



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	49K5.R6
True Name	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector, Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Circumvent PCV M G2 - Merck Animal Health Circumvent PCV M G2 - No distributor specified
Date of Compilation Summary	April 23, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy																														
Pertaining to	Porcine Circovirus Type 2a (PCV2a)																														
Study Purpose	Efficacy against disease caused by PCV2a including the prevention of viremia, the reduction of virus shedding and reduction of lymphoid depletion and infection																														
Product Administration	Two doses, administered intramuscularly at 3-week intervals																														
Study Animals	Commercial pigs, 3-5 days of age, 25 vaccinates and 24 controls																														
Challenge Description	Pigs were challenged 49 days post second vaccination with combination PCV2a and Porcine Reproductive and Respiratory Syndrome (PRRSv) viruses																														
Interval observed after challenge	Animals were evaluated 34 days post challenge																														
Results	<p><u>Viremia</u></p> <table border="1"> <thead> <tr> <th>Group¹</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>24/24</td> </tr> <tr> <td>Vaccinates</td> <td>1/25</td> </tr> </tbody> </table> <p><u>Nasal Shedding</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>24/24</td> </tr> <tr> <td>Vaccinates</td> <td>25/25</td> </tr> </tbody> </table> <p><u>Fecal Shedding</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>24/24</td> </tr> <tr> <td>Vaccinates</td> <td>25/25</td> </tr> </tbody> </table> <p><u>Lymphoid Depletion</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>19/24</td> </tr> <tr> <td>Vaccinates</td> <td>4/25</td> </tr> </tbody> </table> <p><u>Lymphoid Infection</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>19/24</td> </tr> <tr> <td>Vaccinates</td> <td>9/25</td> </tr> </tbody> </table> <p>¹One pig from the control group was removed from the study from cause unrelated to the study, prior to challenge.</p>	Group ¹	# Positive/ Total Animals	Controls	24/24	Vaccinates	1/25	Group	# Positive/ Total Animals	Controls	24/24	Vaccinates	25/25	Group	# Positive/ Total Animals	Controls	24/24	Vaccinates	25/25	Group	# Positive/ Total Animals	Controls	19/24	Vaccinates	4/25	Group	# Positive/ Total Animals	Controls	19/24	Vaccinates	9/25
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	Raw data shown on attached pages.
USDA Approval Date	July 6, 2012

PCV2 qPCR Results (log₁₀ DNA Copies/mL) of Serum Samples for Viremia

Pig ID	Treatment	15-Jun-11	01-Jul-11	22-Jul-11	18-Aug-11	25-Aug-11	2-Sep-11	9-Sep-11	16-Sep-11	22-Sep-11
		0DP1V	0DP2V	21DP2V	-1DPC	6DPC	14DPC	21DPC	28DPC	34DPC
319	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
321	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
323	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
325	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
326	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
327	Vaccine	*	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
331	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
333	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
334	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
336	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
337	Vaccine	*	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
343	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
344	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
345	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
348	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
350	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
354	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
357	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
359	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
361	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
365	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
367	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
368	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
373	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	4.1
374	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
318	Placebo	BLD	BLD	BLD	BLD	BLD	7.7	5.4	5.5	5.8
320	Placebo	BLD	BLD	BLD	BLD	BLD	7.1	6.8	7.4	6.3
322	Placebo	BLD	BLD	BLD	BLD	BLD	7.7	6.3	6.7	6.6
324	Placebo	BLD	BLD	BLD	BLD	BLD	6.5	5.7	5.8	6.3
328	Placebo	BLD	BLD	BLD	BLD	BLD	5.9	5.6	5.6	6.1
329	Placebo	BLD	BLD	BLD	BLD	BLD	6.7	6.5	6.5	6.8
330	Placebo	BLD	BLD	BLD	BLD	BLD	7.2	6.4	6.9	6.1
335	Placebo	*	BLD	BLD	BLD	BLD	7.4	7.7	5.6	5.6
339	Placebo	BLD	BLD	BLD	BLD	BLD	7.1	5.9	5.4	5.7
340	Placebo	BLD	BLD	BLD	BLD	BLD	7.7	6.6	6.1	6.1
341	Placebo	BLD	BLD	BLD	BLD	BLD	6.9	6.6	7.0	6.8
342	Placebo	BLD	BLD	BLD	BLD	BLD	7.2	6.1	6.4	6.3
346	Placebo	BLD	BLD	BLD	BLD	BLD	7.5	7.2	6.2	6.0
347	Placebo	BLD	BLD	BLD	BLD	BLD	3.9	7.6	6.6	6.7
349	Placebo	BLD	BLD	BLD	BLD	BLD	6.6	5.7	5.6	5.9
353	Placebo	BLD	BLD	BLD	BLD	BLD	6.7	6.0	6.0	6.2
356	Placebo	BLD	BLD	BLD	BLD	BLD	5.4	5.6	5.5	5.9
358	Placebo	BLD	BLD	BLD	BLD	BLD	NS	NS	NS	NS
362	Placebo	BLD	BLD	BLD	BLD	BLD	6.3	5.9	6.0	6.3
363	Placebo	*	BLD	BLD	BLD	BLD	5.2	5.9	5.7	6.2
366	Placebo	BLD	BLD	BLD	BLD	BLD	6.2	6.6	5.9	6.6
369	Placebo	BLD	BLD	BLD	BLD	BLD	5.4	6.1	5.2	5.7
370	Placebo	BLD	BLD	BLD	BLD	BLD	6.3	6.9	4.9	5.3
371	Placebo	BLD	BLD	BLD	BLD	BLD	7.5	8.3	7.1	7.6
372	Placebo	BLD	BLD	BLD	BLD	BLD	7.1	6.0	5.6	6.1

BLD = below limit of detection in qPCR assay DP1V = day post-first vaccination DP2V = day post-second vaccination DPC = day post-challenge NS = no sample
 * Two ODP1V serum tubes were labeled #327 and two were labeled #335, and samples #337 and 363 were missing. All four samples were BLD by qPCR

PCV2 qPCR Results (log10 DNA Copies/mL) of Nasal Swab Samples

Pig ID	Treatment	01-Jul-11 ODP2V	22-Jul-11 21DP2V	18-Aug-11 -1DPC	25-Aug-11 6DPC	2-Sep-11 14DPC	9-Sep-11 21DPC	16-Sep-11 28DPC	22-Sep-11 34DPC
319	Vaccine	BLD	BLD	BLD	BLD	4.3	4.5	BLD	BLD
321	Vaccine	BLD	BLD	BLD	BLD	5.0	5.3	4.5	BLD
323	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	4.2	4.4
325	Vaccine	BLD	BLD	BLD	BLD	BLD	4.0	BLD	BLD
326	Vaccine	BLD	BLD	BLD	BLD	4.6	4.7	4.0	BLD
327	Vaccine	BLD	BLD	BLD	BLD	4.8	5.2	4.1	3.9
331	Vaccine	BLD	BLD	BLD	BLD	4.5	4.1	3.9	BLD
333	Vaccine	BLD	BLD	BLD	BLD	4.4	4.1	4.2	3.9
334	Vaccine	BLD	BLD	BLD	BLD	4.0	4.3	BLD	BLD
336	Vaccine	BLD	BLD	BLD	BLD	4.1	4.2	4.0	4.0
337	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	BLD	4.2
343	Vaccine	BLD	BLD	BLD	BLD	5.2	4.6	4.2	BLD
344	Vaccine	BLD	BLD	BLD	BLD	4.6	4.6	BLD	4.1
345	Vaccine	BLD	BLD	BLD	BLD	4.9	4.9	4.0	BLD
348	Vaccine	BLD	BLD	BLD	BLD	4.8	4.4	4.2	BLD
350	Vaccine	BLD	BLD	BLD	BLD	4.8	5.6	4.1	4.1
354	Vaccine	BLD	BLD	BLD	BLD	BLD	4.2	3.9	BLD
357	Vaccine	BLD	BLD	BLD	BLD	3.9	4.7	BLD	BLD
359	Vaccine	BLD	BLD	BLD	BLD	BLD	4.9	4.0	BLD
381	Vaccine	BLD	BLD	BLD	BLD	4.0	5.2	BLD	BLD
365	Vaccine	BLD	BLD	BLD	BLD	3.9	4.3	BLD	4.0
367	Vaccine	BLD	BLD	BLD	BLD	BLD	5.2	4.6	3.9
368	Vaccine	BLD	BLD	BLD	BLD	BLD	5.3	4.0	BLD
373	Vaccine	BLD	BLD	BLD	BLD	BLD	5.1	4.1	4.3
374	Vaccine	BLD	BLD	BLD	BLD	BLD	5.6	4.8	4.1
318	Placebo	BLD	BLD	BLD	BLD	7.7	5.9	5.9	5.3
320	Placebo	BLD	BLD	BLD	BLD	7.7	5.9	6.9	5.7
322	Placebo	BLD	BLD	BLD	BLD	8.5	6.5	7.1	6.3
324	Placebo	BLD	BLD	BLD	BLD	7.5	5.9	5.6	5.5
328	Placebo	BLD	BLD	BLD	BLD	7.6	6.6	6.3	5.8
329	Placebo	BLD	BLD	BLD	BLD	6.8	6.9	7.6	5.8
330	Placebo	BLD	BLD	BLD	BLD	6.2	6.3	6.9	6.5
335	Placebo	BLD	BLD	BLD	BLD	8.4	5.8	5.8	6.1
339	Placebo	BLD	BLD	BLD	BLD	7.7	6.8	5.6	6.6
340	Placebo	BLD	BLD	BLD	BLD	8.7	7.5	6.8	6.2
341	Placebo	BLD	BLD	BLD	BLD	7.8	6.7	6.1	6.4
342	Placebo	BLD	BLD	BLD	BLD	8.8	6.8	6.4	5.6
346	Placebo	BLD	BLD	BLD	BLD	8.8	6.9	6.6	6.0
347	Placebo	BLD	BLD	BLD	BLD	8.5	7.1	6.0	5.1
349	Placebo	BLD	BLD	BLD	BLD	7.7	6.5	6.1	4.7
353	Placebo	BLD	BLD	BLD	BLD	8.2	7.1	6.5	6.5
356	Placebo	BLD	BLD	BLD	BLD	4.7	7.2	5.8	5.0
358	Placebo	BLD	BLD	BLD	BLD	NS	NS	NS	NS
362	Placebo	BLD	BLD	BLD	BLD	6.8	7.0	6.0	6.0
363	Placebo	BLD	BLD	BLD	BLD	6.1	7.3	6.8	5.7
366	Placebo	BLD	BLD	BLD	BLD	6.9	7.7	6.4	7.0
369	Placebo	BLD	BLD	BLD	BLD	5.8	7.2	5.6	6.2
370	Placebo	BLD	BLD	BLD	BLD	6.3	7.0	5.8	6.9
371	Placebo	BLD	BLD	BLD	BLD	7.4	8.2	6.7	6.3
372	Placebo	BLD	BLD	BLD	BLD	7.1	7.7	6.7	6.3

