Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	49L5.R0
True Name	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector, Lawsonia Intracellularis-Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health
Date of Compilation Summary	May 05, 2022

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 PCV2a</td></tr>
<tr><td>Product Administration</td><td>Single dose, administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>24 vaccinate and 24 control pigs, negative for PCV2 antibodies, 3 weeks of age</td></tr>
<tr><td>Challenge Description</td><td>Porcine Circovirus Type 2a and Porcine Reproductive and Respiratory Syndrome Virus (PRRSv), administered 7 weeks post vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were observed daily for 35 days. The pigs were evaluated weekly for viremia. On day 35, lymphoid tissues were evaluated for changes (depletion) compatible with PCV2 infection.</td></tr>
<tr><td>Results</td><td><u>Summary for Viremia</u>

<table>
<tr><th>Group</th><th>No. Pigs</th><th>Positive</th><th>Negative</th></tr>
<tr><td>Vaccinate</td><td>24</td><td>5</td><td>19</td></tr>
<tr><td>Control</td><td>24</td><td>24</td><td>0</td></tr>
</table>

<u>Summary for Lymphoid Depletion</u>

<table>
<tr><th>Group</th><th>No. Pigs</th><th>Positive</th><th>Negative</th></tr>
<tr><td>Vaccinate</td><td>24</td><td>0</td><td>24</td></tr>
<tr><td>Control</td><td>24</td><td>13</td><td>11</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>March 22, 2017</td></tr>
</table>

Table 1: Number of Pigs with Viremia due to PCV

Vaccination Group (DNA copies/mL)						
ID	**DOC[a]**	**6 dpc[b]**	**13 dpc**	**20 dpc**	**27 dpc**	**34 dpc**
106	BLD[c]	BLD	BLD	BLD	BLD	BLD
109	BLD	BLD	BLD	BLD	BLD	BLD
111	BLD	BLD	6809.37	219524	20570	166392
117	BLD	BLD	BLD	BLD	BLD	BLD
119	BLD	BLD	498932	19245.9	15780.3	7975.12
120	BLD	BLD	BLD	BLD	BLD	BLD
121	BLD	BLD	BLD	BLD	BLD	BLD
125	BLD	BLD	BLD	BLD	BLD	BLD
126	BLD	BLD	BLD	BLD	BLD	BLD
128	BLD	BLD	BLD	BLD	2918.08	BLD
129	BLD	BLD	BLD	BLD	BLD	BLD
131	BLD	BLD	BLD	BLD	BLD	BLD
133	BLD	BLD	BLD	BLD	BLD	BLD
137	BLD	BLD	BLD	BLD	BLD	BLD
138	BLD	BLD	BLD	BLD	BLD	BLD
139	BLD	BLD	BLD	BLD	BLD	BLD
140	BLD	BLD	BLD	BLD	BLD	BLD
141	BLD	BLD	BLD	BLD	BLD	BLD
144	BLD	BLD	BLD	BLD	BLD	BLD
146	BLD	BLD	BLD	BLD	BLD	BLD
147	BLD	BLD	BLD	BLD	BLD	BLD
148	BLD	BLD	BLD	18261.5	BLD	BLD
150	BLD	BLD	BLD	BLD	BLD	BLD
152	BLD	BLD	BLD	12879.8	BLD	BLD

[a]DOC = Day of Challenge [b]dpc = days post challenge [c]BLD = Below Limit of Detection
Numeric values represent detected virus.

Table 1: Number of Pigs with Viremia due to PCV2 (continued)

Placebo Group (DNA copies/mL)						
ID	**DOC**	**6 dpc**	**13 dpc**	**20 dpc**	**27 dpc**	**34 dpc**
107	BLD	BLD	BLD	BLD	109527	15988800
108	BLD	BLD	BLD	44378.6	20215000	6786680
110	BLD	BLD	BLD	420162	84578.2	27346.2
112	BLD	BLD	BLD	BLD	1049480	271801
113	BLD	BLD	555439	66598300	8283520	18765500
114	BLD	BLD	BLD	BLD	1244520	25449900
115	BLD	BLD	7363790	9256390	3009470	10534300
116	BLD	BLD	162391	6813070	1015180	1742470
122	BLD	BLD	20013.3	25124100	3109890	28320600
123	BLD	BLD	BLD	10029800	1642430	1.15E+08
124	BLD	BLD	BLD	345722	2176170	279749
127	BLD	BLD	148244	15266100	1619460	594307
130	BLD	BLD	2203.09	27713300	15993500	17167400
132	BLD	BLD	3411660	1.07E+08	904591	2419920
134	BLD	BLD	6348970	14928900	1915690	3246460
135	BLD	BLD	1628490	28481200	2456950	4205560
136	BLD	BLD	51171.4	68297900	440534	1111410
142	BLD	BLD	BLD	23415800	1562560	857442
143	BLD	BLD	BLD	407254	268508	418970
145	BLD	BLD	23043.1	3170090	153855	248638
149	BLD	BLD	7384280	24295100	3166850	9424740
151	BLD	BLD	49452.4	22586100	9529420	1388790
153	BLD	BLD	1152600	2230520	1191490	1738440
154	BLD	BLD	68927.8	14372500	3983270	4372120

[a]DOC = Day of Challenge [b]dpc = days post challenge [c]BLD = Below Limit of Detection
Numeric values represent detected virus.

Table 2: Lymphoid Depletion due to PCV2

	Placebo Group (Lymphoid Depletion Score)				Vaccination Group (Lymphoid Depletion Score)		
ID	**Tonsil**	**BLN[a]**	**MLN[b]**	**ID**	**Tonsil**	**BLN**	**MLN**
107	0	0	0	106	0	0	0
108	NA[c]	0	1	109	0	0	0
110	0	0	0	111	0	0	0
112	0	0	0	117	0	0	0
113	1	1	1	119	0	0	0
114	0	1	1	120	0	0	0
115	1	1	1	121	0	0	0
116	0	0	0	125	0	0	0
122	0	0	0	126	0	0	0
123	1	3	0	128	0	0	0
124	0	1	0	129	0	0	0
127	0	2	1	131	0	0	0
130	1	1	1	133	0	0	0
132	0	0	1	137	0	0	0
134	0	0	0	138	0	0	0
135	0	1	0	139	0	0	0
136	0	0	0	140	0	0	0
142	0	0	0	141	0	0	0
143	0	0	0	144	0	0	0
145	0	0	0	146	0	0	0
149	1	0	0	147	0	0	0
151	1	1	1	148	0	0	0
153	0	0	0	150	0	0	0
154	1	1	0	152	0	0	0

[a]BLN = Bronchial Lymph Node
[b]MLN = Mesenteric Lymph Node
[c]NA = Sample sent was not tonsil

