Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	19S1.20
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prevacent PRRS - Elanco US Inc.
Date of Compilation Summary	July 08, 2020

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 Reproductive and Respiratory Syndrome Virus (PRRSV)</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory form of PRRSV disease</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly.</td></tr>
<tr><td>Study Animals</td><td>Crossbred pigs, 14-15 days old, seronegative to PRRSV. Twenty placebo controls and one group of 20 vaccinates.</td></tr>
<tr><td>Challenge Description</td><td>28 Days after vaccination, pigs were challenged with virulent PRRSV Type 2.</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 14 days after challenge.</td></tr>
<tr><td>Results</td><td>The percent of the lung mass that was abnormal was calculated for every animal. A pig was considered affected if the lung lesion score was ≥2%.

5-number summary for lung consolidation (%)

<table>
<tr><th>Treatment Group</th><th>Min</th><th>Q1</th><th>Med</th><th>Q3</th><th>Max</th></tr>
<tr><td>Placebo Control</td><td>8.2</td><td>47.2</td><td>56.0</td><td>68.5</td><td>76.5</td></tr>
<tr><td>Vaccinate</td><td>0.0</td><td>0.4</td><td>1.2</td><td>3.7</td><td>56.5</td></tr>
</table>

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

Lung Consolidation scores (%), in order of rank	
Placebo Control Group	**Vaccinate Group**
8.2	0.0
32.5	0.1
42.5	0.1
45.0	0.2
46.0	0.3
48.5	0.4
49.5	0.4
50.5	0.5
52.5	0.5
55.0	1.0
57.0	1.5
57.5	1.7
58.5	2.2
59.5	2.4
67.0	3.6
70.0	3.8
70.0	4.3
71.5	4.5
74.5	21.8
76.5	56.5

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate 26 week Duration of Immunity against PRRSV-associated respiratory disease.</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>Sixty-eight (68) Crossbred pigs, 14 days old, seronegative to PRRSV were randomized into 2 treatment groups. Thirty-two (32) placebo controls and 36 vaccinates were used for the study analysis.</td></tr>
<tr><td>Challenge Description</td><td>Twenty-six weeks (182 days) after vaccination pigs were challenged with PRRSV.</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 14 days after challenge.</td></tr>
<tr><td>Results</td><td>Primary outcome of the study was the reduction in lung lesion score. The percent of the lung mass that was abnormal was calculated for every animal.

5-number summary for lung consolidation (%)

<table>
<tr><th>Treatment Group</th><th>Min</th><th>Q1</th><th>Med</th><th>Q3</th><th>Max</th></tr>
<tr><td>Placebo</td><td>0</td><td>2.9</td><td>18.6</td><td>35.5</td><td>66</td></tr>
<tr><td>Vaccinate - low dose</td><td>0</td><td>0</td><td>0.2</td><td>0.4</td><td>34</td></tr>
</table>

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>April 30, 2018</td></tr>
</table>

Lung Consolidation Scores (%) in order of rank	
Vaccinates	Controls
0	0
0	0.1
0	0.1
0	0.1
0	0.4
0	0.55
0	0.8
0	1.2
0	3.45
0	4.15
0	4.95
0	8.65
0	11.45
0	11.8
0.1	12.9
0.1	18
0.1	19.35
0.1	21.75
0.2	26.25
0.2	27
0.2	28.7
0.2	32.5
0.2	33.6
0.2	35.5
0.2	35.5
0.3	38.5
0.35	46
0.45	51.5
0.5	52.2
0.6	55.5
1.75	64
1.95	66
2.5	
3.6	
7.9	
34	

<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 use conditions</td></tr>
<tr><td>Product Administration</td><td>1 Dose administered by the IM route</td></tr>
<tr><td>Study Animals</td><td>920 crossbred/ mixed pigs 14-24 days of age were enrolled in the study into 3 groups: one group was administered Serial 1 of the vaccine; another group was administered Serial 2 of the vaccine; and the Control Product group was administered sterile diluent. The Serial 1 group and the Control Product group each consisted of 132 pigs receiving a dose at 14 days of age and 175 pigs receiving a dose at 15-24 days of age. The Serial 2 group consisted of 131 pigs receiving a dose at 14 days of age and 175 pigs receiving a dose at 15-24 days of age. Pigs were located in three distinct geographical areas.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were observed 1-2 hours post vaccination. Daily pen-side observations were conducted from day 1 through 21 days post vaccination. Palpation of injection site was performed on day 7 post vaccination.</td></tr>
<tr><td>Results</td><td>Palpable injection site reactions were not observed.

Frequency of Events:
<table>
<tr><th>Reaction Type</th><th>Control Product (Sterile Diluent) No. of Pigs</th><th>Serial 1 No. of Pigs</th><th>Serial 2 No. of Pigs</th></tr>
<tr><td>Injection Site Scab post-vaccination</td><td>0</td><td>1</td><td>1</td></tr>
<tr><td>Loss of Condition</td><td>10</td><td>17</td><td>9</td></tr>
<tr><td>Decreased Appetite</td><td>1</td><td>2</td><td>1</td></tr>
<tr><td>Anorexia</td><td>0</td><td>2</td><td>2</td></tr>
<tr><td>Diarrhea</td><td>2</td><td>1</td><td>1</td></tr>
<tr><td>Ataxia</td><td>0</td><td>1</td><td>1</td></tr>
<tr><td>Tremor</td><td>0</td><td>1</td><td>0</td></tr>
<tr><td>Lameness</td><td>4</td><td>2</td><td>1</td></tr>
<tr><td>Depression</td><td>2</td><td>2</td><td>3</td></tr>
<tr><td>Dyspnea</td><td>0</td><td>2</td><td>1</td></tr>
<tr><td>Inguinal hernia</td><td>0</td><td>1</td><td>0</td></tr>
<tr><td>Death*</td><td>3</td><td>5</td><td>3</td></tr>
<tr><td>No Reaction</td><td>285</td><td>270</td><td>283</td></tr>
</table>
* Deaths not attributable to vaccine affirmed by licensee</td></tr>
</table>

USDA Approval Date	April 10, 2018