BLD = below limit of detection in qPCR assay DP2V = day post-second vaccination DPC = day post-challenge NS = no sample

PCV2 qPCR Results (log10 DNA Copies/mL) of Fecal Swab Samples

Pig ID	Treatment	01-Jul-11	22-Jul-11	18-Aug-11	25-Aug-11	2-Sep-11	9-Sep-11	16-Sep-11	22-Sep-11
		0DP2V	21DP2V	-1DPC	6DPC	14DPC	21DPC	28DPC	34DPC
319	Vaccine	BLD	BLD	BLD	BLD	5.0	4.8	BLD	BLD
321	Vaccine	BLD	BLD	BLD	BLD	4.6	5.1	4.6	BLD
323	Vaccine	BLD	BLD	BLD	BLD	4.9	4.1	3.9	BLD
325	Vaccine	BLD	BLD	BLD	BLD	4.4	5.0	3.9	BLD
326	Vaccine	BLD	BLD	BLD	BLD	4.6	5.2	3.9	BLD
327	Vaccine	BLD	BLD	BLD	BLD	5.4	4.9	3.9	BLD
331	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	3.9	BLD
333	Vaccine	BLD	BLD	BLD	BLD	BLD	3.9	4.5	BLD
334	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	BLD	BLD
336	Vaccine	BLD	BLD	BLD	BLD	4.3	BLD	BLD	BLD
337	Vaccine	BLD	BLD	BLD	BLD	4.1	BLD	BLD	BLD
343	Vaccine	BLD	BLD	BLD	BLD	4.7	4.7	4.0	BLD
344	Vaccine	BLD	BLD	BLD	BLD	4.3	5.0	3.9	BLD
345	Vaccine	BLD	BLD	BLD	BLD	4.8	4.6	BLD	BLD
348	Vaccine	BLD	BLD	BLD	BLD	4.6	4.5	BLD	BLD
350	Vaccine	BLD	BLD	BLD	BLD	5.2	5.1	4.7	BLD
354	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	BLD	BLD
357	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	BLD	BLD
359	Vaccine	BLD	BLD	BLD	BLD	4.0	4.4	BLD	BLD
361	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	BLD	BLD
365	Vaccine	BLD	BLD	BLD	BLD	BLD	3.9	BLD	BLD
367	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	4.1	BLD
368	Vaccine	BLD	BLD	BLD	BLD	4.0	4.5	4.0	BLD
373	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	BLD	BLD
374	Vaccine	BLD	BLD	BLD	BLD	4.0	4.2	4.2	BLD
318	Placebo	BLD	BLD	BLD	BLD	6.5	5.9	5.9	4.9
320	Placebo	BLD	BLD	BLD	BLD	6.6	6.8	5.9	5.6
322	Placebo	BLD	BLD	BLD	BLD	7.0	7.2	6.7	6.1
324	Placebo	BLD	BLD	BLD	BLD	6.3	6.6	5.6	4.8
328	Placebo	BLD	BLD	BLD	BLD	5.4	6.6	5.4	4.7
329	Placebo	BLD	BLD	BLD	BLD	4.9	8.5	6.9	6.0
330	Placebo	BLD	BLD	BLD	BLD	6.0	6.8	6.8	6.2
335	Placebo	BLD	BLD	BLD	BLD	6.3	5.6	5.4	4.9
339	Placebo	BLD	BLD	BLD	BLD	6.5	6.5	5.6	5.4
340	Placebo	BLD	BLD	BLD	BLD	6.4	6.9	6.2	6.0
341	Placebo	BLD	BLD	BLD	BLD	6.2	6.5	5.9	5.3
342	Placebo	BLD	BLD	BLD	BLD	6.4	6.5	5.6	5.3
346	Placebo	BLD	BLD	BLD	BLD	6.2	6.5	6.3	5.8
347	Placebo	BLD	BLD	BLD	BLD	7.1	7.3	6.1	5.6
349	Placebo	BLD	BLD	BLD	BLD	5.8	6.2	6.0	5.8
353	Placebo	BLD	BLD	BLD	BLD	5.9	6.7	6.1	5.4
356	Placebo	BLD	BLD	BLD	BLD	BLD	6.0	5.3	5.1
358	Placebo	BLD	BLD	BLD	BLD	NS	NS	NS	NS
362	Placebo	BLD	BLD	BLD	BLD	5.5	6.5	5.7	5.0
363	Placebo	BLD	BLD	BLD	BLD	4.2	6.3	5.2	5.1
366	Placebo	BLD	BLD	BLD	BLD	5.3	6.7	5.5	5.8
369	Placebo	BLD	BLD	BLD	BLD	4.9	6.4	6.7	6.0
370	Placebo	BLD	BLD	BLD	BLD	4.5	6.5	7.5	5.6
371	Placebo	BLD	BLD	BLD	BLD	5.9	7.8	7.4	6.6
372	Placebo	BLD	BLD	BLD	BLD	5.5	6.1	6.6	5.6

BLD = below limit of detection in qPCR assay DP2V = day post-second vaccination DPC = day post-challenge NS = no sample

Immunohistochemistry and Histopathology Scores of Lymphoid Tissues

Pig ID	Treatment	Lymphoid Infection (IHC)			Lymphoid Depletion		
		Tonsil	MLN	BLN	Tonsil	MLN	BLN
319	Vaccine	0	0	0	0	0	0
321	Vaccine	0	0	0	0	0	0
323	Vaccine	0	0	0	0	0	0
325	Vaccine	1 ^a	0	1 ^a	0	0	0
326	Vaccine	0	1 ^b	0	0	0	0
327	Vaccine	0	0	0	0	0	0
331	Vaccine	0	0	0	0	0	0
333	Vaccine	0	0	0	0	0	0
334	Vaccine	0	0	0	0	0	0
336	Vaccine	0	0	0	0	0	0
337	Vaccine	1	0	0	0	0	0
343	Vaccine	0	0	0	0	0	0
344	Vaccine	0	1 ^b	1 ^a	0	0	0
345	Vaccine	0	0	0	0	0	0
348	Vaccine	0	0	0	0	0	0
350	Vaccine	0	0	0	0	0	0
354	Vaccine	0	0	0	0	0	0
357	Vaccine	1 ^a	0	0	0	0	0
359	Vaccine	0	0	0	0	0	0
361	Vaccine	1	0	2	1	0	1
365	Vaccine	1	1	2	1	1	1
367	Vaccine	1 ^a	1 ^b	0	0	1	0
368	Vaccine	1	0	0 ^b	0	1	1
373	Vaccine	0	0	0	0	0	0
374	Vaccine	0	0	0	0	0	0
318	Placebo	0	0	0	0	0	0
320	Placebo	0	0	2	0	0	1
322	Placebo	1	1	2	1	1	1
324	Placebo	1	1	1	1	1	1
328	Placebo	0	0	1	0	0	1
329	Placebo	1	2	2	1	1	1
330	Placebo	0	1	2	0	1	1
335	Placebo	1	0	2	1	0	1
339	Placebo	1 ^a	0	1	0	0	1
340	Placebo	0	1	2	0	1	1
341	Placebo	1 ^a	0	2	0	0	1
342	Placebo	2	2	1	1	1	1
346	Placebo	1	1 ^a	2	1	1	1
347	Placebo	2	2	2	1	1	1
349	Placebo	0	1	2	0	1	1
353	Placebo	2	1	3	1	1	2
356	Placebo	1 ^a	0	1	0	0	1
362	Placebo	0	0	1	0	1	1
363	Placebo	0	0	0	0	0	0
366	Placebo	0	0	0	0	0	0
369	Placebo	0	1	0 ^b	0	1	1
370	Placebo	0	1	1	0	1	1
371	Placebo	0	0	0	0	0	0
372	Placebo	0	0	0	0	0	0

MLN = mesenteric lymph node; BLN = bronchial lymph node

^a Rare positive cells staining

^b Changes in the BLN, with extensive hemorrhage with plasma cells and eosinophils, are not typical for PCV2 infection, and appear most consistent with acute trauma and hemorrhage associated with bleeding prior to postmortem examination

Study Type	Efficacy																														
Pertaining to	Porcine Circovirus Type 2a (PCV2a)																														
Study Purpose	Efficacy against disease caused by PCV2a including the prevention of viremia, the reduction of virus shedding and reduction of lymphoid depletion and infection																														
Product Administration	Single dose, administered intramuscularly at 3 weeks of age																														
Study Animals	Commercial pigs, 3 weeks of age, 25 vaccinates and 26 controls																														
Challenge Description	Pigs were challenged 49 days post vaccination with combination PCV2a and Porcine Reproductive and Respiratory Syndrome (PRRSv) viruses																														
Interval observed after challenge	Animals were evaluated 35 days post challenge																														
Results	<p><u>Viremia</u></p> <table border="1"> <thead> <tr> <th>Group¹</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>26/26</td> </tr> <tr> <td>Vaccinates</td> <td>0/24</td> </tr> </tbody> </table> <p><u>Nasal Shedding</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>26/26</td> </tr> <tr> <td>Vaccinates</td> <td>19/24</td> </tr> </tbody> </table> <p><u>Fecal Shedding</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>26/26</td> </tr> <tr> <td>Vaccinates</td> <td>21/24</td> </tr> </tbody> </table> <p><u>Lymphoid Depletion</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>13/26</td> </tr> <tr> <td>Vaccinates</td> <td>4/25</td> </tr> </tbody> </table> <p><u>Lymphoid Infection</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive/ Total Animals</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>15/26</td> </tr> <tr> <td>Vaccinates</td> <td>5/25</td> </tr> </tbody> </table> <p>¹One pig from the vaccinate group was removed from the study from cause unrelated to the study, prior to challenge.</p> <p>Raw data shown on attached pages.</p>	Group ¹	# Positive/ Total Animals	Controls	26/26	Vaccinates	0/24	Group	# Positive/ Total Animals	Controls	26/26	Vaccinates	19/24	Group	# Positive/ Total Animals	Controls	26/26	Vaccinates	21/24	Group	# Positive/ Total Animals	Controls	13/26	Vaccinates	4/25	Group	# Positive/ Total Animals	Controls	15/26	Vaccinates	5/25
Group ¹	# Positive/ Total Animals																														
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Vaccinates	0/24																														
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Vaccinates	4/25																														
Group	# Positive/ Total Animals																														
Controls	15/26																														
Vaccinates	5/25																														
USDA Approval Date	November 5, 2012																														