Scoring Guide

Histopathology - Lymphoid Depletion

0 Normal
1 Mild lymphoid depletion with loss of overall cellularity
2 Moderate lymphoid depletion
3 Severe lymphoid depletion with loss of follicle structure

<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>Demonstrate duration of immunity against Porcine Circovirus Type 2d (PCV2d)</td></tr>
<tr><td>Product Administration</td><td>A single dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>21 vaccinate and 22 control pigs, 3 weeks of age</td></tr>
<tr><td>Challenge Description</td><td>PCV2d, administered 16 weeks post vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>For 28 days post-challenge, pigs were evaluated weekly for the presence of PCV2 virus in serum (viremia). On day 28, lymphoid tissues were evaluated for signs of PCV-associated disease (lymphoid depletion, infection and inflammation).</td></tr>
<tr><td>Results</td><td>Number of animals considered positive for each variable, and total number of animals scored, were as follows:

<table>
<tr><th>Treatment Group</th><th>Viremia</th><th>Lymphoid Depletion</th><th>Lymphoid Infection</th><th>Lymphoid Inflammation</th></tr>
<tr><td>Vaccinate</td><td>13 / 21</td><td>10 / 21</td><td>8 / 21</td><td>4 / 21</td></tr>
<tr><td>Control</td><td>22 / 22</td><td>21 / 22</td><td>21 / 22</td><td>20 / 22</td></tr>
</table>

Raw data tables are shown on the following pages.</td></tr>
<tr><td>USDA Approval Date</td><td>September 17, 2020</td></tr>
</table>

RAW DATA TABLES

Table 1: Viremia Due To PCV2d

Vaccinate Group (DNA copies/mL)					
ID	-1 dpc[a]	7 dpc	14 dpc	21 dpc	28 dpc
2	BLD[b]	BLD	BLD	BLD	BLD
3	BLD	1,419	2,157	BLD	BLD
4	BLD	BLD	BLD	BLD	BLD
7	BLD	BLD	BLD	BLD	BLD
9	BLD	1,757	BLD	2,553	BLD
12	BLD	BLD	BLD	BLD	BLD
13	BLD	BLD	2,892	7,037	15,007
15	BLD	59,265	83,475	26,391	10,551
16	BLD	BLD	BLD	BLD	BLD
18	BLD	BLD	5,755	24,059	BLD
23	BLD	BLD	584,650	6,312	164,951
24	BLD	BLD	460,239	1,915	1,801
25	BLD	BLD	BLD	BLD	BLD
28	BLD	BLD	1,097	BLD	BLD
32	BLD	BLD	BLD	BLD	BLD
36	BLD	BLD	6728	2,047	10,761
39	BLD	BLD	11,631	4,263	BLD
40	BLD	BLD	BLD	BLD	BLD
44	BLD	3,380	17,965	1,689	15,745
45	BLD	2,080	247,458	59,082	20,379
48	BLD	BLD	34,451	4,343	1,557

[a] : dpc, days post challenge
[b] : BLD, below limit of detection

Virus was detected where numeric values are shown. Higher values represent that more virus was detected.

Table 1 (continued)

Placebo Group (DNA copies/mL)					
ID	-1 dpc	7 dpc	14 dpc	21 dpc	28 dpc
1	BLD	4,262	68,474	14,585	5,357
5	BLD	BLD	651,285	907,017	235,094
6	BLD	46,529	222,720	632,653	402,738
8	BLD	230,146	15,442,239	19,652,927	3,402,986
10	BLD	605,347	437,423	132,505	48,156
11	BLD	55,198	2,481,197	2,831,757	738,879
14	BLD	201,185	7,558	223,854	201,752
17	BLD	59,829	449,287	127,615	71,967
19	BLD	452,535	8,720,401	939,964	618,998
20	BLD	123,167	373,433	102,225	209,828
21	BLD	BLD	201,240	39,597	29,326
22	BLD	36,262	216,854	453,312	221,835
26	BLD	178,543	1,690,055	1,752,287	553,003
30	BLD	14,435	199,576	94,579	468,363
31	BLD	38,504	428,746	168,070	170,077
34	BLD	58,357	865,787	106,237	226,947
35	BLD	45,431	3,899,269	3,190,204	1,769,323
37	BLD	5,732	46,809,798	1,112,347	1,996,982
38	BLD	BLD	487,880	1,367,065	502,352
41	BLD	22,125	851,178	105,323	78,990
43	BLD	76,472	547,116	225,271	108,909
46	BLD	9,262	1,183,937	344,318	216,571

Table 2: Lymphoid Depletion due to PCV2d

Scoring Guide: Histopathology
0 Normal
1 Mild lymphoid depletion with loss of overall cellularity
2 Moderate lymphoid depletion
3 Severe lymphoid depletion with loss of follicle structure

Vaccinate Group (DNA copies/mL)								
ID	Tonsil	MLN 1 [a]	MLN 2	BLN 1	BLN 2	Spleen 1	Spleen 2	PP [b]
2	0	0	0	1	1	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	1	1	0	0	0
7	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0
15	0	1	1	1	1	0	0	0
16	0	0	0	1	0	0	0	0
18	0	0	0	1	0	0	0	0
23	0	1	1	0	0	0	0	NS
24	0	0	0	0	0	0	0	0
25	0	0	1	0	0	0	0	NS
28	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0
36	0	1	1	0	0	0	0	0
39	0	0	0	0	NS	0	0	0
40	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0
45	1	1	1	1	0	0	0	0
48	0	0	0	1	0	0	0	0

[a] : Two samples each were evaluated from Mesenteric Lymph Node (MLN), Bronchial Lymph Node (BLN) and Spleen
[b] : Peyer's Patch
NS : No Sample (Incorrect tissue type was collected)

Table 2 (continued)

Placebo Group (DNA copies/mL)								
ID	Tonsil	MLN 1	MLN 2	BLN 1	BLN 2	Spleen 1	Spleen 2	PP
1	0	0	0	1	1	0	0	0
5	1	1	1	1	2	0	0	1
6	1	1	1	1	1	1	1	1
8	1	2	1	2	1	1	1	2
10	1	1	1	1	1	0	0	0
11	1	1	2	1	1	0	0	1
14	1	1	1	1	1	0	0	1
17	0	1	1	0	1	0	0	0
19	1	1	1	1	1	0	1	0
20	1	2	1	1	1	0	1	1
21	0	1	0	0	1	0	0	0
22	0	1	1	0	0	0	0	0
26	0	1	1	1	1	0	0	0
30	1	2	1	1	0	0	0	1
31	1	1	1	0	1	0	0	0
34	0	0	0	0	0	0	0	0
35	2	2	1	1	1	0	0	1
37	1	1	2	1	0	0	0	0
38	1	2	2	1	2	0	0	1
41	1	1	1	1	1	0	0	1
43	1	1	2	1	1	0	0	NS
46	1	2	2	1	1	0	0	1

