



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19A5.R8
True Name	Swine Influenza Vaccine, N1 & N2, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Sequivity - Merck Animal Health
Date of Compilation Summary	June 24, 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.

Study Type	Efficacy																					
Pertaining to	Swine Influenza Virus, H1N1																					
Study Purpose	Demonstrate efficacy against swine influenza virus, H1N1, 12-weeks after 2 nd vaccination to establish the duration of immunity.																					
Product Administration	Two doses, administered intramuscularly, three weeks apart. NA1 (A/swine/IA/A01410307/2014 (H1N1)) – NA6 (A/swine/MN/A01483170/2014 (H1N1)) NA4 (A/swine/MI/A02077465/2015 (H1N2)) – NA2 (A/swine/IL/A01475495/2014 (H1N2))																					
Study Animals	Commercial pigs, three days of age, 32 vaccinates and 30 controls (placebo vaccinated).																					
Challenge Description	All pigs were challenged 12 weeks post second vaccination with swine influenza strain A/swine/Indiana/A02429505/2019 (H1N1).																					
Interval observed after challenge	Lung lesion scores were assessed 5 days post challenge on a subgroup of 20 vaccinates and 18 controls.																					
Results	<p>Five number summary for lung lesion scores*:</p> <table border="1"> <thead> <tr> <th><i>Group</i></th> <th><i>Number</i></th> <th><i>Minimum</i></th> <th><i>Q1</i></th> <th><i>Median</i></th> <th><i>Q3</i></th> <th><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td><i>Vaccinate</i></td> <td>20</td> <td>0.3</td> <td>0.7</td> <td>1.2</td> <td>2.8</td> <td>6.9</td> </tr> <tr> <td><i>Placebo</i></td> <td>18</td> <td>3.8</td> <td>6.0</td> <td>8.9</td> <td>13.1</td> <td>24.7</td> </tr> </tbody> </table> <p>*Lesion scores were calculated as the percentage of total lung area</p> <p>Raw data are shown below.</p>	<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>	<i>Vaccinate</i>	20	0.3	0.7	1.2	2.8	6.9	<i>Placebo</i>	18	3.8	6.0	8.9	13.1	24.7
<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>																
<i>Vaccinate</i>	20	0.3	0.7	1.2	2.8	6.9																
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USDA Approval Date	June 10, 2020																					

Table 1: Lung Lesion Scoring (LLS) by 1st Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
2904	Vaccinate	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0	0.0	0.0	0.0	0.0	2.5	0.21
2908	Vaccinate	0.0	14.0	5.0	0.5	14.5	1.5	0.0	10.0	2.0	0.0	15.0	1.0	2.5	66.0	5.59
2913	Vaccinate	0.0	2.0	0.0	0.0	2.0	0.0	0.0	2.0	0.0	0.0	1.5	0.0	0.0	7.5	0.64
2914	Vaccinate	0.0	2.0	1.0	0.0	2.0	0.0	0.0	1.5	0.0	0.0	1.5	1.5	0.0	9.5	0.80
2915	Vaccinate	0.0	8.5	1.5	0.0	9.5	0.0	0.0	2.5	0.0	0.0	4.0	1.5	0.0	27.5	2.33
2920	Vaccinate	0.0	4.5	2.0	0.0	4.5	2.5	1.0	3.0	1.5	0.5	6.0	0.5	1.5	27.5	2.33
2924	Vaccinate	0.0	0.5	0.0	0.0	2.0	0.0	0.0	1.0	0.0	0.0	2.5	0.0	0.0	6.0	0.51
2927	Vaccinate	0.0	2.0	0.0	0.0	1.0	1.0	0.0	2.0	0.0	0.0	1.0	0.5	0.5	8.0	0.68
2932	Vaccinate	0.0	0.5	0.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0	1.5	1.5	1.5	6.5	0.55
2935	Vaccinate	0.0	3.0	2.0	0.0	1.5	0.0	0.0	3.5	2.0	0.0	1.0	1.0	0.0	14.0	1.19
2945	Vaccinate	0.0	2.5	1.5	1.5	2.0	1.0	0.5	2.0	1.0	1.5	2.0	1.0	1.0	17.5	1.48
2947	Vaccinate	0.0	2.0	1.0	0.5	1.5	1.0	0.0	0.5	0.0	0.5	2.0	0.5	1.5	11.0	0.93
2957	Vaccinate	0.0	1.5	0.0	0.0	2.0	0.0	0.0	1.5	0.0	0.0	1.5	0.0	0.0	6.5	0.55
2959	Vaccinate	0.0	3.0	2.5	0.0	4.0	1.5	0.0	1.0	1.5	0.0	2.0	1.0	0.0	16.5	1.40
2972	Vaccinate	2.5	5.0	5.5	2.5	5.0	7.0	2.0	4.0	0.0	4.0	7.0	2.5	2.5	49.5	4.19
2975	Vaccinate	0.0	6.0	4.0	0.0	6.5	0.5	0.0	4.5	3.0	0.0	7.5	3.5	1.0	36.5	3.09
2983	Vaccinate	0.0	2.5	0.0	0.0	1.5	0.0	0.0	2.0	0.0	0.0	2.5	0.0	0.0	8.5	0.72
2986	Vaccinate	0.0	8.0	2.5	9.0	8.5	5.0	0.0	9.0	3.0	8.5	14.0	3.0	2.0	72.5	6.14
2987	Vaccinate	1.5	1.5	0.0	1.0	4.5	0.0	1.0	2.0	1.5	0.0	5.0	1.0	0.0	19.0	1.61
2990	Vaccinate	0.0	6.5	0.0	4.0	9.0	1.0	0.0	4.5	1.0	3.0	8.0	1.5	2.0	40.5	3.43
2901	Placebo	2.5	18.5	4.0	3.0	24.0	1.5	5.5	21.5	2.0	4.5	27.5	1.0	3.5	119.0	10.08
2910	Placebo	0.5	23.0	3.0	1.0	11.5	1.0	1.5	12.0	8.0	1.5	19.0	2.0	2.0	86.0	7.28
2916	Placebo	1.0	12.0	0.0	2.5	4.5	0.0	2.0	4.5	0.0	1.0	5.5	0.5	1.5	35.0	2.96
2918	Placebo	0.0	3.0	2.0	1.5	6.0	7.0	2.5	2.5	2.0	3.0	9.0	2.5	5.5	46.5	3.94
2919	Placebo	0.0	21.5	4.0	2.5	13.5	3.0	1.5	11.5	2.0	0.0	10.5	2.5	3.5	76.0	6.44
2922	Placebo	2.5	16.0	8.5	7.0	28.0	17.0	8.0	16.0	4.5	9.5	40.0	7.5	5.0	169.5	14.35
2923	Placebo	3.5	31.5	26.0	5.5	27.0	5.5	11.5	25.0	18.5	5.0	40.0	3.0	10.5	212.5	17.99
2933	Placebo	5.0	8.0	14.5	7.0	16.0	8.5	9.0	11.0	12.0	14.0	22.0	6.5	8.0	141.5	11.98
2934	Placebo	1.0	22.0	3.0	1.0	11.0	1.0	1.5	11.5	2.5	1.0	13.5	0.0	1.0	70.0	5.93
2941	Placebo	0.5	12.5	3.0	5.0	5.5	2.5	1.5	8.0	1.5	7.5	15.0	2.0	6.0	70.5	5.97
2946	Placebo	1.5	6.0	3.5	15.5	15.5	13.0	2.0	9.0	2.0	19.5	23.5	8.0	5.5	124.5	10.54
2952	Placebo	1.5	23.5	14.5	8.5	22.0	5.5	8.0	14.5	8.5	11.0	38.0	2.5	4.5	162.5	13.76
2956	Placebo	2.5	23.0	4.0	6.0	28.0	5.0	1.0	22.0	2.0	5.5	35.0	4.0	4.5	142.5	12.07
2977	Placebo	10.0	26.0	20.0	12.5	25.0	27.0	18.5	30.5	26.0	21.0	60.0	20.0	10.5	307.0	25.99
2982	Placebo	0.0	11.5	4.0	3.5	10.0	5.0	4.0	4.5	3.5	7.5	14.0	2.0	1.0	70.5	5.97
2984	Placebo	1.5	31.0	15.0	8.5	17.0	3.0	3.5	16.5	26.0	5.0	33.0	3.0	3.0	166.0	14.06
2993	Placebo	0.0	5.5	3.0	6.5	6.5	0.0	3.5	10.5	1.5	6.0	7.0	1.5	2.0	53.5	4.53
2994	Placebo	2.0	23.5	3.0	7.0	7.5	0.0	7.0	16.0	3.0	7.5	11.5	5.0	4.0	97.0	8.21