PCV2 qPCR Results (log10 DNA Copies/mL) of Serum Samples for Viremia

Pig ID	Treatment	29-Jun-11	29-Jul-11	17-Aug-11	24-Aug-11	31-Aug-11	7-Sep-11	14-Sep-11	21-Sep-11
		0DPV*	21DPV	Challenge	7DPC	14DPC	21DPC	28DPC	35DPC
199	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
200	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
202	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
204	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
207	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
209	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
212	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
214	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
218	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
219	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
221	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
222	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
223	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
229	Vaccine	BLD	BLD	NS	NS	NS	NS	NS	NS
230	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
232	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
237	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
240	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
243	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
246	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
248	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	NS	NS
249	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
250	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
251	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
259	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
260	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
198	Placebo	BLD	BLD	BLD	BLD	6.8	7.6	6.2	6.7
201	Placebo	BLD	BLD	BLD	BLD	4.9	5.8	5.5	5.6
203	Placebo	BLD	BLD	BLD	BLD	7.0	7.0	6.8	6.5
205	Placebo	BLD	BLD	BLD	BLD	BLD	5.1	5.5	5.1
208	Placebo	BLD	BLD	BLD	BLD	5.3	5.8	5.6	4.6
210	Placebo	BLD	BLD	BLD	BLD	5.7	9.6	6.4	5.7
211	Placebo	BLD	BLD	BLD	4.0	7.7	7.4	6.4	6.2
213	Placebo	BLD	BLD	BLD	BLD	6.7	6.0	5.5	5.0
215	Placebo	BLD	BLD	BLD	BLD	6.0	6.0	5.7	5.4
216	Placebo	BLD	BLD	BLD	BLD	6.2	7.2	5.5	6.2
217	Placebo	BLD	BLD	BLD	BLD	8.1	6.0	5.7	5.3
220	Placebo	BLD	BLD	BLD	BLD	6.2	8.0	5.5	5.1
225	Placebo	BLD	BLD	BLD	BLD	4.6	8.3	5.5	5.3
226	Placebo	BLD	BLD	BLD	BLD	4.3	7.5	6.5	5.3
227	Placebo	BLD	BLD	BLD	BLD	6.1	5.7	6.0	5.5
231	Placebo	BLD	BLD	BLD	BLD	5.8	6.8	5.6	5.7
235	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	6.1	5.2
236	Placebo	BLD	BLD	BLD	BLD	BLD	6.2	5.5	4.9
241	Placebo	BLD	BLD	BLD	BLD	BLD	6.1	5.6	5.0
242	Placebo	BLD	BLD	BLD	BLD	8.3	6.2	5.9	6.6
252	Placebo	BLD	BLD	BLD	BLD	BLD	5.9	4.6	4.3
253	Placebo	BLD	BLD	BLD	BLD	7.3	7.9	5.7	6.1
254	Placebo	BLD	BLD	BLD	BLD	BLD	6.8	5.3	5.2
255	Placebo	BLD	BLD	BLD	4.0	6.8	7.2	5.9	5.4
256	Placebo	BLD	BLD	BLD	BLD	7.1	5.6	5.6	5.0
261	Placebo	BLD	BLD	BLD	BLD	5.8	8.3	6.5	6.2

BLD = below limit of detection in qPCR assay DPV = day post-vaccination DPC = day post-challenge NS = no sample

PCV2 qPCR Results (log10 DNA Copies/mL) of Nasal Swab Samples

Pig ID	Treatment	20-Jul-11	17-Aug-11	24-Aug-11	31-Aug-11	7-Sep-11	14-Sep-11	21-Sep-11
		21DPV*	Challenge	7DPC	14DPC	21DPC	28DPC	35DPC
199	Vaccine	BLD	BLD	BLD	BLD	4.6	4.9	BLD
200	Vaccine	BLD	BLD	BLD	BLD	4.3	4.3	BLD
202	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	BLD
204	Vaccine	BLD	BLD	BLD	BLD	4.3	4.0	4.0
207	Vaccine	BLD	BLD	BLD	BLD	BLD	4.2	BLD
209	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
212	Vaccine	BLD	BLD	BLD	BLD	4.4	4.6	BLD
214	Vaccine	BLD	BLD	BLD	4.0	4.2	4.6	BLD
218	Vaccine	BLD	BLD	BLD	BLD	3.9	4.1	BLD
219	Vaccine	BLD	BLD	BLD	BLD	4.7	4.5	BLD
221	Vaccine	BLD	BLD	BLD	BLD	4.5	4.2	BLD
222	Vaccine	BLD	BLD	BLD	4.6	4.0	4.8	BLD
223	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
229	Vaccine	BLD	NS	NS	NS	NS	NS	NS
230	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
232	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
237	Vaccine	BLD	BLD	BLD	BLD	BLD	3.9	BLD
240	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
243	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
246	Vaccine	BLD	BLD	BLD	BLD	BLD	4.2	BLD
248	Vaccine	BLD	BLD	BLD	3.9	4.7	NS	NS
249	Vaccine	BLD	BLD	BLD	4.1	5.0	5.1	BLD
250	Vaccine	BLD	BLD	BLD	4.3	4.3	3.9	BLD
251	Vaccine	BLD	BLD	BLD	4.1	4.8	5.1	4.1
259	Vaccine	BLD	BLD	BLD	4.3	4.2	4.4	BLD
260	Vaccine	BLD	BLD	BLD	BLD	BLD	4.6	BLD
198	Placebo	BLD	BLD	BLD	5.2	6.5	5.9	5.8
201	Placebo	BLD	BLD	BLD	6.3	7.4	6.0	5.8
203	Placebo	BLD	BLD	BLD	6.5	7.9	5.9	6.5
205	Placebo	BLD	BLD	BLD	BLD	7.3	6.0	5.2
208	Placebo	BLD	BLD	BLD	4.2	6.7	5.3	5.3
210	Placebo	BLD	BLD	BLD	7.2	7.2	5.5	6.9
211	Placebo	BLD	BLD	4.6	6.3	7.4	5.6	7.5
213	Placebo	BLD	BLD	BLD	6.7	6.0	5.7	5.1
215	Placebo	BLD	BLD	BLD	4.5	5.1	5.3	4.6
216	Placebo	BLD	BLD	BLD	5.0	5.9	5.6	5.5
217	Placebo	BLD	BLD	BLD	6.7	6.7	6.0	5.3
220	Placebo	BLD	BLD	BLD	5.1	6.3	5.2	4.8
225	Placebo	BLD	BLD	BLD	BLD	6.7	6.1	6.3
226	Placebo	BLD	BLD	BLD	BLD	5.3	5.2	4.8
227	Placebo	BLD	BLD	BLD	5.4	6.1	6.6	6.0
231	Placebo	BLD	BLD	BLD	4.1	5.7	5.7	5.7
235	Placebo	BLD	BLD	BLD	BLD	3.0	5.2	5.3
236	Placebo	BLD	BLD	BLD	BLD	5.3	5.1	5.0
241	Placebo	BLD	BLD	BLD	BLD	5.6	5.1	5.1
242	Placebo	BLD	BLD	BLD	6.3	5.1	5.6	5.5
252	Placebo	BLD	BLD	BLD	4.0	5.3	5.4	5.9
253	Placebo	BLD	BLD	BLD	6.5	5.6	6.1	6.2
254	Placebo	BLD	BLD	BLD	4.0	5.8	5.5	5.1
255	Placebo	BLD	BLD	BLD	6.1	6.1	6.0	6.4
256	Placebo	BLD	BLD	BLD	7.7	7.2	6.1	5.3
261	Placebo	BLD	BLD	BLD	6.8	7.7	6.9	6.1

BLD = below limit of detection in qPCR assay DPV = day post-vaccination DPC = day post-challenge NS = no sample

PCV2 qPCR Results (log10 DNA Copies/mL) of Fecal Swab Samples

Pig ID	Treatment	20-Jul-11	17-Aug-11	24-Aug-11	31-Aug-11	7-Sep-11	14-Sep-11	21-Sep-11
		21DPV*	Challenge	7DPC	14DPC	21DPC	28DPC	35DPC
199	Vaccine	BLD	BLD	BLD	BLD	3.9	BLD	BLD
200	Vaccine	BLD	BLD	BLD	BLD	5.4	4.1	3.9
202	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	BLD
204	Vaccine	BLD	BLD	BLD	BLD	4.9	3.9	BLD
207	Vaccine	BLD	BLD	BLD	4.4	4.0	BLD	BLD
209	Vaccine	BLD	BLD	BLD	4.1	4.1	4.3	3.9
212	Vaccine	BLD	BLD	BLD	BLD	4.5	4.7	4.3
214	Vaccine	BLD	BLD	BLD	BLD	4.6	4.3	BLD
218	Vaccine	BLD	BLD	BLD	4.0	4.9	5.4	4.0
219	Vaccine	BLD	BLD	BLD	4.1	4.3	4.5	3.9
221	Vaccine	BLD	BLD	BLD	4.5	4.7	4.0	BLD
222	Vaccine	BLD	BLD	BLD	BLD	4.6	4.7	BLD
223	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
229	Vaccine	BLD	NS	NS	NS	NS	NS	NS
230	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	BLD
232	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
237	Vaccine	BLD	BLD	BLD	BLD	4.0	4.1	BLD
240	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
243	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD
246	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	4.2
248	Vaccine	BLD	BLD	BLD	BLD	4.3	NS	NS
249	Vaccine	BLD	BLD	BLD	4.2	4.1	4.9	BLD
250	Vaccine	BLD	BLD	BLD	4.7	5.4	4.6	3.9
251	Vaccine	BLD	BLD	BLD	4.4	5.1	4.3	BLD
259	Vaccine	BLD	BLD	BLD	4.1	4.0	BLD	BLD
260	Vaccine	BLD	BLD	BLD	4.0	BLD	3.9	BLD
198	Placebo	BLD	BLD	BLD	6.0	7.0	6.6	6.0
201	Placebo	BLD	BLD	BLD	4.1	5.8	5.0	5.2
203	Placebo	BLD	BLD	BLD	6.1	7.7	7.7	6.3
205	Placebo	BLD	BLD	BLD	4.0	5.7	6.1	5.0
208	Placebo	BLD	BLD	BLD	4.4	5.6	5.8	4.7
210	Placebo	BLD	BLD	BLD	BLD	7.6	7.2	6.5
211	Placebo	BLD	BLD	BLD	7.4	8.2	6.2	6.2
213	Placebo	BLD	BLD	BLD	5.2	6.2	5.9	5.7
215	Placebo	BLD	BLD	BLD	4.8	6.8	6.0	5.2
216	Placebo	BLD	BLD	BLD	5.4	5.6	6.3	5.3
217	Placebo	BLD	BLD	BLD	6.4	6.3	6.1	5.8
220	Placebo	BLD	BLD	BLD	BLD	6.0	5.4	5.6
225	Placebo	BLD	BLD	BLD	BLD	5.8	6.0	5.3
226	Placebo	BLD	BLD	BLD	BLD	6.4	7.2	6.4
227	Placebo	BLD	BLD	BLD	6.1	6.4	6.6	6.3
231	Placebo	BLD	BLD	BLD	3.9	5.7	6.0	5.2
235	Placebo	BLD	BLD	BLD	BLD	BLD	5.0	5.5
236	Placebo	BLD	BLD	BLD	BLD	6.1	6.3	5.8
241	Placebo	BLD	BLD	BLD	BLD	6.0	6.3	5.9
242	Placebo	BLD	BLD	BLD	6.7	6.5	6.2	5.3
252	Placebo	BLD	BLD	BLD	4.0	6.1	5.4	5.6
253	Placebo	BLD	BLD	BLD	6.5	7.2	6.9	6.8
254	Placebo	BLD	BLD	BLD	4.3	6.0	6.0	6.3
255	Placebo	BLD	BLD	BLD	7.2	7.0	5.8	6.4
256	Placebo	BLD	BLD	BLD	6.8	7.3	6.7	6.0
261	Placebo	BLD	BLD	BLD	5.4	7.5	6.8	6.2