Table 3: Lymphoid Infection due to PCV2d

Scoring Guide: Immunohistochemistry
0 Negative, no staining
1 Positive, sparce staining
2 Positive, moderate staining
3 Positive, extreme staining

Vaccinate Group (DNA copies/mL)								
ID	Tonsil	MLN 1	MLN 2	BLN 1	BLN 2	Spleen 1	Spleen 2	PP
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0
12	0	1	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0
15	0	0	1	1	0	0	0	0
16	0	1	1	0	0	0	0	0
18	0	0	0	0	0	0	0	0
23	1	1	1	1	0	0	0	NS
24	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	NS
28	0	1	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0
36	0	1	0	0	1	0	0	0
39	0	0	0	0	NS	0	0	0
40	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0
45	1	2	2	2	0	0	0	0
48	0	0	0	1	0	0	0	0

Table 3 (continued)

Placebo Group (DNA copies/mL)								
ID	Tonsil	MLN 1	MLN 2	BLN 1	BLN 2	Spleen 1	Spleen 2	PP
1	1	0	0	1	1	0	0	0
5	2	2	1	1	1	0	0	0
6	1	1	1	1	1	0	0	0
8	2	3	3	2	1	1	0	2
10	0	1	1	1	1	0	0	1
11	1	1	2	1	1	0	0	0
14	1	1	1	1	1	0	1	0
17	0	1	2	0	1	0	0	1
19	1	2	2	1	1	0	1	1
20	1	2	1	1	1	0	0	0
21	0	1	1	1	1	0	0	0
22	1	2	1	0	1	0	0	0
26	1	2	1	1	1	0	0	0
30	1	2	1	1	0	0	1	0
31	1	1	1	0	1	0	0	0
34	0	0	0	0	0	0	0	0
35	1	2	1	1	1	0	0	0
37	2	2	2	0	0	0	0	1
38	1	2	2	1	1	1	0	0
41	2	2	2	1	1	0	1	1
43	1	1	2	1	0	0	0	NS
46	2	3	1	1	2	0	0	1

Table 4: Lymphoid Inflammation due to PCV2d

Scoring Guide: Immunohistochemistry
0 Normal
1 Mild histiocytic to granulomatous inflammation
2 Moderate histiocytic to granulomatous inflammation
3 Severe histiocytic to granulomatous inflammation with replacement of follicles

Vaccinate Group (DNA copies/mL)								
ID	Tonsil	MLN 1	MLN 2	BLN 1	BLN 2	Spleen 1	Spleen 2	PP
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0
15	0	0	1	0	0	0	0	0
16	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	NS
24	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	NS
28	0	0	0	1	0	0	0	0
32	0	0	0	0	0	0	0	0
36	0	1	0	0	0	0	0	0
39	0	0	0	0	NS	0	0	0
40	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0
45	0	1	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0

Table 4 (continued)

Placebo Group (DNA copies/mL)								
ID	Tonsil	MLN 1	MLN 2	BLN 1	BLN 2	Spleen 1	Spleen 2	PP
1	2	1	2	1	1	0	0	0
5	1	1	2	0	1	0	0	0
6	2	1	2	1	2	0	1	2
8	3	3	3	2	1	2	1	2
10	0	1	1	2	1	0	0	0
11	2	2	3	1	2	0	0	2
14	2	1	2	1	2	0	0	1
17	0	0	1	0	0	0	0	0
19	0	1	2	1	0	0	0	0
20	1	2	2	1	0	0	0	2
21	0	0	0	0	0	0	0	0
22	0	1	0	0	0	0	0	0
26	0	1	0	0	0	0	0	0
30	1	0	0	0	0	0	0	1
31	2	2	1	0	0	0	0	1
34	0	0	0	0	0	0	0	0
35	2	1	1	2	1	0	0	0
37	1	1	1	0	0	0	0	0
38	2	3	3	2	2	0	0	1
41	2	2	2	0	1	0	0	1
43	2	1	1	0	0	0	0	NS
46	3	1	0	0	1	0	0	0

<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>Demonstrate efficacy against disease caused by Porcine Circovirus Type 2d (PCV2d)</td></tr>
<tr><td>Product Administration</td><td>A single dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>24 vaccinate and 25 control pigs, 3 weeks of age</td></tr>
<tr><td>Challenge Description</td><td>PCV2d, administered 4 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>For 35 days after challenge, pigs were evaluated weekly for the presence of PCV2 virus in serum (viremia). On day 35, lymphoid tissues were evaluated for signs of PCV-associated disease (lymphoid depletion, infection and inflammation).</td></tr>
<tr><td>Results</td><td>Number of animals considered positive for each variable, and total number of animals scored, were as follows:

<table>
<tr><th>Treatment Group</th><th>Viremia</th><th>Lymphoid Depletion</th><th>Lymphoid Infection</th><th>Lymphoid Inflammation</th></tr>
<tr><td>Vaccinate</td><td>13 / 24</td><td>6 / 24</td><td>4 / 24</td><td>1 / 24</td></tr>
<tr><td>Control</td><td>24 / 25</td><td>25 / 25</td><td>23 / 25</td><td>22 / 25</td></tr>
</table>

Raw data tables are shown on the following pages.</td></tr>
<tr><td>USDA Approval Date</td><td>January 21, 2022</td></tr>
</table>

RAW DATA TABLES

Table 1: Viremia due to PCV2d

Vaccinate Group (DNA copies/mL)						
ID	-1 dpc[a]	7 dpc	14 dpc	21 dpc	28 dpc	35 dpc
378	BLD[b]	BLD	8,532	4,882	16,501	BLD
379	BLD	BLD	4,023	9,827	BLD	BLD
382	BLD	BLD	952	BLD	2,663	BLD
384	BLD	BLD	BLD	BLD	14,959	BLD
386	BLD	BLD	690	BLD	BLD	BLD
387	BLD	BLD	1,020	BLD	BLD	BLD
388	BLD	BLD	BLD	BLD	BLD	BLD
391	BLD	BLD	BLD	BLD	2,551	BLD
393	BLD	BLD	2,230	BLD	BLD	BLD
394	BLD	BLD	2,654	4,208	BLD	BLD
395	BLD	BLD	BLD	BLD	BLD	BLD
398	BLD	BLD	BLD	BLD	BLD	BLD
400	BLD	BLD	BLD	1,261	BLD	BLD
404	BLD	BLD	BLD	BLD	BLD	BLD
407	BLD	BLD	BLD	BLD	BLD	BLD
409	BLD	BLD	BLD	BLD	BLD	BLD
412	BLD	BLD	BLD	BLD	BLD	BLD
414	BLD	BLD	BLD	BLD	BLD	BLD
415	BLD	BLD	961	1,668	BLD	BLD
419	BLD	BLD	BLD	BLD	BLD	BLD
423	BLD	BLD	14,702	14,612	BLD	BLD
424	BLD	BLD	BLD	2,495	BLD	BLD
425	BLD	BLD	BLD	BLD	BLD	BLD
427	BLD	BLD	BLD	BLD	BLD	BLD

[a] : dpc, days post challenge
[b] : BLD, below limit of detection

Virus was detected where numeric values are shown. Higher values represent that more virus was detected.