Code

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- DLA = Dorsal Left Apical Lobe
 - DLC = Dorsal Left Cardiac Lobe
 - DLD = Dorsal Left Diaphragmatic Lobe
 - DRA = Dorsal Right Apical Lobe
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 - VRA = Ventral Right Apical Lobe
 - VRC = Ventral Right Cardiac Lobe
 - VRD = Ventral Right Diaphragmatic Lobe

Table 2: Lung Lesion Scoring (LLS) by 2nd Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
2904	Vaccinate	0.0	2.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0	0.0	0.0	0.0	0.0	3.5	0.30
2908	Vaccinate	0.0	16.5	2.0	0.5	19.0	1.0	0.5	10.5	1.0	1.0	13.5	1.5	0.5	67.5	5.72
2913	Vaccinate	0.0	1.5	0.0	0.0	1.5	1.0	0.0	2.5	0.0	0.0	2.0	0.0	0.0	8.5	0.72
2914	Vaccinate	0.0	3.5	0.5	0.0	4.5	0.5	0.0	2.0	1.0	0.5	3.0	1.0	0.5	17.0	1.44
2915	Vaccinate	0.0	12.0	1.0	0.0	6.0	1.0	0.5	3.0	1.5	0.0	5.0	0.0	0.5	30.5	2.58
2920	Vaccinate	0.0	8.0	2.0	0.5	5.5	2.0	1.0	6.0	0.5	1.0	5.5	2.0	1.5	35.5	3.01
2924	Vaccinate	0.0	0.5	1.0	0.0	1.5	0.0	0.0	1.0	0.0	0.5	2.0	0.0	0.0	6.5	0.55
2927	Vaccinate	0.0	3.0	1.0	0.0	1.5	1.0	0.0	2.0	0.0	0.0	1.5	0.5	0.5	11.0	0.93
2932	Vaccinate	0.0	1.0	1.5	0.5	0.5	0.5	0.0	1.0	0.0	0.5	0.5	1.5	1.0	8.5	0.72
2935	Vaccinate	0.5	1.5	2.0	0.0	1.5	0.0	0.0	3.5	2.0	0.0	3.0	0.5	0.5	15.0	1.27
2945	Vaccinate	0.0	3.0	1.0	1.5	2.0	1.0	1.0	2.5	0.5	1.5	1.0	0.0	1.0	16.0	1.35
2947	Vaccinate	0.0	1.0	0.5	0.0	1.5	0.5	0.0	0.5	0.0	0.0	1.0	0.5	0.5	6.0	0.51
2957	Vaccinate	0.0	1.0	0.0	0.0	1.5	0.0	0.0	2.5	0.0	0.0	1.5	0.0	0.0	6.5	0.55
2959	Vaccinate	0.0	2.0	2.5	0.0	4.0	0.0	0.0	1.0	1.0	0.5	2.0	1.0	0.0	14.0	1.19
2972	Vaccinate	1.0	4.0	4.0	1.0	4.0	7.0	1.5	4.0	3.0	1.5	3.5	6.0	2.0	42.5	3.60
2975	Vaccinate	0.0	8.5	0.0	0.0	6.5	1.5	0.0	7.5	3.0	0.0	8.5	1.5	0.5	37.5	3.18
2983	Vaccinate	0.0	2.0	0.0	0.0	2.0	0.0	0.0	4.0	0.0	0.0	1.5	0.0	0.5	10.0	0.85
2986	Vaccinate	1.0	13.5	4.0	10.0	8.5	5.5	0.0	9.5	3.0	9.0	17.0	6.0	3.5	90.5	7.66
2987	Vaccinate	1.0	2.0	1.5	1.0	2.5	0.0	1.0	3.0	1.5	1.0	5.5	1.0	0.0	21.0	1.78
2990	Vaccinate	0.5	7.0	3.5	4.0	9.5	2.5	0.0	10.5	1.0	1.5	8.5	2.5	0.5	51.5	4.36
2901	Placebo	3.5	24.0	2.5	3.0	17.5	1.5	6.0	23.0	4.0	8.0	28.5	2.0	1.0	124.5	10.54
2910	Placebo	2.0	23.5	6.0	3.0	11.5	2.0	7.0	20.5	4.5	2.5	14.5	3.5	1.5	102.0	8.64
2916	Placebo	2.5	16.0	1.0	3.0	5.0	0.0	3.5	12.0	0.0	2.5	6.5	1.0	1.0	54.0	4.57
2918	Placebo	0.0	6.0	4.0	1.5	6.0	4.5	3.5	4.0	3.5	3.0	11.0	3.0	2.0	52.0	4.40
2919	Placebo	0.0	19.5	3.0	1.5	10.5	3.0	1.5	14.5	2.5	1.0	12.5	2.5	2.5	74.5	6.31
2922	Placebo	3.0	16.5	9.0	5.0	29.5	12.0	4.5	16.0	4.0	9.5	38.0	7.0	5.0	159.0	13.46
2923	Placebo	3.0	26.5	19.5	4.5	29.0	2.0	6.0	21.5	9.5	3.0	40.0	3.0	3.0	170.5	14.44
2933	Placebo	5.0	10.0	10.0	4.5	11.0	5.0	10.5	9.0	6.5	12.0	18.0	6.0	2.0	109.5	9.27
2934	Placebo	0.0	24.0	5.0	1.0	12.0	0.5	2.0	17.5	2.5	1.0	9.5	0.0	0.5	75.5	6.39
2941	Placebo	1.0	5.5	2.5	3.0	6.0	0.5	0.5	6.0	1.0	4.5	12.0	3.0	4.5	50.0	4.23
2946	Placebo	0.5	9.0	5.0	13.5	10.0	8.0	4.0	9.5	1.5	17.5	14.0	7.0	7.0	106.5	9.02
2952	Placebo	3.5	23.5	6.5	7.5	28.5	4.0	7.5	22.0	5.0	8.5	30.5	3.5	6.0	156.5	13.25
2956	Placebo	3.5	28.0	3.0	3.5	30.5	3.5	3.0	21.0	1.5	5.0	32.0	6.0	1.0	141.5	11.98
2977	Placebo	9.5	22.5	17.0	13.0	36.5	21.5	11.5	33.5	25.0	12.0	45.5	22.5	7.5	277.5	23.50
2982	Placebo	0.0	11.0	5.5	4.5	15.0	2.5	2.0	5.0	3.0	5.5	13.0	2.5	1.0	70.5	5.97
2984	Placebo	4.0	31.0	18.0	6.0	19.0	3.0	3.5	18.0	15.0	3.0	35.5	3.0	4.5	163.5	13.84
2993	Placebo	0.0	8.0	4.0	4.5	8.0	0.0	4.0	8.0	2.0	5.0	7.5	2.0	1.5	54.5	4.61
2994	Placebo	2.0	21.0	3.0	7.5	11.0	0.0	7.5	18.0	2.0	6.0	12.0	3.5	1.5	95.0	8.04