BLD = below limit of detection in qPCR assay DPV = day post-vaccination DPC = day post-challenge NS = no sample

Immunohistochemistry and Histopathology Scores of Lymphoid Tissues

Pig ID	Treatment	Lymphoid Infection (IHC)			Lymphoid Depletion		
		Tonsil	MLN	BLN	Tonsil	MLN	BLN
199	Vaccine	0	0	0	0	0	0
200	Vaccine	0	0	0	0	0	0
202	Vaccine	0	0	0	0	0	0
204	Vaccine	0	0	0	0	0	0
207	Vaccine	1 ^a	0	1 ^a	0	0	0
209	Vaccine	0	0	0	0	0	0
212	Vaccine	0	0	0	0	1	1
214	Vaccine	0	0	0	0	0	0
218	Vaccine	0	0	0	0	0	0
219	Vaccine	0	0	1 ^a	0	0	1
221	Vaccine	0	0	0	0	1	1
222	Vaccine	1	0	1 ^a	0	0	1
223	Vaccine	0	0	0	0	0	0
230	Vaccine	0	0	1 ^a	0	0	0
232	Vaccine	0	0	0	0	0	0
237	Vaccine	0	0	0	0	0	0
240	Vaccine	0	0	0	0	0	0
243	Vaccine	0	0	1 ^a	0	0	0
246	Vaccine	0	0	0	0	0	0
248	Vaccine	NS ^c	0 ^c	0 ^c	NS ^c	0 ^c	0 ^c
249	Vaccine	0	0	0	0	0	0
250	Vaccine	0	0	0	0	0	0
251	Vaccine	0	0	0	0	0	0
259	Vaccine	0	0	0	0	0	0
260	Vaccine	0	0	0	0	0	0
198	Placebo	0	0	1 ^a	0	0	0
201	Placebo	0	0	0	0	0	0
203	Placebo	1	0	1	1	1	1
205	Placebo	0	0	1 ^a	0	0	0
208	Placebo	1	0	0	0	0	0
210	Placebo	0	0	0	0	0	0
211	Placebo	0	2	2	0	1	1
213	Placebo	0	1	0	0	1	1
215	Placebo	0	0	0	0	0	1
216	Placebo	1 ^a	1	1	0	1	1
217	Placebo	2	0	1	1	1	1
220	Placebo	0	0	0	0	0	0
225	Placebo	0	0	0	0	0	0
226	Placebo	0	0	0	0	0	0
227	Placebo	0	0	1	0	0	1
231	Placebo	0	0	0	0	0	0
235	Placebo	0	0	0	0	0	0
236	Placebo	0	0	0	0	0	0
241	Placebo	0	0	0	0	0	0
242	Placebo	1	1	1	0	1	1
252	Placebo	0	0	0	0	0	0
253	Placebo	0	0	2	0	0	1
254	Placebo	0	0	2	0	0	1
255	Placebo	0	1	3	0	1	2
256	Placebo	1	1	2	0	1	1
261	Placebo	3	3	3	2	2	2

MLN = mesenteric lymph node; BLN = bronchial lymph node; NS = no sample

^a rare positive cells staining

^b BLN hemorrhage (not typical for PCV2 infection and appears most consistent with acute trauma and hemorrhage associated with bleeding prior to postmortem examination)

^c For pig #248, tonsil was not found (wrong tissue collected) and MLN and BLN were collected three weeks post-challenge

Study Type	Efficacy																					
Pertaining to	<i>Mycoplasma hyopneumoniae</i>																					
Study Purpose	Efficacy against disease caused by <i>Mycoplasma hyopneumoniae</i>																					
Product Administration	A single dose, administered intramuscularly at 3-4 weeks of age																					
Study Animals	Commercial pigs, 3-4 weeks of age, 25 vaccinates and 40 controls																					
Challenge Description	Pigs were challenged 33 days post vaccination with <i>Mycoplasma hyopneumoniae</i>																					
Interval observed after challenge	Lungs were evaluated 28 days post challenge																					
Results	<p>Summary for lung consolidation (%)</p> <table border="1"> <thead> <tr> <th>Group</th> <th>No. of Pigs per Group</th> <th>Min</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>39¹</td> <td>2.9</td> <td>12.4</td> <td>18.4</td> <td>25.7</td> <td>49.4</td> </tr> <tr> <td>Vaccinates</td> <td>25</td> <td>0.3</td> <td>2.4</td> <td>5.4</td> <td>8.1</td> <td>41.2</td> </tr> </tbody> </table> <p>¹One pig from the control group was removed from the study by cause unrelated to the study, prior to challenge.</p> <p>Raw data shown on attached pages.</p>	Group	No. of Pigs per Group	Min	Q1	Median	Q3	Max	Controls	39 ¹	2.9	12.4	18.4	25.7	49.4	Vaccinates	25	0.3	2.4	5.4	8.1	41.2
Group	No. of Pigs per Group	Min	Q1	Median	Q3	Max																
Controls	39 ¹	2.9	12.4	18.4	25.7	49.4																
Vaccinates	25	0.3	2.4	5.4	8.1	41.2																
USDA Approval Date	July 17, 2013																					

Lung Score Data of Control Pigs

Sow No.	Pig No.	Treatment	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
659	245	Placebo	2.60	3.15	2.87
659	247	Placebo	12.80	11.50	12.15
659	248	Placebo	11.61	8.79	10.20
659	497	Placebo	12.15	12.58	12.36
733	747	Placebo	37.85	36.44	37.15
733	749	Placebo	31.24	35.25	33.24
733	750	Placebo	32.86	49.57	41.21
733	753	Placebo	49.78	48.92	49.35
682	759	Placebo	22.78	22.67	22.72
682	763	Placebo	5.64	4.45	5.04
682	764	Placebo	18.22	20.07	19.14
682	765	Placebo	18.87	18.00	18.44
878	770	Placebo	32.75	32.21	32.48
878	771	Placebo	11.71	13.23	12.47
878	773	Placebo	32.10	34.71	33.41
878	775	Placebo	25.49	29.39	27.44
787	776	Placebo	18.66	21.80	20.23
787	777	Placebo	13.23	13.45	13.34
787	778	Placebo	21.48	20.28	20.88
787	784	Placebo	8.79	9.87	9.33
792	790	Placebo	13.99	13.99	13.99
792	791	Placebo	3.47	3.25	3.36
792	793	Placebo	5.42	5.97	5.69
872	800	Placebo	20.72	18.22	19.47
872	803	Placebo	23.86	23.97	23.92
872	806	Placebo	11.93	14.64	13.29
785	810	Placebo	16.27	16.49	16.38
785	813	Placebo	15.62	15.29	15.46
785	814	Placebo	19.09	17.57	18.33
785	818	Placebo	15.94	19.74	17.84
599	819	Placebo	38.72	34.06	36.39
599	820	Placebo	32.43	30.37	31.40
599	826	Placebo	5.21	5.75	5.48
720	830	Placebo	23.64	20.93	22.29
720	831	Placebo	23.10	17.68	20.39
720	838	Placebo	34.06	30.04	32.05

Sow No.	Pig No.	Treatment	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
732	841	Placebo	19.20	18.44	18.82
732	845	Placebo	16.59	15.62	16.11
732	846	Placebo	9.00	9.33	9.16

Lung Score Data of Vaccinated Pigs

Sow No.	Pig No.	Treatment	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
659	243	Vaccinate	9.44	9.54	9.49
659	249	Vaccinate	2.28	2.60	2.44
733	746	Vaccinate	33.41	25.60	29.50
682	755	Vaccinate	8.57	6.40	7.48
682	756	Vaccinate	4.12	4.23	4.18
682	762	Vaccinate	3.15	4.12	3.63
878	767	Vaccinate	5.86	6.94	6.40
878	774	Vaccinate	38.83	43.60	41.21
787	785	Vaccinate	0.00	0.87	0.43
792	789	Vaccinate	1.08	1.19	1.14
792	794	Vaccinate	6.62	5.31	5.97
792	796	Vaccinate	1.84	1.95	1.90
872	797	Vaccinate	1.30	2.17	1.74
872	799	Vaccinate	0.54	0.00	0.27
785	812	Vaccinate	6.18	6.83	6.51
785	815	Vaccinate	3.90	4.34	4.12
785	816	Vaccinate	24.40	28.96	26.68
599	825	Vaccinate	7.92	6.18	7.05
599	827	Vaccinate	17.46	18.11	17.79
720	829	Vaccinate	20.17	21.80	20.99
720	833	Vaccinate	3.80	4.34	4.07
720	835	Vaccinate	5.10	5.64	5.37
732	839	Vaccinate	4.88	3.90	4.39
732	840	Vaccinate	7.70	8.57	8.13
732	844	Vaccinate	2.49	2.17	2.33

