Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19K5.R4
True Name	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Circumvent PCV G2 - Merck Animal Health Circumvent PCV 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.

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

	Raw data shown on attached pages.
USDA Approval Date	July 6, 2012

PCV2 qPCR Results (log_{10} DNA Copies/mL) of Serum Samples for Viremia

		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
Pig ID	Treatment	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	3.9	7.6	6.6	6.7	6.8
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	6.5	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 0DP1V 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

		01-Jul-11	22-Jul-11	18-Aug-11	25-Aug-11	2-Sep-11	9-Sep-11	16-Sep-11	22-Sep-11
Pig ID	Treatment	0DP2V	21DP2V	-1DPC	6DPC	14DPC	21DPC	28DPC	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
361	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

		01-Jul-11	22-Jul-11	18-Aug-11	25-Aug-11	2-Sep-11	9-Sep-11	16-Sep-11	22-Sep-11
Pig ID	Treatment	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

		Lymphoid Infection (IHC)			Lymphoid Depletion		
Pig ID	Treatment	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[a]	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[a]	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[a]	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

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

Raw data shown on attached pages.
</td></tr>
<tr><td>USDA Approval Date</td><td>November 5, 2012</td></tr>
</table>

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

		29-Jun-11	20-Jul-11	17-Aug-11	24-Aug-11	31-Aug-11	7-Sep-11	14-Sep-11	21-Sep-11
Pig ID	Treatment	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	7.5	6.2	5.7
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	5.2
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

		20-Jul-11	17-Aug-11	24-Aug-11	31-Aug-11	7-Sep-11	14-Sep-11	21-Sep-11
Pig ID	Treatment	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	5.5	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

		20-Jul-11	17-Aug-11	24-Aug-11	31-Aug-11	7-Sep-11	14-Sep-11	21-Sep-11
Pig ID	Treatment	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

		Lymphoid Infection (IHC)			Lymphoid Depletion		
Pig ID	Treatment	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

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Circovirus Type 2a (PCV2a)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against PCV2a 20 weeks after vaccination.</td></tr>
<tr><td>Product Administration</td><td>2 doses administered 19 days apart by the intramuscular (IM) route.</td></tr>
<tr><td>Study Animals</td><td>45, 3 – 5-day old, pigs; 23 controls, 22 vaccinates</td></tr>
<tr><td>Challenge Description</td><td>20 weeks post-2nd vaccination, all pigs were challenged with PCV2a and Porcine Reproductive and Respiratory Syndrome Virus.</td></tr>
<tr><td>Interval observed after challenge</td><td>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.</td></tr>
<tr><td>Results</td><td>
<u>Viremia</u>:
<table>
<tr><th>Group</th><th># Positive for Viremia/Total</th></tr>
<tr><td>Vaccinates</td><td>1/22</td></tr>
<tr><td>Controls</td><td>22/23</td></tr>
</table>
<u>Virus Shedding</u>:
Fecal Samples:
<table>
<tr><th>Group</th><th># Positive for Virus Shedding/Total</th></tr>
<tr><td>Vaccinates</td><td>19/22</td></tr>
<tr><td>Controls</td><td>23/23</td></tr>
</table>
Nasal Samples:
<table>
<tr><th>Group</th><th># Positive for Virus Shedding/Total</th></tr>
<tr><td>Vaccinates</td><td>13/22</td></tr>
<tr><td>Controls</td><td>23/23</td></tr>
</table>
<u>Lymphoid Infection</u>: Number of pigs with a score of 1 or greater/total for immunohistochemistry against PCV2a in lymphoid tissue
<table>
<tr><th>Group</th><th>Tonsil</th><th>MLN</th><th>BLN</th><th>Total</th></tr>
<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>
</table>
MLN: mesenteric lymph node; BLN: bronchial lymph node

Raw data shown on attached pages.
</td></tr>
<tr><td>USDA Approval Date</td><td>July 19, 2013</td></tr>
</table>