Code

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Pertaining to	Swine Influenza Virus, H1N1																					
Study Purpose	Demonstrate efficacy against swine influenza virus, H1N1																					
Product Administration	Two doses, administered intramuscularly, three weeks apart. NA1 (A/swine/IA/A01410307/2014 (H1N1)) – NA6 (A/swine/MN/A01483170/2014 (H1N1)) NA4 (A/swine/MI/A02077465/2015 (H1N2)) – NA2 (A/swine/IL/A01475495/2014 (H1N2))																					
Study Animals	Commercial pigs, three days of age, 32 vaccinates and 32 controls (placebo vaccinated).																					
Challenge Description	All pigs were challenged 35 days post second vaccination with swine influenza strain A/swine/MN/A01483170/2014 (H1N1).																					
Interval observed after challenge	Lung lesion scores were assessed 5 days post challenge on a subgroup of 20 vaccinates and 20 controls.																					
Results	<p>Five number summary for lung lesion scores*:</p> <table border="1"> <thead> <tr> <th><i>Group</i></th> <th><i>Number</i></th> <th><i>Minimum</i></th> <th><i>Q1</i></th> <th><i>Median</i></th> <th><i>Q3</i></th> <th><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td><i>Vaccinate</i></td> <td>20</td> <td>0.5</td> <td>0.9</td> <td>1.4</td> <td>2.6</td> <td>5.5</td> </tr> <tr> <td><i>Placebo</i></td> <td>20</td> <td>0.9</td> <td>6.2</td> <td>10.1</td> <td>13.5</td> <td>20.4</td> </tr> </tbody> </table> <p>*Lesion scores were calculated as the percentage of total lung area</p> <p>Raw data are shown below.</p>	<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>	<i>Vaccinate</i>	20	0.5	0.9	1.4	2.6	5.5	<i>Placebo</i>	20	0.9	6.2	10.1	13.5	20.4
<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>																
<i>Vaccinate</i>	20	0.5	0.9	1.4	2.6	5.5																
<i>Placebo</i>	20	0.9	6.2	10.1	13.5	20.4																
USDA Approval Date	June 5, 2020																					

Table 1: Lung Lesion Scoring (LLS) by 1st Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
5700	Placebo	2.00	31.50	15.50	5.00	28.00	6.00	8.50	38.00	12.50	4.50	52.50	4.50	3.50	212.00	17.95
5701	Placebo	2.00	30.00	20.50	7.50	22.00	30.50	6.00	28.00	12.00	8.00	33.50	27.00	11.50	238.50	20.19
5707	Placebo	1.50	29.50	3.00	0.00	27.50	14.00	3.00	28.00	2.00	0.00	46.50	17.00	17.00	189.00	16.00
5709	Placebo	2.00	13.50	4.00	1.00	17.00	4.00	2.50	10.00	5.00	1.00	14.00	7.00	3.50	84.50	7.15
5725	Placebo	0.00	17.50	6.00	0.00	16.00	2.50	0.00	10.00	3.00	0.00	11.50	3.00	1.00	70.50	5.97
5730	Placebo	3.00	13.00	6.00	1.00	9.00	6.50	5.00	7.00	4.00	0.00	7.50	5.00	0.00	67.00	5.67
5734	Placebo	0.00	7.00	0.00	1.00	3.00	2.50	3.00	5.00	0.50	1.00	4.00	1.50	1.50	30.00	2.54
5739	Placebo	3.00	17.50	2.00	1.00	22.50	12.00	6.50	17.00	2.50	1.00	32.50	16.00	6.50	140.00	11.85
5744	Placebo	0.00	23.00	5.50	0.00	25.50	13.00	1.50	15.00	5.00	1.50	31.50	9.00	8.00	138.50	11.73
5751	Placebo	1.00	24.00	12.50	5.50	25.00	8.50	3.00	18.50	19.00	4.00	33.50	7.50	3.50	165.50	14.01
5757	Placebo	1.50	22.00	13.00	2.00	21.50	7.50	2.50	15.00	8.00	1.00	17.00	7.00	1.50	119.50	10.12
5759	Placebo	4.50	31.50	35.00	9.00	27.50	19.50	6.00	20.50	13.50	8.00	26.50	23.00	5.50	230.00	19.48
5762	Placebo	8.00	15.00	2.50	2.00	28.00	43.50	7.00	15.50	3.50	2.50	24.00	35.00	11.50	198.00	16.77
5763	Placebo	1.00	21.00	18.50	2.50	16.00	17.50	3.50	13.00	9.50	3.50	10.00	15.50	2.50	134.00	11.35
5766	Placebo	1.00	7.50	2.00	1.50	9.00	7.50	2.50	10.00	0.50	1.00	8.50	7.00	2.00	60.00	5.08
5772	Placebo	4.50	16.00	2.00	0.00	25.50	5.00	3.50	16.50	2.50	1.00	34.00	5.50	7.50	123.50	10.46
5778	Placebo	0.00	15.00	5.50	1.00	16.50	4.00	0.50	11.00	4.50	0.50	12.00	4.00	5.00	79.50	6.73
5781	Placebo	3.00	23.00	10.00	4.00	12.50	7.00	4.00	29.00	5.50	2.50	13.00	11.00	3.50	128.00	10.84
5787	Placebo	0.00	13.50	3.00	0.00	27.50	7.00	1.50	6.00	1.50	1.00	26.50	5.50	6.50	99.50	8.43
5796	Placebo	0.00	2.50	1.50	0.00	2.50	0.00	0.00	2.00	0.00	0.00	2.00	0.00	0.00	10.50	0.89
5703	Vaccinate	2.00	3.00	2.00	2.00	4.50	2.00	2.00	2.00	1.00	1.50	4.00	1.50	0.00	27.50	2.33
5704	Vaccinate	0.00	4.00	1.50	0.00	2.50	0.00	0.00	2.50	0.50	0.00	0.50	0.00	0.00	11.50	0.97
5705	Vaccinate	0.00	8.00	7.00	2.00	6.50	7.00	0.00	6.00	4.00	2.00	7.00	4.00	6.50	60.00	5.08
5710	Vaccinate	0.00	1.00	0.00	0.00	8.00	4.00	0.00	1.50	0.00	0.00	5.50	0.00	1.00	21.00	1.78
5722	Vaccinate	0.00	2.50	1.50	1.00	1.50	0.50	0.00	2.00	1.00	0.00	1.00	2.00	0.00	13.00	1.10
5731	Vaccinate	0.00	4.00	4.50	0.00	3.50	3.00	0.00	3.50	1.50	0.00	3.50	1.50	0.00	25.00	2.12
5738	Vaccinate	0.00	1.50	0.50	0.00	2.00	0.50	0.00	3.50	0.00	0.00	2.50	0.50	0.00	11.00	0.93
5740	Vaccinate	0.00	2.00	1.00	0.00	2.50	1.00	0.00	2.00	1.00	0.00	1.50	1.00	0.00	12.00	1.02
5745	Vaccinate	0.00	3.00	1.00	0.00	3.50	2.00	0.00	3.00	0.00	0.00	3.00	0.00	0.00	15.50	1.31
5752	Vaccinate	0.00	2.00	0.00	0.00	2.00	0.00	0.00	1.50	0.00	0.00	2.50	0.00	0.00	8.00	0.68
5754	Vaccinate	1.00	2.00	1.50	1.50	3.00	0.50	0.00	3.00	2.00	1.50	3.50	1.50	1.50	22.50	1.91
5755	Vaccinate	0.00	3.00	0.00	0.50	2.50	0.00	0.00	2.50	0.00	0.00	2.50	0.00	0.00	11.00	0.93
5758	Vaccinate	0.00	5.00	4.50	0.50	6.00	2.00	0.00	5.00	3.50	0.50	5.00	3.00	0.00	35.00	2.96
5761	Vaccinate	0.00	12.00	7.50	0.00	8.00	5.00	0.00	4.50	3.00	0.00	7.50	7.00	3.50	58.00	4.91
5765	Vaccinate	0.00	8.00	6.50	0.50	7.00	3.50	0.00	5.50	4.00	1.00	5.00	2.50	1.50	45.00	3.81
5773	Vaccinate	0.00	1.50	1.00	0.00	1.00	0.00	0.00	1.50	0.50	0.00	0.00	0.00	0.00	5.50	0.47
5784	Vaccinate	1.00	7.00	1.50	1.50	9.00	2.00	1.00	6.00	2.00	1.50	8.00	2.50	2.50	45.50	3.85
5786	Vaccinate	0.00	4.00	0.00	0.00	2.50	1.50	0.00	3.50	0.00	0.00	3.00	1.50	0.50	16.50	1.40
5793	Vaccinate	0.00	1.50	0.00	0.00	1.00	0.00	0.00	2.00	0.00	0.00	1.00	0.00	0.00	5.50	0.47
5798	Vaccinate	0.00	2.00	0.00	0.00	1.50	0.00	0.00	2.50	0.00	0.00	1.50	0.00	0.00	7.50	0.64