Study Type	Efficacy																					
Pertaining to	<i>Mycoplasma hyopneumoniae</i>																					
Study Purpose	Efficacy against disease caused by <i>Mycoplasma hyopneumoniae</i>																					
Product Administration	Two doses, administered intramuscularly at 3-week intervals																					
Study Animals	Commercial pigs, 3-4 days of age, 25 vaccinates and 25 controls																					
Challenge Description	Pigs were challenged from 49-51 days post second vaccination with <i>Mycoplasma hyopneumoniae</i>																					
Interval observed after challenge	Lungs were evaluated 28 days post challenge																					
Results	<p>Summary for lung consolidation (%)</p> <table border="1"> <thead> <tr> <th>Group</th> <th>No. of Pigs per Group</th> <th>Min</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>24¹</td> <td>2.2</td> <td>4.2</td> <td>7.5</td> <td>12.5</td> <td>33.6</td> </tr> <tr> <td>Vaccinates</td> <td>25</td> <td>0</td> <td>0.7</td> <td>3.3</td> <td>4.7</td> <td>45.8</td> </tr> </tbody> </table> <p>¹One pig from the control group died by cause unrelated to the study, prior to challenge.</p> <p>Raw data shown on attached pages.</p>	Group	No. of Pigs per Group	Min	Q1	Median	Q3	Max	Controls	24 ¹	2.2	4.2	7.5	12.5	33.6	Vaccinates	25	0	0.7	3.3	4.7	45.8
Group	No. of Pigs per Group	Min	Q1	Median	Q3	Max																
Controls	24 ¹	2.2	4.2	7.5	12.5	33.6																
Vaccinates	25	0	0.7	3.3	4.7	45.8																
USDA Approval Date	June 18, 2012																					

Lung Score Data of Control Pigs

Sow No.	Pig No.	Treatment	Pig No.	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
447	117	Placebo	2	3.25	1.74	2.49
447	119	Placebo	4	7.81	7.16	7.48
447	111	Placebo	5	36.01	31.13	33.57
573	104	Placebo	7	6.40	4.12	5.26
573	102	Placebo	10	2.17	2.60	2.39
573	110	Placebo	11	10.95	8.57	9.76
573	106	Placebo	13	12.04	12.04	12.04
573	107	Placebo	14	3.69	4.45	4.07
636	129	Placebo	18	13.77	9.98	11.88
636	122	Placebo	19	1.95	2.49	2.22
636	128	Placebo	20	9.54	5.53	7.54
639	155	Placebo	26	32.75	24.19	28.47
641	151	Placebo	29	6.51	5.53	6.02
641	152	Placebo	31	7.05	7.70	7.38
641	148	Placebo	32	6.51	6.40	6.45
765	130	Placebo	34	2.82	3.58	3.20
765	139	Placebo	35	12.91	11.82	12.36
765	132	Placebo	36	4.34	4.23	4.28
765	138	Placebo	40	8.03	7.05	7.54
765	131	Placebo	41	16.16	14.21	15.18
447	116	Placebo	45	3.90	2.93	3.42
444	145	Placebo	50	20.28	18.33	19.31
444	144	Placebo	51	13.77	11.61	12.69
444	141	Placebo	53	19.41	13.88	16.65

Lung Score Data of Vaccinated Pigs

Sow No.	Pig No.	Treatment	Intervet Pig No.	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
447	115	Vaccinate	1	1.08	1.08	1.08
447	112	Vaccinate	3	3.69	2.82	3.25
573	105	Vaccinate	8	4.23	3.47	3.85
573	101	Vaccinate	9	6.72	6.51	6.62
573	109	Vaccinate	12	0.54	0.76	0.65
573	103	Vaccinate	15	0.87	0.87	0.87
636	123	Vaccinate	16	5.10	3.25	4.18
636	124	Vaccinate	17	0.76	0.54	0.65
636	126	Vaccinate	21	15.18	14.32	14.75
636	127	Vaccinate	23	1.19	1.30	1.25
639	154	Vaccinate	24	48.48	43.17	45.82
636	121	Vaccinate	25	6.29	5.10	5.69
641	153	Vaccinate	30	0.00	0.33	0.16
641	150	Vaccinate	33	0.00	0.00	0.00
765	135	Vaccinate	37	0.76	0.00	0.38
765	133	Vaccinate	38	7.16	4.88	6.02
765	134	Vaccinate	39	3.58	3.36	3.47
765	136	Vaccinate	43	0.87	0.43	0.65
444	140	Vaccinate	44	5.42	4.56	4.99
447	118	Vaccinate	46	2.93	2.49	2.71
447	114	Vaccinate	47	4.56	3.15	3.85
641	147	Vaccinate	48	4.77	4.34	4.56
444	143	Vaccinate	49	1.30	0.43	0.87
444	146	Vaccinate	52	0.54	0.87	0.70
444	142	Vaccinate	54	5.75	3.58	4.66

Study Type	Efficacy																																	
Pertaining to	Porcine Circovirus Type 2a (PCV2a)																																	
Study Purpose	To demonstrate efficacy against PCV2a 20 weeks after vaccination.																																	
Product Administration	2 doses administered 19 days apart by the intramuscular (IM) route.																																	
Study Animals	45, 3 – 5-day old, pigs; 23 controls, 22 vaccinates																																	
Challenge Description	20 weeks post-2 nd vaccination, all pigs were challenged with PCV2a and Porcine Reproductive and Respiratory Syndrome Virus.																																	
Interval observed after challenge	Pigs were observed daily for 35 days following challenge for clinical signs of PCV2a disease. Samples were collected weekly to evaluate viremia and shedding. Lymphoid tissue was examined at Day 35 post challenge.																																	
Results	<p><u>Viremia:</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive for Viremia/Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>1/22</td> </tr> <tr> <td>Controls</td> <td>22/23</td> </tr> </tbody> </table> <p><u>Virus Shedding:</u> Fecal Samples:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive for Virus Shedding/Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>19/22</td> </tr> <tr> <td>Controls</td> <td>23/23</td> </tr> </tbody> </table> <p>Nasal Samples:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive for Virus Shedding/Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>13/22</td> </tr> <tr> <td>Controls</td> <td>23/23</td> </tr> </tbody> </table> <p><u>Lymphoid Infection:</u> Number of pigs with a score of 1 or greater/total for immunohistochemistry against PCV2a in lymphoid tissue</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Tonsil</th> <th>MLN</th> <th>BLN</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>5/22</td> <td>1/22</td> <td>3/22</td> <td>7/22</td> </tr> <tr> <td>Controls</td> <td>9/23</td> <td>7/23</td> <td>12/23</td> <td>14/23</td> </tr> </tbody> </table> <p>MLN: mesenteric lymph node; BLN: bronchial lymph node</p> <p>Raw data shown on attached pages.</p>	Group	# Positive for Viremia/Total	Vaccinates	1/22	Controls	22/23	Group	# Positive for Virus Shedding/Total	Vaccinates	19/22	Controls	23/23	Group	# Positive for Virus Shedding/Total	Vaccinates	13/22	Controls	23/23	Group	Tonsil	MLN	BLN	Total	Vaccinates	5/22	1/22	3/22	7/22	Controls	9/23	7/23	12/23	14/23
Group	# Positive for Viremia/Total																																	
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Group	Tonsil	MLN	BLN	Total																														
Vaccinates	5/22	1/22	3/22	7/22																														
Controls	9/23	7/23	12/23	14/23																														
USDA Approval Date	July 19, 2013																																	

PCV2 Results (log₁₀ DNA Copies/mL) of Serum Samples for Viremia

Pig ID	Treatment	0 DPV1	0 DPV2	28 DPV2	84 DPV2	0 DPC	7 DPC	14 DPC	21 DPC	28 DPC	35 DPC
713	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
716	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
718	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
719	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
722	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
723	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
724	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
727	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
729	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
730	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
731	Vaccine	BLD	BLD	NS	NS	NS	NS	NS	NS	NS	NS
732	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
733	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
734	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	4.2	BLD	BLD	BLD
741	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
742	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
745	Vaccine	BLD	BLD	BLD	BLD	NS	NS	NS	NS	NS	NS
746	Vaccine	BLD	BLD	BLD	BLD	NS	NS	NS	NS	NS	NS
747	Vaccine	BLD	BLD	NS	NS	NS	NS	NS	NS	NS	NS
748	Vaccine	BLD	NS	NS	NS	NS	NS	NS	NS	NS	NS
749	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
752	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
755	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
757	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
759	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
714	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	4.0	6.0	5.6	5.2
715	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.8	4.9	5.3	5.0
717	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	6.7	5.7	5.8	5.4
720	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.8	5.9	4.8	4.5
721	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.2	6.0	5.2	5.2
725	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.0	5.3	5.4	5.7
726	Placebo	BLD	BLD	BLD	BLD	BLD	4.8	7.3	5.6	5.9	5.3
728	Placebo	BLD	BLD	BLD	BLD	BLD	4.1	6.7	5.6	5.6	5.1
735	Placebo	BLD	BLD	BLD	BLD	BLD	7.7	7.7	7.6	6.6	5.8
736	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	6.3	5.2	5.6	4.8
737	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	6.0	5.3	5.1	4.8
738	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	6.8	5.8	7.0	4.7
739	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	7.2	6.4	5.9	5.3
740	Placebo	BLD	BLD	BLD	BLD	BLD	4.8	6.8	6.1	6.1	5.4
743	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.5	5.9	6.3	6.1
744	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.8	5.2	4.7	4.2
750	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.8	5.9	5.6	5.2
751	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	7.2	5.6	5.4	BLD
753	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	5.7	6.4	6.0	5.1
754	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	4.1	BLD	BLD	BLD
756	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
758	Placebo	BLD	BLD	BLD	BLD	BLD	4.0	7.0	6.3	6.3	5.8
760	Placebo	BLD	BLD	BLD	BLD	NS	NS	NS	NS	NS	NS
761	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	6.8	8.1	6.3	5.5
762	Placebo	BLD	NS	NS	NS	NS	NS	NS	NS	NS	NS

BLD = below limit of detection in qPCR assay DP1V = day post-first vaccination DP2V = day post-second vaccination DPC = day post-challenge NS = no sample