PCV2 Results (log_{10} 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	BLD	BLD	BLD	BLD	BLD	BLD
746	Vaccine	BLD	BLD	BLD	NS	NS	NS	NS	NS	NS	NS
747	Vaccine	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD	BLD
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	BLD	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 (log_{10} 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	4.5	BLD
742	Vaccine	BLD	BLD	BLD	BLD	BLD	4.4	3.9	BLD
745	Vaccine	BLD	BLD	BLD	BLD	4.4	4.4	BLD	BLD
746	Vaccine	BLD	BLD	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	NS	NS	NS
749	Vaccine	BLD	BLD	BLD	BLD	4.0	5.3	4.8	BLD
752	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	4.0	3.9
755	Vaccine	BLD	BLD	BLD	BLD	BLD	4.5	4.4	BLD
757	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	4.8	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	4.4	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	5.4	4.7
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	4.5
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	BLD	BLD	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 (log_{10} 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	NS	NS	NS	NS	NS	NS	NS
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	BLD	4.2	BLD
741	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	4.0	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	3.9	4.4	4.1	BLD
752	Vaccine	BLD	BLD	BLD	BLD	BLD	4.3	BLD	BLD
755	Vaccine	BLD	BLD	BLD	BLD	4.1	BLD	BLD	BLD
757	Vaccine	BLD	BLD	BLD	BLD	BLD	4.1	4.1	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	5.3	6.1	BLD
717	Placebo	BLD	BLD	BLD	BLD	6.8	5.3	6.1	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	4.7
726	Placebo	BLD	BLD	BLD	BLD	6.0	5.7	5.3	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	BLD	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

		Lymphoid Infection (IHC)		
Pig ID	Treatment	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

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

Raw data shown on attached pages.
</td></tr>
<tr><td>USDA Approval Date</td><td>July 19, 2013</td></tr>
</table>

PCV2 Results (log_{10} 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	BLD	BLD	BLD	BLD	BLD	BLD	BLD
906	Vaccine	BLD	BLD	NS	NS	NS	NS	NS	NS	NS
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	BLD	6.9	6.4	5.5	5.9
764	Placebo	BLD	BLD	BLD	BLD	4.4	7.3	6.6	5.9	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 (log_{10} 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	4.6	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	BLD
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	BLD	BLD	BLD	BLD	4.8	4.6	BLD
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	6.5	6.7	6.8	4.9
767	Placebo	BLD	BLD	BLD	BLD	4.6	5.5	5.5	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	5.5	6.0
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	5.8	6.2	5.7
904	Placebo	BLD	BLD	BLD	BLD	BLD	BLD	3.9	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 qPCR assay DPV = day post-vaccination DPC = day post-challenge NS = no sample

PCV2 Results (log_{10} 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	BLD	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	4.2	BLD
830	Vaccine	BLD	BLD	BLD	BLD	4.2	BLD	BLD	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	BLD	BLD	BLD	BLD	BLD	BLD	BLD
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	5.1	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	5.4	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

		IHC Score		
Pig ID	Treatment	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	Group 1: 2 doses administered by the intramuscular (IM) route 12-17 days apart. Group 2: 1 dose administered by the IM route.
Study Animals	Group 1: 3-5 days of age 1st vaccination; 350 males, 362 females Group 2: 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	Treatment Group 1:

Dose	AE Type	Number of Animals with AEs	Duration of Local Injection Site Reactions
1st	Systemic Reactions	37/712 (5%)	--
	Local Injection Site Reactions	46/712 (6%)	1-10 days
2nd	Systemic Reactions	34/690 (5%)	--
	Local Injection Site Reactions	335/690 (49%)	1-35 days

Summary of Systemic Reactions for Treatment Group 1*:

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**

[1] Mortality not caused by product as affirmed by licensee
[2] NOS = Not otherwise specified.

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