Code

DLA = Dorsal Left Apical Lobe	VLA = Ventral Left Apical Lobe
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DRC = Dorsal Right Cardiac Lobe	VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe	VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe	

Table 2: Lung Lesion Scoring (LLS) by 2nd Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
5700	Placebo	4.50	34.00	8.00	2.00	27.50	5.50	3.00	36.00	6.50	18.50	51.00	17.00	2.00	215.50	18.25
5701	Placebo	1.50	43.00	12.00	4.00	37.50	25.00	6.00	37.50	24.00	6.00	32.00	10.50	4.50	243.50	20.62
5707	Placebo	1.50	35.00	3.00	0.00	37.50	13.00	5.00	25.00	2.00	1.00	45.00	17.50	17.50	203.00	17.19
5709	Placebo	2.00	15.00	4.50	1.50	22.00	3.50	3.00	11.00	6.00	1.50	15.50	7.50	2.50	95.50	8.09
5725	Placebo	0.50	13.50	4.50	0.00	12.50	2.50	0.00	9.00	2.00	0.00	12.00	2.50	1.50	60.50	5.12
5730	Placebo	1.50	7.00	6.50	0.50	9.50	2.50	3.50	6.50	3.00	1.00	6.00	4.50	0.50	52.50	4.45
5734	Placebo	1.00	6.50	1.00	0.00	3.00	1.50	3.00	4.50	0.50	1.50	5.00	2.00	0.50	30.00	2.54
5739	Placebo	3.50	14.50	1.50	1.00	20.50	8.00	6.00	12.50	3.50	1.00	30.00	16.00	3.50	121.50	10.29
5744	Placebo	0.50	19.50	5.50	1.50	26.50	10.00	1.50	15.00	3.50	1.00	34.00	10.50	2.00	131.00	11.09
5751	Placebo	1.00	16.00	10.00	4.00	28.00	2.00	3.50	11.00	9.50	3.00	30.50	8.00	1.00	127.50	10.80
5757	Placebo	2.00	24.50	13.50	1.50	16.50	4.00	2.00	16.50	7.50	1.00	26.00	7.50	1.00	123.50	10.46
5759	Placebo	4.00	28.00	14.50	8.50	35.50	16.00	7.50	24.00	10.00	16.00	33.00	18.50	4.00	219.50	18.59
5762	Placebo	6.50	20.00	4.00	2.50	31.50	33.50	7.00	20.00	2.00	6.50	19.50	41.50	10.00	204.50	17.32
5763	Placebo	2.50	19.00	14.00	1.50	14.50	13.50	3.00	14.50	7.00	3.50	14.00	10.50	2.00	119.50	10.12
5766	Placebo	1.00	14.50	1.00	0.50	10.00	2.50	1.00	9.00	0.50	1.00	11.50	6.00	2.00	60.50	5.12
5772	Placebo	2.00	13.50	2.50	0.50	23.00	4.50	3.50	12.00	2.50	0.50	34.00	5.00	3.50	107.00	9.06
5778	Placebo	1.50	16.00	3.50	2.00	11.50	2.00	2.00	9.50	3.00	1.00	14.00	4.50	1.50	72.00	6.10
5781	Placebo	1.50	26.00	4.50	2.50	11.00	3.50	3.50	17.00	4.00	2.00	15.00	8.00	2.00	100.50	8.51
5787	Placebo	0.00	11.00	2.50	0.00	21.50	4.00	1.50	7.50	1.50	1.00	26.00	4.50	3.00	84.00	7.11
5796	Placebo	0.00	2.00	1.50	0.00	2.00	0.50	0.00	2.00	0.00	0.00	1.50	0.00	1.00	10.50	0.89
5703	Vaccinate	0.50	3.00	2.00	2.00	7.50	1.00	1.50	2.50	1.00	1.50	6.00	1.00	0.50	30.00	2.54
5704	Vaccinate	0.00	5.00	1.50	0.00	2.00	0.50	0.00	5.00	0.50	0.50	2.00	0.50	0.00	17.50	1.48
5705	Vaccinate	0.00	13.50	6.50	1.50	9.00	5.00	1.00	10.00	3.50	2.00	10.00	6.00	3.00	71.00	6.01
5710	Vaccinate	0.00	1.50	0.50	0.00	5.00	2.00	1.00	1.50	0.50	0.50	5.50	2.00	0.50	20.50	1.74
5722	Vaccinate	0.00	2.00	1.00	1.00	2.00	1.00	0.00	2.00	1.50	0.50	2.00	1.50	0.50	15.00	1.27
5731	Vaccinate	0.00	3.50	2.50	0.00	2.00	1.50	0.00	4.50	1.50	0.00	2.50	2.00	0.00	20.00	1.69
5738	Vaccinate	0.00	2.00	0.50	0.00	2.00	0.50	0.00	3.50	0.50	0.00	2.50	0.00	0.50	12.00	1.02
5740	Vaccinate	0.00	1.50	1.50	0.00	1.50	1.00	0.00	0.50	1.00	0.00	1.50	1.00	0.00	9.50	0.80
5745	Vaccinate	0.00	2.50	1.50	0.00	2.00	2.00	0.00	3.00	1.50	0.50	3.50	1.50	0.00	18.00	1.52
5752	Vaccinate	0.00	0.50	0.00	0.00	1.50	0.00	0.00	0.50	0.00	0.00	1.50	0.00	0.00	4.00	0.34
5754	Vaccinate	0.50	1.50	0.50	1.00	4.50	0.50	0.50	3.50	1.00	1.50	5.00	1.00	1.00	22.00	1.86
5755	Vaccinate	0.00	2.50	0.00	1.00	1.50	0.50	0.50	2.00	0.50	0.00	1.50	0.00	0.00	10.00	0.85
5758	Vaccinate	0.00	7.50	1.50	0.00	7.00	2.00	0.00	6.50	2.50	1.00	9.00	2.50	0.50	40.00	3.39
5761	Vaccinate	2.00	14.50	6.50	0.50	12.00	5.50	1.00	7.50	3.50	0.50	7.00	7.50	0.50	68.50	5.80
5765	Vaccinate	0.00	7.00	5.00	1.00	6.50	3.50	1.00	5.50	4.00	0.50	4.50	3.50	0.50	42.50	3.34
5773	Vaccinate	0.00	1.50	0.50	0.00	1.00	0.00	0.00	1.00	1.00	0.00	0.50	0.00	0.50	6.00	0.51
5784	Vaccinate	1.00	6.00	1.00	2.00	6.50	1.00	0.00	4.50	1.50	1.50	6.00	2.00	2.00	35.00	2.96
5786	Vaccinate	0.00	2.00	1.00	0.00	2.50	1.00	0.00	4.00	1.50	0.00	2.00	1.00	0.50	15.50	1.31
5793	Vaccinate	0.00	2.00	0.50	0.00	1.00	0.50	0.00	2.50	0.50	0.50	1.50	0.00	0.50	9.50	0.80
5798	Vaccinate	0.00	1.50	0.00	0.00	1.50	0.00	0.00	2.00	0.00	0.00	2.50	0.00	0.00	7.50	0.64