PCV2 Results (log₁₀ DNA Copies/mL) of Fecal Swab Samples

Pig ID	Treatment	28 DPV2	84 DPV2	0 DPC	7 DPC	14 DPC	21 DPC	28 DPC	35 DPC
713	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
716	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	3.9	BLD
718	Vaccine	BLD	BLD	BLD	BLD	5.6	4.3	BLD	BLD
719	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
722	Vaccine	BLD	BLD	BLD	BLD	BLD	4.6	BLD	BLD
723	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
724	Vaccine	BLD	BLD	BLD	BLD	BLD	4.6	BLD	BLD
727	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	BLD	BLD
729	Vaccine	BLD	BLD	BLD	BLD	BLD	4.0	BLD	BLD
730	Vaccine	BLD	BLD	BLD	BLD	BLD	4.0	BLD	BLD
731	Vaccine	NS	NS	NS	NS	NS	NS	NS	NS
732	Vaccine	BLD	BLD	BLD	BLD	BLD	4.7	BLD	BLD
733	Vaccine	BLD	BLD	BLD	BLD	BLD	3.9	BLD	BLD
734	Vaccine	BLD	BLD	BLD	BLD	4.4	5.6	BLD	4.1
741	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	BLD	BLD
742	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	BLD	BLD
745	Vaccine	BLD	BLD	BLD	BLD	4.4	4.4	BLD	BLD
746	Vaccine	BLD	NS	NS	NS	NS	NS	NS	NS
747	Vaccine	BLD	BLD	BLD	BLD	4.1	6.5	4.1	BLD
748	Vaccine	NS	NS	NS	NS	NS	5.3	NS	NS
749	Vaccine	BLD	BLD	BLD	BLD	4.0	4.5	4.0	BLD
752	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	4.0	3.9
755	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	BLD	BLD
757	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	BLD	BLD
759	Vaccine	BLD	BLD	BLD	BLD	3.9	4.6	4.1	BLD
714	Placebo	BLD	BLD	BLD	BLD	BLD	6.6	5.2	BLD
715	Placebo	BLD	BLD	BLD	BLD	3.9	5.8	5.5	BLD
717	Placebo	BLD	BLD	BLD	BLD	5.9	6.6	5.1	BLD
720	Placebo	BLD	BLD	BLD	BLD	5.3	5.0	4.5	BLD
721	Placebo	BLD	BLD	BLD	BLD	4.0	5.6	4.5	BLD
725	Placebo	BLD	BLD	BLD	BLD	BLD	5.3	BLD	BLD
726	Placebo	BLD	BLD	BLD	BLD	6.9	6.7	6.0	BLD
728	Placebo	BLD	BLD	BLD	BLD	5.7	5.0	4.6	BLD
735	Placebo	BLD	BLD	BLD	BLD	5.6	7.8	6.2	5.1
736	Placebo	BLD	BLD	BLD	BLD	5.8	6.4	6.0	4.3
737	Placebo	BLD	BLD	BLD	BLD	4.2	5.5	4.7	4.6
738	Placebo	BLD	BLD	BLD	BLD	5.4	5.9	4.9	4.6
739	Placebo	BLD	BLD	BLD	BLD	5.9	7.0	6.6	5.8
740	Placebo	BLD	BLD	BLD	BLD	7.1	7.1	6.2	5.5
743	Placebo	BLD	BLD	BLD	BLD	4.4	7.2	5.8	5.6
744	Placebo	BLD	BLD	BLD	BLD	5.0	5.2	5.4	4.3
750	Placebo	BLD	BLD	BLD	BLD	4.4	6.6	5.3	5.0
751	Placebo	BLD	BLD	BLD	BLD	5.3	6.1	5.3	4.4
753	Placebo	BLD	BLD	BLD	BLD	5.0	7.7	6.4	5.5
754	Placebo	BLD	BLD	BLD	BLD	BLD	5.2	4.5	4.1
756	Placebo	BLD	BLD	BLD	BLD	4.3	4.6	4.3	BLD
758	Placebo	BLD	BLD	BLD	BLD	5.5	6.5	5.7	BLD
760	Placebo	BLD	BLD	NS	NS	NS	NS	NS	NS
761	Placebo	NS	NS	BLD	BLD	5.3	7.0	6.9	4.6
762	Placebo	NS	NS	NS	NS	NS	NS	NS	NS

BLD = below limit of detection in qPCR assay DP1V = day post-1st vaccination DP2V = day post-2nd vaccination DPC = day post-challenge NS = no sample

PCV2 Results (log₁₀ DNA Copies/mL) of Nasal Swab Samples

Pig ID	Treatment	28 DPV2	84 DPV2	0 DPC	7 DPC	14 DPC	21 DPC	28 DPC	35 DPC
713	Vaccine	BLD	BLD	BLD	BLD	BLD	4.7	BLD	BLD
716	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
718	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
719	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
722	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	BLD	BLD
723	Vaccine	BLD	BLD	BLD	BLD	BLD	4.6	BLD	BLD
724	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
727	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
729	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
730	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
731	Vaccine	NS	NS	NS	NS	NS	NS	NS	NS
732	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
733	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
734	Vaccine	BLD	BLD	BLD	BLD	BLD	4.2	BLD	BLD
741	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	BLD	BLD
742	Vaccine	BLD	BLD	BLD	BLD	BLD	4.7	BLD	BLD
745	Vaccine	BLD	BLD	BLD	BLD	BLD	3.9	BLD	BLD
746	Vaccine	BLD	NS	NS	NS	NS	NS	NS	NS
747	Vaccine	BLD	BLD	BLD	BLD	BLD	4.6	BLD	BLD
748	Vaccine	NS	NS	NS	NS	NS	NS	NS	NS
749	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	BLD	BLD
752	Vaccine	BLD	BLD	BLD	BLD	3.9	4.3	BLD	BLD
755	Vaccine	BLD	BLD	BLD	BLD	4.1	BLD	BLD	BLD
757	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	BLD	BLD
759	Vaccine	BLD	BLD	BLD	BLD	BLD	5.0	BLD	BLD
714	Placebo	BLD	BLD	BLD	BLD	BLD	5.3	4.6	BLD
715	Placebo	BLD	BLD	BLD	BLD	6.3	6.1	6.1	BLD
717	Placebo	BLD	BLD	BLD	BLD	6.8	5.3	5.6	5.6
720	Placebo	BLD	BLD	BLD	BLD	5.3	4.6	4.4	BLD
721	Placebo	BLD	BLD	BLD	BLD	4.2	5.3	4.6	BLD
725	Placebo	BLD	BLD	BLD	BLD	4.4	5.1	5.5	BLD
726	Placebo	BLD	BLD	BLD	BLD	6.0	5.7	4.7	4.7
728	Placebo	BLD	BLD	BLD	BLD	6.2	4.5	4.9	4.7
735	Placebo	BLD	BLD	BLD	BLD	7.0	7.6	6.2	BLD
736	Placebo	BLD	BLD	BLD	BLD	6.3	4.9	4.7	BLD
737	Placebo	BLD	4.0	BLD	BLD	5.8	5.3	5.1	BLD
738	Placebo	BLD	BLD	BLD	BLD	5.6	6.0	4.7	BLD
739	Placebo	BLD	BLD	BLD	BLD	5.8	5.9	5.5	BLD
740	Placebo	BLD	BLD	BLD	BLD	6.4	4.4	6.5	BLD
743	Placebo	BLD	BLD	BLD	BLD	5.9	5.4	5.4	BLD
744	Placebo	BLD	BLD	BLD	BLD	4.9	4.7	4.5	BLD
750	Placebo	BLD	BLD	BLD	BLD	5.0	BLD	4.3	BLD
751	Placebo	BLD	BLD	BLD	BLD	5.0	5.5	4.9	BLD
753	Placebo	BLD	BLD	BLD	BLD	6.0	6.1	6.4	BLD
754	Placebo	BLD	BLD	BLD	BLD	4.0	BLD	BLD	BLD
756	Placebo	BLD	BLD	BLD	BLD	BLD	4.0	BLD	BLD
758	Placebo	BLD	BLD	BLD	BLD	6.4	6.2	6.4	4.1
760	Placebo	BLD	BLD	NS	NS	NS	NS	NS	NS
761	Placebo	NS	BLD	BLD	BLD	7.0	7.2	5.6	BLD
762	Placebo	NS	NS	NS	NS	NS	NS	NS	NS

BLD = below limit of detection in qPCR assay DP1V = day post-1st vaccination DP2V = day post-2nd vaccination DPC = day post-challenge NS = no sample

Immunohistochemistry Scores of Lymphoid Tissues

Fig ID	Treatment	Lymphoid Infection (IHC)		
		Tonsil	MLN	BLN
713	Vaccine	0	0	0
716	Vaccine	0	0	0 ^b
718	Vaccine	0	0	0
719	Vaccine	1 ^a	0	0
722	Vaccine	1 ^a	0	0
723	Vaccine	0	0	0
724	Vaccine	0	0	0
727	Vaccine	0	0	1
729	Vaccine	0	0	0
730	Vaccine	0	0	0
732	Vaccine	0	0	0
733	Vaccine	1 ^a	0	0
734	Vaccine	1 ^a	0	0
741	Vaccine	0	0	0
742	Vaccine	1	0	1
745	Vaccine	0	0	0
747	Vaccine	0	0	0
749	Vaccine	0	0	0
752	Vaccine	0	0	0
755	Vaccine	0	0	0
757	Vaccine	0	1	1
759	Vaccine	0	0	0
714	Placebo	0	0	0
715	Placebo	0	0	0
717	Placebo	0	1	1 ^b
720	Placebo	0	0	1
721	Placebo	0	0	0 ^b
725	Placebo	1 ^a	1 ^a	0
726	Placebo	0	1	2
728	Placebo	0	0	0
735	Placebo	1	1	1
736	Placebo	0	0	1
737	Placebo	0	0	0
738	Placebo	0	0	1
739	Placebo	1	0	2
740	Placebo	1	1	1
743	Placebo	0	0	0
744	Placebo	1 ^a	0	1
750	Placebo	1 ^a	1 ^a	1 ^a
751	Placebo	1	0	0
753	Placebo	1 ^a	0	1 ^a
754	Placebo	0	0	0
756	Placebo	0	0	0
758	Placebo	0	0	0
761	Placebo	1	1	1

MLN = mesenteric lymph node; BLN = bronchial lymph node

^a Rare positive cells staining

^b BLN hemorrhage

Scoring:

- 0 IHC negative, no staining
- 1 IHC positive, sparse staining
- 2 IHC positive, moderate staining
- 3 IHC positive, extensive staining