Table 1 (continued)

Placebo Group (DNA copies/mL)						
ID	-1 dpc	7 dpc	14 dpc	21 dpc	28 dpc	35 dpc
380	BLD	BLD	2,353,452	250,123	177,646	123,584
381	BLD	BLD	198,460	417,162	94,376	139,430
383	BLD	BLD	BLD	1,264	149,566	69,432
385	BLD	BLD	232,231	284,585	134,877	356,955
389	BLD	BLD	BLD	2,514,503	15,345,861	1,552,982
390	BLD	BLD	91,320	1,066,535	501,876	396,603
392	BLD	BLD	17,773	4,346,139	73,556	52,150
396	BLD	BLD	363,493	98,781	27,068	20,616
397	BLD	BLD	2,251	436,719	77,316	56,483
399	BLD	BLD	715,268	932,715	79,298	201,210
401	BLD	BLD	BLD	Dead		
402	BLD	BLD	5,145	2,216,283	1,234,540	814,586
403	BLD	BLD	94,160	117,596	17,740	18,806
405	BLD	BLD	1,948,430	3,546,360	402,697	88,588
406	BLD	BLD	BLD	196,474	164,017	13,068
408	BLD	BLD	50,108	12,348,228	338,472	267,348
410	BLD	BLD	18,789	435,718	990,977	47,809
411	BLD	BLD	26,752	18,182,779	739,462	166,706
413	BLD	BLD	BLD	BLD	996,408	55,430
416	BLD	BLD	BLD	1,149	65,416	8,691
417	BLD	BLD	102,343	107,853,250	118,233	3,591,390
418	BLD	768	29,468,372	359,954	230,421	274,662
420	BLD	BLD	124,807	1,787,334	54,052	54,422
421	BLD	BLD	2,264,810	499,073	119,540	32,648
422	BLD	BLD	BLD	14,668	16,569	7,018

Pig 401 died from causes unrelated to the challenge, as affirmed by the licensee.

Table 2: Lymphoid Depletion due to PCV2d

Scoring Guide: Histopathology
0 Normal
1 Mild lymphoid depletion with loss of overall cellularity
2 Moderate lymphoid depletion
3 Severe lymphoid depletion with loss of follicle structure

Vaccinate Group				
ID	Tonsil	BLN [a]	MLN	PP
378	0	0	0	0
379	NS	0	1	0
382	0	0	0	0
384	0	1	1	0
386	0	0	0	0
387	0	1	0	0
388	0	0	0	0
391	0	0	0	0
393	0	0	0	0
394	0	1	0	1
395	0	0	0	0
398	0	1	0	0
400	0	0	0	0
404	0	0	0	0
407	0	0	0	0
409	0	0	0	0
412	0	0	0	0
414	0	0	0	0
415	0	1	0	0
419	0	0	0	0
423	0	0	0	0
424	0	0	0	0
425	0	0	0	0
427	0	0	0	0

Control Group				
ID	Tonsil	BLN	MLN	PP
380	0	0	1	0
381	0	1	1	0
383	0	1	1	1
385	0	0	1	0
389	2	2	2	3
390	2	1	2	1
392	1	1	1	1
396	1	1	1	0
397	0	0	1	0
399	2	1	2	1
401	0	0	1	1
402	2	1	2	1
403	1	1	1	0
405	1	1	1	1
406	2	1	1	1
408	2	2	2	2
410	2	1	1	1
411	1	0	1	1
413	1	1	2	0
416	2	1	2	1
417	1	1	0	0
418	1	0	1	1
420	1	0	1	0
421	1	0	0	1
422	0	0	1	0

[a] : BLN: Bronchial Lymph Node; MLN: Mesenteric Lymph Node; PP: Peyer's Patch

NS : No Sample (Incorrect tissue type was collected)

Table 3: Lymphoid Infection due to PCV2d

Scoring Guide: Immunohistochemistry
0 Negative, no staining
1 Positive, sparce staining
2 Positive, moderate staining
3 Positive, extreme staining

Vaccinate Group				
ID	Tonsil	BLN	MLN	PP
378	0	0	0	0
379	NS	0	0	0
382	0	0	0	0
384	0	0	1	0
386	0	0	0	0
387	0	2	0	0
388	0	0	0	0
391	0	0	0	0
393	0	0	0	0
394	0	0	0	0
395	0	0	0	0
398	0	0	0	0
400	0	0	0	0
404	0	0	0	0
407	0	0	0	0
409	0	0	0	0
412	0	0	0	0
414	0	0	0	0
415	0	1	0	0
419	0	1	0	0
423	0	0	0	0
424	0	0	0	0
425	0	0	0	0
427	0	0	0	0

Control Group				
ID	Tonsil	BLN	MLN	PP
380	1	2	1	1
381	0	1	2	1
383	2	1	1	2
385	0	0	0	0
389	3	3	1	3
390	2	1	2	1
392	2	2	3	1
396	1	1	0	0
397	1	0	2	0
399	1	1	2	1
401	0	0	0	0
402	2	2	2	1
403	1	0	1	0
405	1	0	1	1
406	2	0	1	1
408	2	1	2	1
410	2	1	2	1
411	2	1	2	2
413	2	0	2	1
416	1	0	0	1
417	1	1	1	2
418	1	0	2	1
420	1	1	2	1
421	1	0	1	1
422	0	0	0	1

Table 4: Lymphoid Inflammation due to PCV2d

Scoring Guide: Immunohistochemistry
0 Normal
1 Mild histiocytic to granulomatous inflammation
2 Moderate histiocytic to granulomatous inflammation
3 Severe histiocytic to granulomatous inflammation with replacement of follicles

Vaccinate Group				
ID	Tonsil	BLN	MLN	PP
378	0	0	0	0
379	NS	0	0	0
382	0	0	0	0
384	0	0	0	0
386	0	0	0	0
387	0	1	0	0
388	0	0	0	0
391	0	0	0	0
393	0	0	0	0
394	0	0	0	0
395	0	0	0	0
398	0	0	0	0
400	0	0	0	0
404	0	0	0	0
407	0	0	0	0
409	0	0	0	0
412	0	0	0	0
414	0	0	0	0
415	0	0	0	0
419	0	0	0	0
423	0	0	0	0
424	0	0	0	0
425	0	0	0	0
427	0	0	0	0