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Study Type	Efficacy																					
Pertaining to	Swine Influenza Virus, H1N2																					
Study Purpose	Demonstrate efficacy against swine influenza virus, H1N2																					
Product Administration	Two doses, administered intramuscularly, three weeks apart. NA1 (A/swine/IA/A01410307/2014 (H1N1)) – NA6 (A/swine/MN/A01483170/2014 (H1N1)) NA4 (A/swine/MI/A02077465/2015 (H1N2)) – NA2 (A/swine/IL/A01475495/2014 (H1N2))																					
Study Animals	Commercial pigs, three days of age at 1 st vaccination; 32 vaccinates and 32 controls (placebo vaccinated).																					
Challenge Description	All pigs were challenged 38 days post second vaccination with swine influenza strain A/swine/Illinois/A01475495/2014 (H1N2)																					
Interval observed after challenge	Lung lesion scores were assessed 5 days post challenge on a subgroup of 20 vaccinates and 20 controls.																					
Results	<p>Five number summary for lung lesion scores*:</p> <table border="1"> <thead> <tr> <th><i>Group</i></th> <th><i>Number</i></th> <th><i>Minimum</i></th> <th><i>Q1</i></th> <th><i>Median</i></th> <th><i>Q3</i></th> <th><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td><i>Vaccinate</i></td> <td>20</td> <td>0.5</td> <td>0.7</td> <td>1.2</td> <td>3.1</td> <td>6.9</td> </tr> <tr> <td><i>Placebo</i></td> <td>20</td> <td>5</td> <td>9.1</td> <td>11.8</td> <td>22.1</td> <td>37.3</td> </tr> </tbody> </table> <p>*Lesion scores were calculated as the percentage of total lung area</p> <p>Raw data are shown below.</p>	<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>	<i>Vaccinate</i>	20	0.5	0.7	1.2	3.1	6.9	<i>Placebo</i>	20	5	9.1	11.8	22.1	37.3
<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>																
<i>Vaccinate</i>	20	0.5	0.7	1.2	3.1	6.9																
<i>Placebo</i>	20	5	9.1	11.8	22.1	37.3																
USDA Approval Date	August 12, 2020																					

Table 1: Lung Lesion Scoring (LLS) by 1st Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
3006	Vaccinate	0.00	1.50	1.00	0.00	1.00	1.50	0.00	1.00	0.00	0.00	1.50	0.00	0.00	7.50	0.64
3009	Vaccinate	0.00	2.00	1.00	0.00	3.50	1.00	0.00	2.50	1.00	0.00	2.50	1.50	0.00	15.00	1.27
3014	Vaccinate	0.00	2.50	1.50	1.00	5.00	0.00	0.00	3.50	2.00	1.00	3.50	0.00	0.00	20.00	1.69
3015	Vaccinate	0.00	5.00	4.50	0.50	4.00	1.50	0.50	4.50	3.00	0.00	5.50	1.50	0.00	30.50	2.58
3024	Vaccinate	0.00	5.00	2.00	0.00	0.00	0.00	0.00	4.50	0.00	0.00	0.00	0.00	0.50	12.00	1.02
3027	Vaccinate	0.00	3.50	1.50	0.00	5.00	0.00	0.00	2.00	1.00	1.00	3.50	0.00	0.00	18.00	1.52
3036	Vaccinate	0.00	10.00	5.00	8.00	12.00	5.50	1.00	8.50	2.00	7.50	9.00	5.00	2.50	76.00	6.44
3037	Vaccinate	0.00	1.50	0.00	0.00	1.50	0.00	0.00	1.50	1.50	0.00	1.00	1.00	0.00	8.00	0.68
3041	Vaccinate	0.00	3.50	1.00	0.00	1.50	0.00	0.00	3.00	0.00	0.00	2.00	0.00	0.00	11.00	0.93
3042	Vaccinate	0.00	1.50	3.50	0.00	1.00	0.00	0.00	2.00	0.00	0.00	1.00	0.00	0.00	9.00	0.76
3046	Vaccinate	0.00	1.50	2.00	0.00	1.50	0.00	0.00	0.50	0.00	0.00	1.50	0.00	0.00	7.00	0.59
3047	Vaccinate	1.00	7.00	4.50	0.50	7.50	4.00	1.00	4.50	4.00	1.50	7.00	3.00	1.00	46.50	3.94
3052	Vaccinate	0.00	2.00	0.00	1.00	2.00	1.00	0.00	3.50	0.00	1.00	2.00	1.00	0.00	13.50	1.14
3056	Vaccinate	0.00	2.00	0.00	0.00	1.50	1.00	0.00	2.00	0.00	0.00	2.00	0.00	0.00	8.50	0.72
3066	Vaccinate	0.00	19.00	6.50	1.00	9.00	1.50	0.00	15.00	4.50	2.00	14.00	1.50	3.50	77.50	6.56
3067	Vaccinate	1.00	4.00	1.50	0.00	5.50	1.00	0.00	5.00	2.00	0.00	5.00	1.50	0.00	26.50	2.24
3068	Vaccinate	0.00	6.50	8.00	1.00	5.00	5.00	0.00	4.50	2.00	0.50	3.50	1.50	2.00	39.50	3.34
3070	Vaccinate	0.00	5.00	9.50	2.50	3.50	6.50	1.00	6.50	5.00	2.00	10.50	6.50	2.00	60.50	5.12
3076	Vaccinate	0.00	3.50	2.00	0.00	1.00	2.50	0.00	4.50	0.50	0.00	2.50	1.50	0.00	18.00	1.52
3078	Vaccinate	0.00	6.50	5.00	1.50	2.50	5.00	0.00	6.00	3.50	1.00	3.00	4.00	0.00	38.00	3.22
3003	Placebo	4.00	21.00	7.50	2.50	20.00	5.00	7.00	17.50	6.00	3.00	30.50	4.50	14.00	142.50	12.07
3005	Placebo	0.00	8.50	7.00	0.00	14.00	0.00	0.00	8.00	5.50	1.00	10.50	3.00	3.00	60.50	5.12
3017	Placebo	2.00	10.00	13.00	3.00	17.50	6.50	2.00	8.50	5.00	2.50	11.00	7.50	1.00	89.50	7.58
3020	Placebo	4.50	25.00	21.50	21.50	27.50	5.50	5.50	34.00	9.50	17.00	32.00	4.00	7.50	215.00	18.20
3021	Placebo	0.00	10.50	20.50	1.00	30.00	2.50	3.00	14.00	10.50	1.50	32.50	6.50	5.50	138.00	11.69
3022	Placebo	0.00	16.50	3.00	1.50	15.50	1.50	4.00	14.00	1.00	1.50	18.50	2.50	3.50	83.00	7.03
3034	Placebo	1.50	12.50	10.50	1.50	17.00	12.50	2.50	9.00	6.50	2.00	21.00	5.50	6.50	108.50	9.19
3039	Placebo	0.00	8.00	10.50	10.00	17.00	4.50	1.50	10.50	3.00	8.50	23.00	7.00	2.50	106.00	8.98
3043	Placebo	12.00	37.50	13.50	9.50	24.00	11.00	11.50	52.00	19.00	26.00	57.00	6.50	19.00	298.50	25.28
3044	Placebo	0.00	16.00	11.00	0.00	31.50	9.50	3.00	11.50	4.50	0.00	37.50	4.50	12.50	141.50	11.98
3045	Placebo	14.50	42.50	36.00	10.50	31.00	16.50	26.50	52.00	63.00	9.00	68.00	31.50	34.50	435.50	36.88
3049	Placebo	4.50	33.00	12.00	7.00	18.00	24.50	9.00	28.50	12.00	12.50	47.00	20.00	13.00	241.00	20.41
3058	Placebo	12.00	23.00	31.50	13.50	28.50	18.50	16.00	24.00	36.50	15.00	43.50	20.50	16.50	299.00	25.32
3061	Placebo	0.00	23.00	3.00	9.50	22.50	17.50	1.50	14.00	2.00	7.50	19.00	10.00	4.00	133.50	11.30
3064	Placebo	5.00	38.50	20.00	4.50	29.50	15.00	16.00	52.00	16.50	8.00	47.00	18.00	8.00	278.00	23.54
3065	Placebo	0.00	18.00	9.00	2.00	21.50	9.00	1.00	14.50	4.00	2.00	15.00	5.50	3.50	105.00	8.89
3069	Placebo	2.00	18.00	15.50	5.50	15.50	19.50	4.50	9.50	11.00	5.50	28.50	13.00	7.00	155.00	13.12
3072	Placebo	6.00	25.50	21.50	10.50	27.50	38.50	10.00	23.50	27.00	18.50	43.00	36.50	24.50	312.50	26.46
3081	Placebo	6.50	24.00	37.00	1.00	31.50	24.50	13.00	32.00	31.50	4.50	46.00	35.00	15.00	301.50	25.53
3082	Placebo	3.50	17.00	29.00	1.00	19.50	26.50	10.00	12.00	36.00	1.00	41.50	20.00	20.50	237.50	20.11