Study Type	Efficacy																																	
Pertaining to	Porcine Circovirus Type 2a (PCV2a)																																	
Study Purpose	To demonstrate efficacy against PCV2a 21 weeks after vaccination.																																	
Product Administration	1 dose administered by the IM route																																	
Study Animals	49, 3-week-old, pigs; 25 controls, 24 vaccinates																																	
Challenge Description	21 weeks post-vaccination, all pigs were challenged with PCV2a and Porcine Reproductive and Respiratory Syndrome Virus.																																	
Interval observed after challenge	Pigs were observed daily for 35 days following challenge for clinical signs of PCV2a disease. Fecal and nasal swabs were collected weekly.																																	
Results	<p><u>Viremia:</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive for Viremia/Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>4/24</td> </tr> <tr> <td>Controls</td> <td>24/25</td> </tr> </tbody> </table> <p><u>Virus Shedding:</u></p> <p>Fecal Samples:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive for Virus Shedding/Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>19/24</td> </tr> <tr> <td>Controls</td> <td>25/25</td> </tr> </tbody> </table> <p>Nasal Samples:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive for Virus Shedding/Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>13/24</td> </tr> <tr> <td>Controls</td> <td>25/25</td> </tr> </tbody> </table> <p><u>Lymphoid Infection:</u> Number pigs with a score of 1 or greater/total for immunohistochemistry against PCV2a in lymphoid tissue</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Tonsil</th> <th>MLN</th> <th>BLN</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>1/24</td> <td>3/24</td> <td>2/24</td> <td>5/24</td> </tr> <tr> <td>Controls</td> <td>8/25</td> <td>1/25</td> <td>14/25</td> <td>17/25</td> </tr> </tbody> </table> <p>MLN: mesenteric lymph node; BLN: bronchial lymph node</p> <p>Raw data shown on attached pages.</p>	Group	# Positive for Viremia/Total	Vaccinates	4/24	Controls	24/25	Group	# Positive for Virus Shedding/Total	Vaccinates	19/24	Controls	25/25	Group	# Positive for Virus Shedding/Total	Vaccinates	13/24	Controls	25/25	Group	Tonsil	MLN	BLN	Total	Vaccinates	1/24	3/24	2/24	5/24	Controls	8/25	1/25	14/25	17/25
Group	# Positive for Viremia/Total																																	
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Vaccinates	1/24	3/24	2/24	5/24																														
Controls	8/25	1/25	14/25	17/25																														
USDA Approval Date	July 19, 2013																																	

PCV2 Results (log₁₀ DNA Copies/mL) of Serum Samples for Viremia

Pig ID	Treatment	0 DPV	28 DPV	83 DPV	-1 DPC	7 DPC	14 DPC	21 DPC	27 DPC	35 DPC
765	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
766	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
768	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	3.9
771	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
775	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
830	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
832	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
835	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
836	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	4.4
837	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
838	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
840	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
841	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
842	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
846	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	3.9
847	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	4.6
848	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
849	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
901	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
903	Vaccine	BLD	BLD	NS	NS	NS	NS	NS	NS	NS
906	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
908	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
910	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
915	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
916	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
763	Placebo	BLD	BLD	BLD	BLD	4.4	6.9	6.4	5.5	5.9
764	Placebo	BLD	BLD	BLD	BLD	4.4	7.3	6.6	6.6	6.7
767	Placebo	BLD	BLD	BLD	BLD	BLD	5.5	6.3	5.3	5.6
769	Placebo	BLD	BLD	BLD	BLD	BLD	6.1	6.7	6.0	6.8
770	Placebo	BLD	BLD	BLD	BLD	BLD	5.0	6.0	5.1	5.5
772	Placebo	BLD	BLD	BLD	BLD	BLD	6.6	5.9	5.1	5.7
773	Placebo	BLD	BLD	BLD	BLD	BLD	6.6	5.8	5.1	5.3
774	Placebo	BLD	BLD	BLD	BLD	BLD	6.3	6.2	5.4	5.7
831	Placebo	BLD	BLD	BLD	BLD	BLD	4.8	6.0	4.6	5.2
833	Placebo	BLD	BLD	BLD	BLD	BLD	5.1	6.6	5.1	5.4
834	Placebo	BLD	BLD	BLD	BLD	BLD	6.9	6.7	6.0	6.3
839	Placebo	BLD	BLD	BLD	BLD	BLD	6.7	6.0	4.9	5.5
843	Placebo	BLD	BLD	BLD	BLD	BLD	7.3	7.1	6.2	6.8
844	Placebo	BLD	BLD	BLD	BLD	4.1	7.5	8.7	6.4	5.7
845	Placebo	BLD	BLD	BLD	BLD	BLD	5.1	6.4	5.4	4.8
850	Placebo	BLD	BLD	BLD	BLD	BLD	6.0	6.6	5.3	6.0
902	Placebo	BLD	BLD	BLD	BLD	BLD	6.7	5.8	5.3	5.0
904	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
905	Placebo	BLD	BLD	BLD	BLD	BLD	6.6	5.6	5.6	5.0
907	Placebo	BLD	BLD	BLD	BLD	BLD	4.1	5.4	4.5	4.5
909	Placebo	BLD	BLD	BLD	BLD	BLD	6.0	6.1	6.0	5.8
911	Placebo	BLD	BLD	BLD	BLD	BLD	6.0	5.0	4.7	4.3
912	Placebo	BLD	BLD	BLD	BLD	BLD	6.3	5.4	5.0	4.7
913	Placebo	BLD	BLD	BLD	BLD	BLD	6.5	5.8	5.2	5.0
914	Placebo	BLD	BLD	BLD	BLD	BLD	6.1	6.1	6.1	5.4

BLD = below limit of detection in qPCR assay DPV = day post-vaccination DPC = day post-challenge NS = no sample

PCV2 Results (log₁₀ DNA Copies/mL) of Fecal Swab Samples

Pig ID	Treatment	28 DPV	83 DPV	-1 DPC	7 DPC	14 DPC	21 DPC	27 DPC	35 DPC
765	Vaccine	BLD	BLD	BLD	BLD	BLD	4.9	BLD	BLD
766	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
768	Vaccine	BLD	BLD	BLD	BLD	4.1	4.7	4.2	BLD
771	Vaccine	BLD	BLD	BLD	BLD	4.2	BLD	BLD	BLD
775	Vaccine	BLD	BLD	BLD	BLD	4.5	4.0	4.1	BLD
830	Vaccine	BLD	BLD	BLD	BLD	5.2	4.2	4.3	BLD
832	Vaccine	BLD	BLD	BLD	BLD	4.8	4.5	4.4	4.0
835	Vaccine	BLD	BLD	BLD	BLD	BLD	3.9	5.2	BLD
836	Vaccine	BLD	BLD	BLD	BLD	4.5	BLD	4.2	BLD
837	Vaccine	BLD	BLD	BLD	BLD	3.9	3.9	4.2	BLD
838	Vaccine	BLD	BLD	BLD	BLD	4.9	4.5	4.4	BLD
840	Vaccine	BLD	BLD	BLD	BLD	4.8	4.5	BLD	BLD
841	Vaccine	BLD	BLD	BLD	BLD	4.0	BLD	BLD	BLD
842	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
846	Vaccine	BLD	BLD	BLD	BLD	BLD	4.8	4.2	BLD
847	Vaccine	BLD	BLD	BLD	BLD	3.9	4.7	4.1	4.1
848	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
849	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	4.5	BLD
901	Vaccine	4.0	BLD	BLD	BLD	BLD	BLD	BLD	BLD
903	Vaccine	BLD	NS	NS	NS	NS	NS	NS	NS
906	Vaccine	BLD	NS	NS	NS	NS	NS	NS	NS
908	Vaccine	BLD	BLD	BLD	BLD	BLD	4.9	4.5	BLD
910	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
915	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	BLD	BLD
916	Vaccine	BLD	BLD	BLD	BLD	BLD	3.9	BLD	BLD
763	Placebo	BLD	BLD	BLD	BLD	6.6	5.8	5.6	4.9
764	Placebo	BLD	BLD	BLD	BLD	6.7	6.7	6.8	4.9
767	Placebo	BLD	BLD	BLD	BLD	6.5	5.5	6.8	4.6
769	Placebo	BLD	BLD	BLD	BLD	4.6	6.6	6.6	5.1
770	Placebo	BLD	BLD	BLD	BLD	BLD	4.4	4.9	4.7
772	Placebo	BLD	BLD	BLD	BLD	6.2	4.6	4.9	5.2
773	Placebo	BLD	BLD	BLD	BLD	5.7	5.1	4.8	4.7
774	Placebo	BLD	BLD	BLD	BLD	5.8	6.4	5.8	5.2
831	Placebo	BLD	BLD	BLD	BLD	4.0	5.0	5.3	BLD
833	Placebo	BLD	BLD	BLD	BLD	4.4	6.6	5.7	4.8
834	Placebo	BLD	BLD	BLD	BLD	6.9	6.6	6.0	BLD
839	Placebo	BLD	BLD	BLD	BLD	6.1	5.6	5.1	BLD
843	Placebo	BLD	BLD	BLD	BLD	6.0	7.5	7.0	6.5
844	Placebo	BLD	BLD	BLD	BLD	5.8	6.9	7.2	6.1
845	Placebo	BLD	BLD	BLD	BLD	4.3	6.4	5.4	5.1
850	Placebo	BLD	BLD	BLD	BLD	4.6	6.5	5.4	5.5
902	Placebo	BLD	BLD	BLD	BLD	5.9	3.8	6.2	5.7
904	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
905	Placebo	BLD	BLD	BLD	BLD	5.2	5.3	5.7	5.2
907	Placebo	BLD	BLD	BLD	BLD	BLD	5.1	4.8	4.3
909	Placebo	BLD	BLD	BLD	BLD	4.6	5.9	5.2	5.1
911	Placebo	BLD	BLD	BLD	BLD	4.8	5.4	5.0	4.4
912	Placebo	BLD	BLD	BLD	BLD	5.1	5.7	5.9	4.9
913	Placebo	BLD	BLD	BLD	BLD	5.3	5.8	5.8	5.3
914	Placebo	BLD	BLD	BLD	BLD	6.2	6.4	6.0	5.3

BLD = below limit of detection in oPCR assay DPV = day post-vaccination DPC = day post-challenge NS = no sample

