydroxide): 2.0 mg 1 Antigenic units as determined in the in vitro potency test (ELISA). 2 Relative potency units defined against a reference vaccine.

www.pcv2-mhyo-control.com

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