Code

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INT = Intermediate Lobe	

Table 2: Lung Lesion Scoring (LLS) by 2nd Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
3006	Vaccinate	0.00	1.50	0.50	0.00	1.50	1.00	0.00	1.00	0.00	0.50	1.00	0.00	0.00	7.00	0.59
3009	Vaccinate	0.00	2.00	1.00	0.00	4.00	1.00	0.00	1.50	1.00	0.00	2.00	1.00	0.50	14.00	1.19
3014	Vaccinate	0.00	0.50	1.50	0.00	2.50	0.00	0.00	1.00	2.50	0.00	1.50	0.00	0.50	10.00	0.85
3015	Vaccinate	0.50	3.50	1.50	0.00	3.00	1.50	0.50	4.50	2.50	0.00	3.00	1.50	0.00	22.00	1.86
3024	Vaccinate	0.00	2.50	0.50	0.00	0.00	0.00	0.00	1.50	1.00	0.00	0.00	0.00	0.00	5.50	0.47
3027	Vaccinate	0.00	1.00	2.00	0.00	2.50	0.00	0.00	2.00	0.00	0.00	2.00	0.00	0.00	9.50	0.80
3036	Vaccinate	0.00	9.00	2.50	4.50	6.50	5.00	0.00	9.50	2.00	6.00	8.00	4.00	1.50	58.50	4.95
3037	Vaccinate	0.00	1.00	0.00	0.00	1.50	0.00	0.00	0.00	0.00	0.00	2.50	0.00	0.00	5.00	0.42
3041	Vaccinate	1.00	3.50	0.50	0.00	2.00	0.00	0.00	3.00	0.00	0.00	1.50	0.50	0.00	12.00	1.02
3042	Vaccinate	0.00	0.00	2.50	0.00	0.00	0.00	0.00	2.50	0.00	0.00	0.00	0.00	0.00	5.00	0.42
3046	Vaccinate	0.00	1.00	2.00	0.00	0.50	0.00	0.00	0.50	1.00	0.50	0.00	0.00	0.00	5.50	0.47
3047	Vaccinate	0.50	4.50	2.50	0.00	7.00	3.50	0.00	4.00	2.00	0.00	7.50	4.50	0.50	36.50	3.09
3052	Vaccinate	0.00	2.00	0.50	0.50	2.00	0.00	0.00	3.00	0.00	1.50	1.00	1.50	0.00	12.00	1.02
3056	Vaccinate	0.00	1.50	0.00	0.00	1.00	0.00	0.00	1.50	0.50	0.00	2.00	0.00	0.00	6.50	0.55
3066	Vaccinate	0.00	24.00	7.00	1.50	9.50	2.50	1.50	17.50	5.00	2.50	11.00	2.00	2.00	86.00	7.28
3067	Vaccinate	1.00	8.00	3.00	0.00	9.00	1.00	0.50	5.50	2.50	0.00	9.50	1.00	1.00	42.00	3.56
3068	Vaccinate	0.00	7.00	5.50	1.50	6.00	3.00	0.50	7.00	3.00	2.00	9.50	1.50	2.00	48.50	4.11
3070	Vaccinate	0.50	5.00	8.50	1.00	6.00	4.00	0.00	5.50	5.00	2.00	7.00	7.00	2.50	54.00	4.57
3076	Vaccinate	0.00	2.00	3.00	0.00	1.50	0.50	0.50	1.50	0.00	0.00	2.00	1.50	0.00	12.50	1.06
3078	Vaccinate	0.00	4.50	5.50	0.50	2.00	3.50	0.00	4.00	2.50	0.50	2.00	5.00	0.00	30.00	2.54
3003	Placebo	2.00	19.00	4.00	3.50	28.00	3.50	6.50	19.50	6.00	3.00	24.50	4.50	12.50	136.50	11.56
3005	Placebo	0.00	11.50	5.50	0.00	11.00	0.00	0.00	10.00	3.00	1.00	10.50	4.00	1.50	58.00	4.91
3017	Placebo	1.50	5.50	9.00	1.50	26.50	8.00	4.50	9.00	8.00	3.00	20.50	10.00	1.50	108.50	9.19
3020	Placebo	4.50	26.50	13.50	9.00	27.00	3.00	8.50	30.50	12.00	20.00	37.00	4.50	5.00	201.00	17.02
3021	Placebo	0.00	11.00	13.50	0.00	26.50	2.00	2.50	13.50	8.50	2.00	33.00	5.00	3.50	121.00	10.25
3022	Placebo	0.00	11.50	2.00	3.00	11.50	0.50	1.00	13.00	0.50	0.50	16.00	2.00	2.00	63.50	5.38
3034	Placebo	2.00	11.50	5.50	1.50	30.00	7.00	1.00	11.50	4.00	1.50	21.50	5.50	6.50	109.00	9.23
3039	Placebo	0.50	8.00	6.50	9.50	18.50	2.00	2.00	9.50	7.00	10.00	22.00	10.00	0.00	105.50	8.93
3043	Placebo	10.00	32.50	15.50	17.50	37.00	11.00	15.50	48.50	20.00	30.50	53.50	10.50	24.50	326.50	27.65
3044	Placebo	0.00	21.50	6.00	0.00	28.00	7.00	4.00	11.00	6.00	0.50	33.00	7.50	13.00	137.50	11.64
3045	Placebo	16.50	34.00	44.00	8.50	36.50	28.00	25.00	52.00	72.00	10.00	57.00	32.50	29.50	445.50	37.72
3049	Placebo	3.50	32.50	13.00	6.00	19.00	16.50	7.50	31.00	13.00	10.00	32.00	10.00	7.50	201.50	17.06
3058	Placebo	10.00	25.50	18.00	5.50	22.50	12.00	14.50	29.50	28.50	10.50	38.50	17.50	14.00	246.50	20.87
3061	Placebo	0.00	21.50	3.00	6.50	26.50	8.00	2.00	15.50	3.50	5.00	21.00	7.00	2.00	121.50	10.29
3064	Placebo	4.50	30.50	15.00	4.50	41.50	16.00	9.00	36.50	14.00	9.00	33.00	17.00	7.00	237.50	20.11
3065	Placebo	0.50	12.00	6.50	3.50	18.00	8.50	1.00	12.00	4.00	3.50	22.00	6.50	1.50	99.50	8.43
3069	Placebo	2.00	12.00	10.00	4.50	17.50	11.50	2.50	9.50	6.00	2.50	32.00	11.50	3.00	124.50	10.54
3072	Placebo	7.50	29.00	19.00	8.00	30.00	14.00	10.00	26.50	17.00	8.50	40.00	33.50	25.00	268.00	22.69
3081	Placebo	4.00	22.00	17.00	1.50	36.00	27.00	12.00	24.00	30.00	6.50	45.00	33.50	10.50	269.00	22.78
3082	Placebo	4.50	13.50	14.50	0.00	29.00	14.00	6.00	17.50	26.00	1.50	30.00	15.50	15.50	187.50	15.88

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Study Type	Efficacy																					
Pertaining to	Swine Influenza Virus, H1N2																					
Study Purpose	Demonstrate efficacy against swine influenza virus, H1N2																					
Product Administration	Two doses, administered intramuscularly, three weeks apart. NA1 (A/swine/IA/A01410307/2014 (H1N1)) – NA6 (A/swine/MN/A01483170/2014 (H1N1)) NA4 (A/swine/MI/A02077465/2015 (H1N2)) – NA2 (A/swine/IL/A01475495/2014 (H1N2))																					
Study Animals	Commercial pigs, three days of age at 1 st vaccination; 31 vaccinates and 32 controls (placebo vaccinated).																					
Challenge Description	All pigs were challenged 34 days post second vaccination with swine influenza strain A/swine/Oklahoma/A01409770/2014 (H1N2, N2 ₁₉₉₈ clade)																					
Interval observed after challenge	Lung lesion scores were assessed 5 days post challenge on a subgroup of 20 vaccinates and 20 controls.																					
Results	<p>Five number summary for lung lesion scores*:</p> <table border="1"> <thead> <tr> <th><i>Group</i></th> <th><i>Number</i></th> <th><i>Minimum</i></th> <th><i>Q1</i></th> <th><i>Median</i></th> <th><i>Q3</i></th> <th><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td><i>Vaccinate</i></td> <td>20</td> <td>0.1</td> <td>0.3</td> <td>0.6</td> <td>1.2</td> <td>6.9</td> </tr> <tr> <td><i>Placebo</i></td> <td>20</td> <td>1.9</td> <td>4.3</td> <td>7.2</td> <td>9.8</td> <td>17.2</td> </tr> </tbody> </table> <p>*Lesion scores were calculated as the percentage of total lung area</p> <p>Raw data are shown below.</p>	<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>	<i>Vaccinate</i>	20	0.1	0.3	0.6	1.2	6.9	<i>Placebo</i>	20	1.9	4.3	7.2	9.8	17.2
<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>																
<i>Vaccinate</i>	20	0.1	0.3	0.6	1.2	6.9																
<i>Placebo</i>	20	1.9	4.3	7.2	9.8	17.2																
USDA Approval Date	February 16, 2021																					