PCV2 Results (log₁₀ DNA Copies/mL) of Nasal Swab Samples

Pig ID	Treatment	28 DPV	83 DPV	-1 DPC	7 DPC	14 DPC	21 DPC	27 DPC	35 DPC
765	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
766	Vaccine	BLD	BLD	BLD	BLD	4.3	BLD	BLD	BLD
768	Vaccine	BLD	BLD	BLD	BLD	4.3	BLD	3.9	BLD
771	Vaccine	BLD	BLD	BLD	BLD	4.3	BLD	BLD	BLD
775	Vaccine	BLD	BLD	BLD	BLD	4.1	4.1	BLD	BLD
830	Vaccine	BLD	BLD	BLD	BLD	4.2	BLD	4.2	BLD
832	Vaccine	BLD	BLD	BLD	BLD	4.2	BLD	4.6	BLD
835	Vaccine	BLD	BLD	BLD	BLD	4.0	BLD	BLD	BLD
836	Vaccine	BLD	BLD	BLD	BLD	4.7	BLD	BLD	BLD
837	Vaccine	BLD	BLD	BLD	BLD	4.1	BLD	3.9	BLD
838	Vaccine	BLD	BLD	BLD	BLD	5.0	BLD	BLD	BLD
840	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	BLD	BLD
841	Vaccine	BLD	BLD	BLD	BLD	4.2	BLD	BLD	BLD
842	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
846	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
847	Vaccine	BLD	BLD	BLD	BLD	BLD	4.8	BLD	BLD
848	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
849	Vaccine	BLD	BLD	BLD	BLD	4.0	4.5	BLD	BLD
901	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
903	Vaccine	BLD	NS	NS	NS	NS	NS	NS	NS
906	Vaccine	BLD	NS	NS	NS	NS	NS	NS	NS
908	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
910	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
915	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
916	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
763	Placebo	BLD	BLD	BLD	BLD	5.5	4.9	5.4	4.6
764	Placebo	BLD	BLD	BLD	BLD	6.8	6.4	6.5	6.0
767	Placebo	BLD	BLD	BLD	BLD	4.8	6.1	5.7	5.3
769	Placebo	BLD	BLD	BLD	BLD	5.4	6.1	5.9	5.2
770	Placebo	BLD	BLD	BLD	BLD	3.1	4.9	4.5	4.3
772	Placebo	BLD	BLD	BLD	BLD	5.0	4.6	4.5	BLD
773	Placebo	BLD	BLD	BLD	BLD	5.9	4.6	4.3	4.8
774	Placebo	BLD	BLD	BLD	BLD	5.3	5.6	5.0	5.7
831	Placebo	BLD	BLD	BLD	BLD	4.1	5.1	4.0	4.9
833	Placebo	BLD	BLD	BLD	BLD	4.5	7.9	5.2	5.5
834	Placebo	BLD	BLD	BLD	BLD	7.7	7.0	6.9	5.7
839	Placebo	BLD	BLD	BLD	BLD	6.5	5.5	4.8	4.5
843	Placebo	BLD	BLD	BLD	BLD	6.5	6.8	5.7	5.7
844	Placebo	BLD	BLD	BLD	BLD	6.8	6.4	5.8	5.8
845	Placebo	BLD	BLD	BLD	BLD	BLD	5.3	5.3	4.6
850	Placebo	BLD	BLD	BLD	BLD	6.8	6.0	4.8	5.6
902	Placebo	BLD	BLD	BLD	BLD	5.9	4.8	4.7	4.7
904	Placebo	BLD	BLD	BLD	4.2	BLD	BLD	BLD	BLD
905	Placebo	BLD	BLD	BLD	BLD	5.2	5.1	4.7	4.7
907	Placebo	BLD	BLD	BLD	BLD	BLD	4.6	4.0	BLD
909	Placebo	BLD	BLD	BLD	BLD	5.0	5.8	6.4	5.2
911	Placebo	BLD	BLD	BLD	BLD	4.7	4.5	5.3	4.2
912	Placebo	BLD	BLD	BLD	BLD	5.9	5.1	6.2	4.5
913	Placebo	BLD	BLD	BLD	BLD	5.2	5.3	5.1	4.0
914	Placebo	BLD	BLD	BLD	BLD	BLD	6.9	5.3	5.4

BLD = below limit of detection in qPCR assay DPV = day post-vaccination DPC = day post-challenge NS = no sample

Immunohistochemistry Scores of Lymphoid Tissues

Pig ID	Treatment	IHC Score		
		Tonsil	MLN	BLN
765	Vaccine	0	0	0
766	Vaccine	0	0	0
768	Vaccine	0	0	0
771	Vaccine	0	0	1 ^a
775	Vaccine	0	1 ^a	1 ^a
830	Vaccine	0	1 ^a	0
832	Vaccine	0	0	0
835	Vaccine	0	0	0
836	Vaccine	0	0	0
837	Vaccine	0	0	0
838	Vaccine	0	0	0
840	Vaccine	0	0	0
841	Vaccine	0	0	0 ^b
842	Vaccine	0	1 ^a	0
846	Vaccine	0	0	0
847	Vaccine	0	0	0 ^b
848	Vaccine	1 ^a	0	0
849	Vaccine	0	0	0
901	Vaccine	0	0	0
903	Vaccine	0	0	0
908	Vaccine	0	0	0
910	Vaccine	0	0	0
915	Vaccine	0	0	0
916	Vaccine	0	0	0 ^b
763	Placebo	1	0	1
764	Placebo	1	0	1
767	Placebo	0	0	1
769	Placebo	0	0	1
770	Placebo	0	0	1
772	Placebo	0	0	1
773	Placebo	0	0	0
774	Placebo	2	0	0
831	Placebo	0	0	0
833	Placebo	0	0	1 ^a
834	Placebo	1	0	0
839	Placebo	0	0	0
843	Placebo	1	1	1
844	Placebo	0	0	1
845	Placebo	1	0	1
850	Placebo	1	0	1 ^c
902	Placebo	0	0	0
904	Placebo	0	0	0
905	Placebo	0	0	2
907	Placebo	0	0	0
909	Placebo	0	0	0
911	Placebo	1	0	0
912	Placebo	0	0	0
913	Placebo	0	0	2
914	Placebo	0	0	1 ^c

MLN = mesenteric lymph node; BLN = bronchial lymph node

^a Rare positive cells staining

^b BLN hemorrhage

^c BLN multinucleated giant cell

Scoring:

- 0 IHC negative, no staining
- 1 IHC positive, sparse staining
- 2 IHC positive, moderate staining
- 3 IHC positive, extensive staining

Study Type	Safety																																																
Pertaining to	ALL																																																
Study Purpose	To demonstrate safety under field conditions.																																																
Product Administration	<u>Group 1:</u> 2 doses administered by the intramuscular (IM) route 12-17 days apart. <u>Group 2:</u> 1 dose administered by the IM route.																																																
Study Animals	<u>Group 1:</u> 3-5 days of age 1 st vaccination; 350 males, 362 females <u>Group 2:</u> 3 weeks of age at vaccination; 363 males, 347 females																																																
Challenge Description	Not Applicable																																																
Interval observed after challenge	All pigs were observed for general health and for systemic and local injection site reactions between 1-4 hours post-vaccination, and then daily for 14 days following each vaccination, or until resolution.																																																
Results	<p><u>Treatment Group 1:</u></p> <table border="1"> <thead> <tr> <th>Dose</th> <th>AE Type</th> <th>Number of Animals with AEs</th> <th>Duration of Local Injection Site Reactions</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1st</td> <td>Systemic Reactions</td> <td>37/712 (5%)</td> <td>--</td> </tr> <tr> <td>Local Injection Site Reactions</td> <td>46/712 (6%)</td> <td>1-10 days</td> </tr> <tr> <td rowspan="2">2nd</td> <td>Systemic Reactions</td> <td>34/690 (5%)</td> <td>--</td> </tr> <tr> <td>Local Injection Site Reactions</td> <td>335/690 (49%)</td> <td>1-35 days</td> </tr> </tbody> </table> <p>Summary of Systemic Reactions for Treatment Group 1*:</p> <table border="1"> <thead> <tr> <th>Systemic Reaction</th> <th># AE</th> </tr> </thead> <tbody> <tr> <td>Mortality, Not Product Related¹</td> <td>34</td> </tr> <tr> <td>Systemic Disorder NOS²</td> <td>26</td> </tr> <tr> <td>Cough</td> <td>3</td> </tr> <tr> <td>Scour</td> <td>2</td> </tr> <tr> <td>Lameness</td> <td>2</td> </tr> <tr> <td>Anaphylactic-type Reaction</td> <td>1</td> </tr> <tr> <td>Septic Arthritis</td> <td>1</td> </tr> <tr> <td>Sneezing</td> <td>1</td> </tr> <tr> <td>Edema of the Extremities</td> <td>1</td> </tr> <tr> <td>Peritonitis [euthanized]</td> <td>1</td> </tr> <tr> <td>Swelling Around Eye</td> <td>1</td> </tr> <tr> <td>Poor Coat Condition</td> <td>1</td> </tr> <tr> <td>Total No. of Animals with AE</td> <td>71</td> </tr> <tr> <td>Total Systemic Reactions:</td> <td>74</td> </tr> </tbody> </table> <p>¹ Mortality not caused by product as affirmed by licensee ² NOS = Not otherwise specified.</p>	Dose	AE Type	Number of Animals with AEs	Duration of Local Injection Site Reactions	1 st	Systemic Reactions	37/712 (5%)	--	Local Injection Site Reactions	46/712 (6%)	1-10 days	2 nd	Systemic Reactions	34/690 (5%)	--	Local Injection Site Reactions	335/690 (49%)	1-35 days	Systemic Reaction	# AE	Mortality, Not Product Related ¹	34	Systemic Disorder NOS ²	26	Cough	3	Scour	2	Lameness	2	Anaphylactic-type Reaction	1	Septic Arthritis	1	Sneezing	1	Edema of the Extremities	1	Peritonitis [euthanized]	1	Swelling Around Eye	1	Poor Coat Condition	1	Total No. of Animals with AE	71	Total Systemic Reactions:	74
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Treatment Group 2:

AE Type	Number of Animals with AEs	Duration of Local Injection Site Reactions
Systemic Reactions	36/710 (5%)	--
Local Injection Site Reactions	42/710 (6%)	1-17 days

Summary of Systemic Reactions for Treatment Group 2*:

Systemic Reaction	# AE
Systemic Disorder NOS ¹	23
Mortality, Not Product Related ²	9
Cough	3
Scour	2
Total No. of Animals with AE	36
Total Systemic Reactions:	37

¹ NOS = Not otherwise specified.

² Mortality not caused by product as affirmed by licensee

* An AE was classified by the low level VeDDRA term "Systemic disorder NOS" for pigs that failed to achieve performance in the barn equal to that of their contemporaries, and included pigs defined as runts, tail-enders, fall-behinds, poor-doers, thin, starved, spine visible, smaller, unthrifty, emaciated, undersized, behind others, not growing, losing weight, or severely ill (unless another finding associated with the pig provided a different diagnosis). This condition may be due to poor nutrition, environmental conditions, or disease.

USDA Approval Date

June 7, 2013