Control Group				
ID	Tonsil	BLN	MLN	PP
380	0	0	1	0
381	0	1	1	0
383	1	0	0	0
385	0	0	0	0
389	2	2	0	2
390	2	0	2	1
392	1	1	2	0
396	0	0	1	0
397	0	0	1	0
399	2	0	2	1
401	0	0	0	0
402	1	1	1	0
403	1	1	1	1
405	0	0	0	0
406	2	1	2	1
408	2	2	2	2
410	2	1	2	2
411	1	0	1	0
413	1	0	2	0
416	2	2	2	2
417	1	1	1	1
418	1	0	1	0
420	2	0	1	0
421	1	0	0	1
422	0	1	1	0

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Lawsonia intracellularis</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate 20-week duration of immunity against ileitis</td></tr>
<tr><td>Product Administration</td><td>A single dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>A total of 30 vaccinate and 26 control pigs, 3 weeks of age</td></tr>
<tr><td>Challenge Description</td><td>Lawsonia intracellularis administered 20 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Gross and microscopic (histopathological) lesions of the ileum were scored 21 days post-challenge.</td></tr>
<tr><td>Results</td><td>Animals were considered affected by the challenge if they presented with a gross lesion score > 1 OR presented with a microscopic histopathological lesion score > 0

<table>
<tr><td>Treatment Group</td><td>Gross Lesion Score >1</td><td>Histopathological Lesion Score >0</td></tr>
<tr><td>Vaccinates</td><td>13/30</td><td>12/30</td></tr>
<tr><td>Control</td><td>21/26</td><td>24/26</td></tr>
</table>

Raw data shown on Table 1.</td></tr>
<tr><td>USDA Approval Date</td><td>October 5, 2016</td></tr>
</table>

Appendix 1: SCORING GUIDE

Gross Lesion Score

0 Normal mucosa
1 Slight mucosal edema or slight hyperemia
2 Moderate ileitis
3 Severe ileitis
4 Severe ileitis plus additionally hemorrhaging and/or necrosis, blood clots or yellowish pseudomembrane

Microscopic Histopathological Lesion Score

0 No diagnostic lesions
1 Mild individual crypt proliferative change
2 Marked proliferative enterocolitis

Table 1

Vaccination Group				Control Group			
ID	Gross Lesion Scorer #1	Gross Lesion Scorer #2	Histo-pathological Score	ID	Gross Lesion Scorer #1	Gross Lesion Scorer #2	Histo-pathological Score
1413	0	1	0	1408	4	4	2
1414	1	1	0	1409	2	2	1
1415	2	2	1	1412	4	4	2
1419	0	0	0	1420	3	3	2
1423	2	2	2	1421	2	2	2
1430	2	2	1	1424	3	3	2
1431	2	2	0	1427	1	1	0
1436	2	2	2	1433	3	3	2
1437	1	1	0	1435	2	2	1
1443	4	4	2	1441	3	3	2
1444	1	1	0	1446	2	2	1
1447	1	1	0	1448	1	1	0
1451	1	1	0	1449	3	3	2
1454	0	0	0	1453	4	4	2
1455	2	2	2	1456	3	3	2
1459	3	3	2	1460	4	4	2
1465	1	1	1	1469	2	1	2
1468	2	2	0	1475	1	1	1
1470	0	1	0	1479	3	3	2
1474	0	0	0	1488	3	3	2
1478	2	2	0	1493	2	2	2
1483	0	1	0	1495	1	1	2
1485	0	0	0	1498	4	4	2
1487	2	2	0	1500	1	1	1
1492	2	2	2	1505	4	4	2
1496	2	2	2	1511	3	3	1
1503	1	0	2				
1506	0	1	2				
1507	0	1	0				
1510	1	1	0				

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Lawsonia intracellularis</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against Lawsonia intracellularis</td></tr>
<tr><td>Product Administration</td><td>A single dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>39 vaccinate and 39 control pigs, 3 weeks of age
Group A: 25 vaccinates and 25 placebo controls
Group B: 14 vaccinates and 14 placebo controls</td></tr>
<tr><td>Challenge Description</td><td>Lawsonia intracellularis administered 5 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Group A: For Ileitis and Ileal Colonization, tissues were evaluated 21 days post-challenge
Group B: For Fecal Shedding, feces were evaluated three times a week for 52 days post-challenge</td></tr>
<tr><td>Results</td><td>
<u>Ileitis</u>
Group A animals were considered affected by the challenge if they presented with a gross lesion score > 1 or presented with a microscopic histopathological lesion score > 0 in the ileum.
<table>
<tr><th>Treatment Group</th><th>Gross Lesion Score >1</th><th>Histopathological Lesion Score >0</th><th>Affected</th></tr>
<tr><td>Vaccinate</td><td>5/25</td><td>11/25</td><td>12/25</td></tr>
<tr><td>Control</td><td>19/25</td><td>21/25</td><td>21/25</td></tr>
</table>
<u>Ileal Colonization</u>
Group A animals were considered affected if they presented with a microscopic immunohistochemistry (IHC) score of > 0 in the ileum.
<table>
<tr><th>Treatment Group</th><th>IHC</th><th>Affected</th></tr>
<tr><td>Vaccinate</td><td>11/25</td><td>11/25</td></tr>
<tr><td>Control</td><td>21/25</td><td>21/25</td></tr>
</table>
<u>Fecal Shedding</u>
Group B animals were considered affected if they presented with a qPCR value ≥ limit of detection for Lawsonia in fecal samples for one or more of the postchallenge testing time points. Summary for duration of shedding in days is as follows:
<table>
<tr><th>Treatment Group</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr>
<tr><td>Vaccinate</td><td>14</td><td>26</td><td>28</td><td>34</td><td>53</td></tr>
<tr><td>Control</td><td>24</td><td>31</td><td>36</td><td>48</td><td>53</td></tr>
</table>
Raw data shown on the following pages
</td></tr>
</table>

USDA Approval Date	August 23, 2021

SCORING GUIDE

Ileitis

Gross Lesion Score
0 – Normal mucosa
1 – Slight mucosal edema or slight hyperemia
2 – Moderate ileitis
3 – Severe ileitis
4 – Severe ileitis plus additionally hemorrhaging and/or necrosis, blood clots or yellowish pseudomembrane

Microscopic Histopathological Lesion Score
0 No diagnostic lesions
1 Mild individual crypt proliferative change
2 Marked proliferative enterocolitis

Colonization

Immunohistochemical (IHC) Score
0 Negative, no staining
1 Positive, rare positive staining in fewer than 10 crypts per section
2 Positive, moderate positive staining in 10-20 crypts per section
3 Positive, abundant positive staining in more than 20 crypts per section

Fecal Shedding

qPCR of Fecal Samples
Results shown are Log_{10} DNA copies/mL
B: Below Limit Of Detection