Table 1: Lung Lesion Scoring (LLS) by 1st Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
3	Placebo	2.00	2.50	2.00	1.50	9.50	1.00	3.50	3.00	1.50	3.00	15.00	2.50	4.50	51.50	4.36
5	Placebo	1.00	18.50	29.50	4.50	24.50	51.50	5.50	19.00	15.50	6.00	20.50	19.00	8.00	223.00	18.88
12	Placebo	1.50	8.50	2.50	8.00	6.00	1.00	2.00	8.50	3.00	7.00	6.00	3.00	2.00	59.00	5.00
16	Placebo	2.00	23.00	2.50	6.00	16.50	2.00	5.50	11.50	2.00	6.00	18.00	0.00	6.50	101.50	8.59
23	Placebo	2.00	8.50	1.50	3.00	10.50	3.00	3.00	4.50	1.50	2.00	12.00	3.00	2.50	57.00	4.83
25	Placebo	0.50	1.50	1.00	1.00	3.50	1.00	1.50	1.50	1.50	2.00	3.50	0.00	0.00	18.50	1.57
29	Placebo	1.50	13.50	0.00	2.50	21.00	3.50	2.50	11.00	0.00	2.00	16.50	1.50	5.50	81.00	6.86
32	Placebo	6.50	27.00	6.50	7.00	23.50	12.00	10.50	19.00	8.50	7.50	33.50	9.50	6.00	177.00	14.99
38	Placebo	0.00	6.50	4.00	2.00	5.00	5.00	1.50	4.00	3.00	2.50	6.50	2.50	0.00	42.50	3.60
39	Placebo	1.50	19.00	7.50	6.00	19.50	2.00	4.50	10.00	9.50	6.50	12.50	6.50	4.50	109.50	9.27
49	Placebo	3.00	25.00	2.00	7.50	26.00	7.50	3.00	32.50	8.00	6.00	51.00	10.50	8.50	190.50	16.13
50	Placebo	1.50	32.00	6.50	7.00	18.00	3.50	1.00	31.50	5.00	8.50	24.00	1.50	6.00	146.00	12.36
66	Placebo	0.50	9.00	0.00	3.50	6.50	0.50	0.00	11.50	0.50	4.00	8.50	1.00	5.00	50.50	4.28
68	Placebo	1.50	17.50	4.50	7.00	12.00	9.00	4.00	11.50	9.00	10.00	13.00	2.00	9.50	110.50	9.36
75	Placebo	0.50	15.50	6.00	7.50	23.50	21.50	9.00	20.50	18.00	7.00	32.50	15.00	13.00	189.50	16.05
76	Placebo	0.00	5.50	1.50	3.00	7.00	4.50	0.00	6.00	1.50	3.00	6.50	3.50	1.50	43.50	3.68
87	Placebo	0.50	16.00	3.50	2.50	19.00	1.00	2.00	12.50	0.50	3.00	15.50	2.50	5.00	83.50	7.07
88	Placebo	0.00	6.00	2.50	1.50	20.50	3.00	1.00	11.50	2.50	4.00	19.50	2.00	1.50	75.50	6.39
97	Placebo	0.00	0.00	0.50	8.50	24.00	10.50	0.00	0.00	0.00	8.00	23.00	8.00	5.00	87.50	7.41
99	Placebo	0.00	0.00	0.00	0.00	20.00	0.00	0.00	0.00	0.00	0.00	20.00	0.00	2.00	42.00	3.56
1	Vaccinate	0.00	8.00	6.50	0.00	16.50	11.50	0.00	8.00	8.50	0.00	19.50	8.50	1.00	88.00	7.45
6	Vaccinate	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	1.00	0.08
10	Vaccinate	1.00	4.50	1.50	1.00	1.50	1.00	0.50	2.50	1.00	0.00	0.00	1.50	0.50	16.50	1.40
13	Vaccinate	0.00	0.50	0.50	0.00	0.50	0.00	0.00	0.50	0.00	0.00	0.50	0.00	0.00	2.50	0.21
20	Vaccinate	0.00	1.50	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	1.00	0.00	0.00	3.50	0.30
24	Vaccinate	0.50	3.00	2.50	0.50	2.50	2.00	0.50	2.50	1.00	0.50	1.00	0.00	0.00	16.50	1.40
27	Vaccinate	0.00	1.50	2.00	0.00	3.00	1.50	0.00	1.00	0.50	0.00	3.00	1.00	0.00	13.50	1.14
28	Vaccinate	0.00	1.00	0.50	0.00	0.00	0.00	0.00	1.00	1.00	0.00	0.00	0.00	0.00	3.50	0.30
35	Vaccinate	0.00	1.50	2.00	0.00	1.00	0.00	0.00	1.00	1.50	0.00	1.00	0.50	0.00	8.50	0.72
37	Vaccinate	0.00	5.00	2.50	1.50	4.50	5.00	0.00	8.50	1.50	1.50	5.00	2.00	0.50	37.50	3.18
51	Vaccinate	0.00	3.50	0.00	0.50	1.50	0.50	0.00	1.00	1.00	0.50	1.00	0.50	0.50	10.50	0.89
55	Vaccinate	0.00	1.00	0.00	0.00	0.50	0.00	0.00	1.00	0.00	0.00	0.50	0.00	0.50	3.50	0.30
64	Vaccinate	0.00	2.50	1.00	0.00	4.50	0.00	0.50	2.50	0.50	0.50	3.50	0.00	1.50	17.00	1.44
69	Vaccinate	0.00	0.00	0.00	0.00	1.50	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	2.50	0.21
72	Vaccinate	0.00	1.00	0.00	0.00	2.00	0.00	0.00	1.00	0.00	0.00	1.50	0.00	0.00	5.50	0.47
77	Vaccinate	0.00	1.00	0.00	0.50	1.00	0.00	0.00	0.50	0.00	0.00	0.50	0.00	0.00	3.50	0.30
89	Vaccinate	1.00	16.50	2.50	0.00	3.50	0.00	0.00	4.50	1.00	0.00	3.00	0.50	1.00	33.50	2.84
90	Vaccinate	0.00	0.00	0.00	1.50	0.50	0.00	0.00	0.00	0.00	2.00	0.00	0.00	0.00	4.00	0.34
98	Vaccinate	0.00	1.50	1.00	0.00	1.50	0.50	0.00	1.50	0.50	0.00	1.00	1.00	0.50	9.00	0.76
100	Vaccinate	0.00	1.00	0.00	0.50	1.50	0.00	0.00	0.50	0.00	0.00	3.50	0.00	0.00	7.00	0.59