TABLE 1: GROUP A

ID Vaccinate	Gross Lesion Scores		Microscopic Histopathological Score	IHC Score
	Scorer #1	Scorer #2		
512	0	0	1	2
514	1	1	0	0
521	0	0	0	0
524	1	1	0	0
528	0	0	1	2
534	0	0	1	1
535	0	0	0	0
538	0	0	0	0
541	0	0	0	0
542	0	0	0	0
544	0	0	0	0
548	0	0	0	0
550	0	0	1	1
553	0	0	1	1
556	1	1	2	3
557	0	0	0	0
560	2	2	1	1
564	1	1	0	0
572	4	4	2	3
574	4	4	2	3
577	0	0	0	0
581	3	3	2	3
582	0	0	1	1
583	3	3	0	0
594	0	0	0	0

ID Placebo	Gross Lesion Scores		Microscopic Histopathological Score	IHC Score
	Scorer #1	Scorer #2		
513	4	4	2	3
518	3	3	2	3
525	4	4	2	3
526	0	0	0	0
527	0	0	0	0
529	3	3	2	3
533	2	2	2	3
536	4	4	2	3
537	4	4	2	3
539	1	1	1	1
540	4	4	2	3
551	2	2	1	1
554	4	4	2	3
555	1	0	0	0
559	2	2	2	3
567	4	4	2	3
568	2	2	2	3
569	2	2	1	1
573	3	3	2	3
576	1	0	0	0
580	3	3	2	3
586	3	3	2	3
587	4	4	2	3
588	3	4	2	3
591	1	1	2	3

TABLE 2: FECAL SHEDDING GROUP B

Pig ID	Treatment	Day Post-Challenge																				
		-1	3	5	7	10	12	14	17	19	21	24	26	28	31	33	35	38	40	42	45	47
515	Vaccinate	B*	3.2	4.7	5.0	6.5	7.0	6.6	7.3	5.4	6.1	3.6	3.1	4.0	3.6	B	B	B	B	B	B	B
519	Vaccinate	B	4.7	2.9	4.1	5.8	6.5	6.5	5.7	4.2	5.1	B	B	B	B	B	B	B	B	B	B	B
523	Vaccinate	B	B	4.0	4.2	3.8	5.1	4.9	5.7	4.7	6.4	4.1	B	3.9	B	B	B	B	B	B	B	B
531	Vaccinate	B	B	4.1	4.3	6.8	7.2	6.3	6.1	5.9	6.9	3.1	B	2.5	B	B	B	B	B	B	B	B
543	Vaccinate	B	B	3.4	4.1	5.7	5.0	4.5	5.2	4.2	6.4	4.9	3.7	3.4	B	B	B	B	B	B	B	B
547	Vaccinate	B	B	B	3.5	4.9	5.2	4.6	5.9	4.5	5.6	3.9	4.6	5.3	4.7	B	B	B	B	B	B	B
552	Vaccinate	B	B	4.1	4.9	6.5	6.6	6.2	3.7	B	B	B	B	B	B	B	B	B	B	B	B	B
561	Vaccinate	B	B	4.3	4.8	5.7	6.5	6.3	6.7	4.0	6.8	6.4	6.3	4.8	4.4	2.7	B	4.1	B	B	B	B
565	Vaccinate	B	3.6	4.8	4.3	5.4	6.1	5.2	4.2	2.7	3.5	2.4	B	B	B	B	B	3.4	B	B	B	B
566	Vaccinate	B	B	B	3.6	6.2	5.2	5.2	5.0	4.2	6.3	3.8	4.5	5.2	4.3	3.1	3.0	B	B	B	B	B
571	Vaccinate	B	B	3.9	3.7	6.8	6.0	7.0	7.8	6.9	7.9											
578	Vaccinate	B	B	B	B	4.2	2.9	3.4	3.8	2.9	4.6	3.3	B	2.8	2.4	B	B	B	B	B	B	B
579	Vaccinate	B	3.3	4.5	5.7	6.1	6.4	6.1	7.1	6.3	8.4	6.8	7.4	7.4	5.0	2.6	3.2	4.8	B	3.3	B	B
592	Vaccinate	B	3.9	4.3	6.1	4.3	4.9	4.9	5.5	4.6	6.6	5.7	6.0	5.8	4.3	2.9	B	B	B	B	B	B
517	Placebo	B	B	3.5	2.8	5.4	5.1	4.6	6.0	6.1	7.2	4.6	2.3	3.2	4.6	3.9	2.9	B	B	B	B	B
520	Placebo	B	3.2	3.9	4.0	5.2	6.2	5.2	5.8	3.9	5.0	B	B	B	B	2.8	2.7	B	B	B	B	B
522	Placebo	B	B	4.1	6.4	6.6	7.0	6.6	7.4	5.7	8.5	4.5	5.4	4.9	3.6	B	B	B	B	B	B	B
532	Placebo	B	3.1	4.1	4.5	5.6	6.2	3.9	6.6	6.1	B	6.0	5.0	5.1	5.1	4.2	4.4	3.0	B	B	B	B
545	Placebo	B	B	B	3.8	5.1	6.0	5.6	6.4	5.5	7.7	5.6	4.9	3.2	B	B	B	B	B	B	B	B
546	Placebo	B	B	B	4.8	5.5	6.0	5.9	6.5	4.7	6.8	6.0	6.6	6.2	6.3	6.1	5.4	5.4	B	B	B	B
549	Placebo	B	3.3	5.5	6.1	7.6	8.4	7.9	8.1	6.0	6.6	5.5	2.9	B	2.5	B	B	B	B	B	B	B
558	Placebo	B	2.6	2.6	4.4	5.9	6.6	6.4	7.3	7.5	8.1	5.2	6.5	6.0	5.4	5.1	5.8	6.7	5.2	5.8	6.6	6.0
562	Placebo	B	4.0	5.1	6.8	6.8	7.7	9.1	7.7	5.8	7.5	4.9										
570	Placebo	B	B	B	3.9	5.1	6.8	6.1	6.0	7.6	9.4	7.8										
584	Placebo	B	B	3.3	4.3	6.0	5.5	6.3	6.9	6.0	6.7	5.4	3.9	3.0	B	B	B	B	B	B	B	B
585	Placebo	B	2.7	4.0	B	5.4	5.7	5.4	6.5	6.2	9.3	7.3	5.5	5.2	5.4	4.5	2.4	4.0	B	B	B	B
589	Placebo	B	3.7	5.9	6.8	8.4	7.3	7.3	7.6	6.5	8.1											
590	Placebo	B	3.9	5.3	5.7	7.8	6.5	6.4	8.5	6.9	7.2	6.3	7.8	7.6	6.8	6.1	3.6	2.6	B	B	B	B

All values in $\log_{10}$ DNA copies/mL

*B is below the limit of detection in qPCR assay

The firm affirmed that ID 571, 562, 570 and 589 died or were humanely euthanized as a result of the challenge

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mycoplasma hyopneumoniae</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate a 10-week duration of immunity against respiratory disease caused by Mycoplasma hyopneumoniae</td></tr>
<tr><td>Product Administration</td><td>One dose, administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>Commercial pigs, 3 weeks of age, 35 vaccinates and 35 controls at each of two sites, LIV-090 and LIV-092</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged 10 weeks post vaccination with Mycoplasma hyopneumoniae</td></tr>
<tr><td>Interval observed after challenge</td><td>The pigs were observed for 28-30 days post challenge for clinical signs then lung tissue was examined.</td></tr>
<tr><td>Results</td><td>Summary Lung Lesion Scores

Table 1: Percent Lung Lesions in Study LIV-090.
<table><tr><th>Group</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr><tr><td>Vaccinate</td><td>1</td><td>2</td><td>6</td><td>10</td><td>30</td></tr><tr><td>Control</td><td>3</td><td>9</td><td>12</td><td>19</td><td>30</td></tr></table>Q=quartile

Table 2: Percent Lung Lesions in Study LIV-092.
<table><tr><th>Group</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr><tr><td>Vaccinate</td><td>0</td><td>5</td><td>11</td><td>21</td><td>40</td></tr><tr><td>Control</td><td>1</td><td>17</td><td>32</td><td>38</td><td>65</td></tr></table>Q=quartile
In each of the studies, injection site reactions were noted and resolved within 19 days.

Two pigs from the vaccinate group for study LIV-090 died from causes unrelated to the study, prior to challenge.

Two pigs from the vaccinate group, and one pig from the placebo group for study LIV-092 died from causes unrelated to the study, prior to challenge.

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>April 1, 2019</td></tr>
</table>

Lung Score Data of Placebo Vaccinated Pigs (Study LIV-090)

Sow No.	Study Pig No.	Treatment	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
1456	339	Placebo	6.07	6.72	6.40
1326	341	Placebo	8.57	7.92	8.24
1326	343	Placebo	21.80	16.92	19.36
1326	344	Placebo	8.79	7.92	8.35
1326	348	Placebo	22.13	22.99	22.56
1361	353	Placebo	9.44	7.81	8.62
1361	356	Placebo	17.35	17.68	17.52
1361	358	Placebo	17.46	18.66	18.06
1326	359	Placebo	6.18	6.40	6.29
1456	360	Placebo	10.85	7.70	9.27
1456	362	Placebo	17.68	16.05	16.87
1361	364	Placebo	21.58	23.21	22.40
1456	365	Placebo	10.20	11.06	10.63
1561	368	Placebo	12.58	15.08	13.83
1565	369	Placebo	22.45	21.15	21.80
1561	370	Placebo	22.78	22.56	22.67
1561	379	Placebo	23.97	27.33	25.65
1565	382	Placebo	10.74	9.00	9.87
1565	383	Placebo	5.53	4.77	5.15
1565	384	Placebo	12.80	12.04	12.42
1565	385	Placebo	23.32	23.32	23.32
1243	388	Placebo	9.98	9.11	9.54
1243	389	Placebo	7.81	8.13	7.97
1243	391	Placebo	12.26	15.84	14.05
1243	394	Placebo	2.60	3.15	2.87
1243	395	Placebo	4.56	4.77	4.66
1672	397	Placebo	9.54	7.59	8.57
1672	400	Placebo	9.22	15.18	12.20
1578	402	Placebo	20.17	28.74	24.46
1578 or 1672	405	Placebo	10.95	9.54	10.25
1578	406	Placebo	12.58	12.36	12.47
1578	407	Placebo	8.57	12.80	10.68
1672	408	Placebo	28.63	30.59	29.61
1578	410	Placebo	16.05	14.97	15.51
1578	413	Placebo	9.76	9.54	9.65

Lung Score Data of Vaccinate Pigs (Study LIV-090)

Sow No.	Study Pig No.	Treatment	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
1456	340	Vaccinate	7.27	6.62	6.94
1456	342	Vaccinate	11.71	13.02	12.36
1456	345	Vaccinate	13.45	12.04	12.74
1326	346	Vaccinate	6.72	8.03	7.38
1326	347	Vaccinate	8.35	6.29	7.32
1456	349	Vaccinate	2.17	1.41	1.79
1326	350	Vaccinate	1.3	2.06	1.68
1361	354	Vaccinate	18.66	16.49	17.57
1326	355	Vaccinate	26.46	25.49	25.98
1326	357	Vaccinate	7.59	8.57	8.08
1361	361	Vaccinate	6.83	8.13	7.48
1361	363	Vaccinate	29.28	31.02	30.15
1326	366	Vaccinate	1.19	0.65	0.92
1561	367	Vaccinate	6.4	5.21	5.8
1565	371	Vaccinate	2.39	3.36	2.87
1561	372	Vaccinate	2.17	2.28	2.22
1565	373	Vaccinate	2.17	1.41	1.79
1565	375	Vaccinate	3.58	2.82	3.2
1565	376	Vaccinate	3.58	3.58	3.58
1561	377	Vaccinate	0.65	1.63	1.14
1565	380	Vaccinate	15.62	15.18	15.4
1565	381	Vaccinate	0.65	0.76	0.70
1243	386	Vaccinate	2.71	2.17	2.44
1243	387	Vaccinate	2.39	3.15	2.77
1243	392	Vaccinate	0.76	1.52	1.14
1243	393	Vaccinate	1.52	1.74	1.63
1578 or 1672	396	Vaccinate	9.98	9.54	9.76
1578	398	Vaccinate	18.22	18.33	18.28
1672	399	Vaccinate	1.52	0	0.76
1578	401	Vaccinate	9.87	10.95	10.41
1578	403	Vaccinate	19.09	17.46	18.28
1578	404	Vaccinate	6.18	6.4	6.29
1672	409	Vaccinate	11.50	8.35	9.92

Lung Score Data of Placebo Vaccinated Pigs (Study LIV-092)

Sow No.	Study Pig No.	Treatment	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
3135	1265	Placebo	5.31	4.01	4.66
3135	1268	Placebo	34.16	35.25	34.71
3135	1271	Placebo	15.18	17.14	16.16
3135	1273	Placebo	35.57	32.21	33.89
3141	1279	Placebo	36.88	31.89	34.38
3141	1281	Placebo	43.17	53.25	48.21
3141	1282	Placebo	30.37	35.14	32.75
3139	1292	Placebo	11.93	14.97	13.45
3139	1293	Placebo	1.19	1.30	1.25
3139	1296	Placebo	43.82	45.66	44.74
3139	1298	Placebo	27.44	28.74	28.09
2616	1304	Placebo	35.57	36.33	35.95
2616	1305	Placebo	17.57	15.73	16.65
2616	1306	Placebo	57.27	59.44	58.35
2616	1308	Placebo	26.68	27.22	26.95
2616	1309	Placebo	36.88	42.95	39.91
2623	1314	Placebo	37.31	40.56	38.94
2623	1315	Placebo	21.48	25.49	23.48
2623	1318	Placebo	33.62	31.02	32.32
2623	1319	Placebo	34.71	31.13	32.92
3145	1332	Placebo	11.82	16.59	14.21
3145	1335	Placebo	17.57	16.16	16.87
3145	1338	Placebo	45.12	47.18	46.15
3145	1339	Placebo	26.90	36.88	31.89
3109	1343	Placebo	13.56	13.67	13.61
3109	1345	Placebo	13.56	15.73	14.64
3109	1346	Placebo	27.44	25.05	26.25
3109	1351	Placebo	57.38	72.23	64.80
3109	1353	Placebo	6.18	4.77	5.48
3108	1358	Placebo	18.44	20.61	19.52
3108	1359	Placebo	49.78	51.63	50.70
3108	1360	Placebo	24.73	24.08	24.40
3108	1361	Placebo	29.72	32.65	31.18
3108	1362	Placebo	54.34	56.51	55.42

Lung Score Data of Vaccinate Pigs (Study LIV-092)

Sow No.	Study Pig No.	Treatment	Operator 1 Percent Lung Score	Operator 2 Percent Lung Score	Lung Score Average of Operators 1 and 2
3135	1264	Vaccinate	40.46	39.37	39.91
3135	1266	Vaccinate	20.07	17.35	18.71
3135	1269	Vaccinate	2.39	1.52	1.95
3135	1272	Vaccinate	18.55	13.67	16.11
3141	1275	Vaccinate	34.71	34.06	34.38
3141	1276	Vaccinate	17.79	16.49	17.14
3141	1278	Vaccinate	30.37	36.01	33.19
3139	1291	Vaccinate	7.59	9.76	8.68
3139	1294	Vaccinate	2.71	1.84	2.28
3139	1295	Vaccinate	2.60	2.06	2.33
3139	1297	Vaccinate	3.36	0.43	1.90
2616	1301	Vaccinate	8.03	14.97	11.50
2616	1302	Vaccinate	28.52	32.43	30.48
2616	1307	Vaccinate	5.31	4.77	5.04
2623	1313	Vaccinate	11.06	11.17	11.12
2623	1316	Vaccinate	23.86	22.45	23.16
2623	1317	Vaccinate	15.29	16.81	16.05
2623	1320	Vaccinate	32.43	30.59	31.51
2623	1321	Vaccinate	11.39	7.38	9.38
3145	1330	Vaccinate	3.36	3.25	3.31
3145	1333	Vaccinate	8.89	7.16	8.03
3145	1334	Vaccinate	3.58	4.34	3.96
3145	1336	Vaccinate	39.59	34.60	37.09
3145	1337	Vaccinate	18.98	17.90	18.44
3109	1344	Vaccinate	5.86	6.51	6.18
3109	1347	Vaccinate	0.00	0.00	0.00
3109	1349	Vaccinate	2.06	3.04	2.55
3109	1352	Vaccinate	9.76	10.41	10.09
3108	1354	Vaccinate	15.08	13.67	14.37
3108	1356	Vaccinate	8.46	7.70	8.08
3108	1357	Vaccinate	22.56	18.22	20.39
3108	1365	Vaccinate	31.13	29.28	30.21

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mycoplasma hyopneumoniae</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate protection against respiratory disease due to M. hyopneumoniae</td></tr>
<tr><td>Product Administration</td><td>One dose, administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>Commercial pigs, 3 weeks of age, 35 vaccinates and 35 controls</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged 8 weeks after vaccination with Mycoplasma hyopneumoniae</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 28 days post challenge</td></tr>
<tr><td>Results</td><td>Summary for lung consolidation (%)
<table>
<tr><th>Treatment</th><th>Min</th><th>Q1</th><th>Med</th><th>Q3</th><th>Max</th></tr>
<tr><td>Vaccinates</td><td>0.9</td><td>4.8</td><td>7.8</td><td>14.6</td><td>31.5</td></tr>
<tr><td>Controls</td><td>6.2</td><td>10.3</td><td>15.5</td><td>21.0</td><td>42.0</td></tr>
</table>
One pig from each of the vaccinate and placebo groups died from causes unrelated to the study as affirmed by licensee, prior to challenge.

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>September 16, 2016</td></tr>
</table>

Table 1: Lung Consolidation Scores (%), in order of rank:

Vaccinate	Control
0.87	6.24
1.03	7.16
1.30	8.41
2.28	9.00
3.09	9.71
3.15	9.87
3.31	10.09
3.96	10.14
4.83	10.30
5.21	10.36
5.64	10.90
6.02	11.23
6.67	12.26
6.89	13.39
7.05	13.88
7.48	14.32
7.65	15.46
7.92	15.56
8.08	16.87
8.46	17.30
8.84	17.62
10.20	17.90
12.64	19.63
12.92	19.79
14.37	20.55
14.64	21.04
15.51	22.94
16.11	23.86
20.23	24.62
21.91	25.33
22.51	26.68
23.64	31.07
26.41	41.43
31.45	42.03

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical field conditions</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>681 pigs, 17-24 days of age at 3 geographically distinct study sites</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for one hour after vaccination and then daily for 14 days, or until resolution of any adverse events.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Adverse Events (AE) *
(Total 681 pigs)</th><th>Number</th></tr>
<tr><td>Injection Site Swelling[1]:</td><td>413</td></tr>
<tr><td>S (<1.5 cm)</td><td>208</td></tr>
<tr><td>M (1.5 to 5 cm)</td><td>174</td></tr>
<tr><td>L (>5 to 10 cm)</td><td>31</td></tr>
<tr><td>Anaphylaxis[2]</td><td>4</td></tr>
<tr><td>Anorexia</td><td>8</td></tr>
<tr><td>Ataxia</td><td>1</td></tr>
<tr><td>Bone and joint disorder</td><td>2</td></tr>
<tr><td>Cough</td><td>5</td></tr>
<tr><td>Death[3]</td><td>1</td></tr>
<tr><td>Diarrhoea</td><td>8</td></tr>
<tr><td>Lameness</td><td>8</td></tr>
<tr><td>Lethargy</td><td>28</td></tr>
<tr><td>Tachypnoea</td><td>43</td></tr>
<tr><td>No AEs</td><td>236</td></tr>
</table>
[1]Injection site swellings resolved 5-28 days post-vaccination.

[2]Vaccine related AE. Pigs were laterally recumbent after vaccination which resolved by one-hour post-vaccination.

[3]Affirmed by licensee to have cause not related to vaccination.

*Subjects may have had AE’s in more than one VeDDRA Preferred Term and are counted once in each appropriate class.
</td></tr>
<tr><td>USDA Approval Date</td><td>October 16, 2017</td></tr>
</table>