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Table 2: Lung Lesion Scoring (LLS) by 2nd Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
3	Placebo	2.50	1.00	1.00	2.00	14.00	1.00	3.50	3.00	1.00	4.00	15.00	1.00	3.00	52.00	4.40
5	Placebo	1.50	20.00	17.50	3.50	16.00	42.50	7.00	18.00	8.50	4.00	16.00	21.50	8.00	184.00	15.58
12	Placebo	1.50	10.00	2.50	6.00	4.50	0.50	2.00	10.00	2.00	6.00	4.50	3.50	1.00	54.00	4.57
16	Placebo	3.00	16.00	2.00	11.00	11.50	1.50	5.00	15.00	1.00	10.50	17.50	1.50	4.00	99.50	8.43
23	Placebo	2.00	7.00	1.50	2.50	7.50	3.00	3.00	6.00	0.50	2.50	3.50	3.00	1.00	43.00	3.64
25	Placebo	0.50	2.00	2.00	2.00	7.00	1.50	1.00	1.50	1.50	2.00	4.50	0.50	1.00	27.00	2.29
29	Placebo	1.00	9.50	0.50	2.00	19.00	2.50	0.00	14.00	1.00	2.50	26.50	4.00	5.00	87.50	7.41
32	Placebo	9.00	23.50	8.00	3.00	24.50	7.50	10.50	18.50	7.00	10.00	36.00	9.00	1.00	167.50	14.18
38	Placebo	0.50	4.00	2.50	2.00	3.00	1.50	1.50	4.00	1.50	2.00	5.00	2.00	0.50	30.00	2.54
39	Placebo	2.50	18.50	6.00	5.50	13.50	3.00	3.50	14.50	6.00	7.00	20.50	2.00	2.50	105.00	8.89
49	Placebo	2.00	30.50	3.50	5.00	20.50	6.00	4.00	31.00	8.50	13.00	48.00	10.50	5.00	187.50	15.88
50	Placebo	1.00	30.50	3.50	5.00	19.50	1.00	1.00	31.00	3.00	6.50	24.50	2.50	12.00	141.00	11.94
66	Placebo	1.00	14.00	1.50	6.50	14.50	0.00	0.50	8.50	0.50	6.50	10.00	1.00	5.50	70.00	5.93
68	Placebo	1.00	13.50	4.50	6.00	6.00	4.50	2.50	10.00	5.50	12.00	12.50	2.50	5.00	85.50	7.24
75	Placebo	1.50	13.00	6.00	6.50	28.50	8.00	6.00	19.50	19.00	10.50	36.00	20.00	17.00	191.50	16.22
76	Placebo	0.50	5.00	0.50	2.00	5.00	2.00	0.00	5.50	0.50	3.00	5.50	2.00	1.00	32.50	2.75
87	Placebo	1.50	20.00	5.00	2.00	11.00	2.00	4.00	14.00	0.50	3.00	15.50	3.50	4.00	86.00	7.28
88	Placebo	0.00	7.00	4.00	2.50	13.50	5.50	1.00	12.00	2.50	4.50	22.00	3.50	3.00	81.00	6.86
97	Placebo	0.50	0.00	1.00	6.50	25.50	7.00	0.00	0.50	0.50	6.00	32.00	5.50	2.00	87.00	7.37
99	Placebo	0.00	1.00	0.00	0.00	22.50	0.00	0.00	1.00	0.00	0.50	15.50	0.00	3.50	44.00	3.73
1	Vaccinate	0.00	5.00	8.50	0.50	15.00	10.50	0.50	4.00	4.50	1.50	15.50	8.00	1.00	74.50	6.31
6	Vaccinate	0.00	0.00	0.50	0.50	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.50	0.50	2.50	0.21
10	Vaccinate	0.50	3.50	1.50	1.00	3.50	1.00	1.00	4.00	1.00	0.50	0.50	1.00	0.50	19.50	1.65
13	Vaccinate	0.00	0.50	0.50	0.00	0.50	0.50	0.00	0.50	0.50	0.50	0.50	0.00	0.50	4.50	0.38
20	Vaccinate	0.00	1.50	0.00	0.00	0.50	0.00	0.00	1.50	0.00	0.00	1.00	0.00	0.00	4.50	0.38
24	Vaccinate	0.00	1.00	1.50	0.00	1.00	0.00	0.50	3.50	1.00	0.00	2.00	0.50	0.50	11.50	0.97
27	Vaccinate	0.50	1.50	0.50	0.00	2.00	0.50	1.00	1.00	1.50	0.00	2.00	0.50	0.50	11.50	0.97
28	Vaccinate	0.00	1.00	1.00	0.00	0.00	1.00	0.00	1.00	1.00	0.00	1.00	0.00	0.00	6.00	0.51
35	Vaccinate	0.00	1.50	0.50	0.50	0.50	0.00	0.00	1.00	1.50	0.00	0.50	1.00	0.00	7.00	0.59
37	Vaccinate	0.00	8.50	3.50	1.00	4.00	3.50	1.00	9.00	1.50	2.00	8.00	2.50	0.50	45.00	3.81
51	Vaccinate	0.00	2.50	1.00	1.00	1.50	1.00	0.00	2.50	1.00	1.00	2.00	1.00	1.00	15.50	1.31
55	Vaccinate	0.00	0.50	0.00	0.00	0.50	0.00	0.50	1.00	0.00	0.50	0.50	0.00	0.00	3.50	0.30
64	Vaccinate	0.00	2.00	0.50	0.50	2.00	0.00	0.50	1.50	0.50	0.50	2.50	0.00	1.50	12.00	1.02
69	Vaccinate	0.00	0.00	0.50	0.00	0.50	0.00	0.00	1.00	0.00	0.00	1.00	0.00	0.50	3.50	0.30
72	Vaccinate	0.00	1.50	0.00	0.00	2.50	0.00	0.00	1.50	0.00	0.00	1.50	0.00	0.50	7.50	0.64
77	Vaccinate	0.00	1.50	0.00	0.50	1.00	0.00	0.00	0.50	0.50	0.00	0.50	0.00	0.00	4.50	0.38
89	Vaccinate	2.00	8.00	3.00	0.50	4.00	0.00	0.50	5.50	1.50	0.50	4.50	0.50	0.50	31.00	2.62
90	Vaccinate	0.50	0.00	0.50	1.00	0.00	0.00	0.00	0.00	0.00	2.00	0.00	0.00	0.00	4.00	0.34
98	Vaccinate	0.00	1.00	1.50	0.50	1.50	0.50	0.00	1.50	0.50	0.50	1.00	2.00	0.50	11.00	0.93
100	Vaccinate	0.00	1.00	0.00	0.50	1.50	0.00	0.00	1.00	0.00	0.50	2.00	0.50	0.00	7.00	0.59

Code

DLA = Dorsal Left Apical Lobe VLA = Ventral Left Apical Lobe
DLC = Dorsal Left Cardiac Lobe VLC = Ventral Left Cardiac Lobe
DLD = Dorsal Left Diaphragmatic Lobe VLD = Ventral Left Diaphragmatic Lobe
DRA = Dorsal Right Apical Lobe VRA = Ventral Right Apical Lobe
DRC = Dorsal Right Cardiac Lobe VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe

Study Type	Efficacy																					
Pertaining to	Swine Influenza Virus, H3N2																					
Study Purpose	Demonstrate efficacy against swine influenza virus, H3N2																					
Product Administration	Two doses, administered intramuscularly, three weeks apart. NA1 (A/swine/IA/A01410307/2014 (H1N1)) – NA6 (A/swine/MN/A01483170/2014 (H1N1)) NA4 (A/swine/MI/A02077465/2015 (H1N2)) – NA2 (A/swine/IL/A01475495/2014 (H1N2))																					
Study Animals	Commercial pigs, three days of age at 1 st vaccination; 32 vaccinates and 32 controls (placebo vaccinated).																					
Challenge Description	All pigs were challenged 34 days post second vaccination with swine influenza strain A/swine/Missouri/A01840724/2015 (H3N2, N2 ₂₀₀₂ clade)																					
Interval observed after challenge	Lung lesion scores were assessed 5 days post challenge on a subgroup of 20 vaccinates and 20 controls.																					
Results	<p>Five number summary for lung lesion scores*:</p> <table border="1"> <thead> <tr> <th><i>Group</i></th> <th><i>Number</i></th> <th><i>Minimum</i></th> <th><i>Q1</i></th> <th><i>Median</i></th> <th><i>Q3</i></th> <th><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td><i>Vaccinate</i></td> <td>20</td> <td>0.7</td> <td>1.4</td> <td>2.3</td> <td>3.5</td> <td>9.2</td> </tr> <tr> <td><i>Placebo</i></td> <td>20</td> <td>4</td> <td>5.7</td> <td>10.5</td> <td>13.7</td> <td>21.2</td> </tr> </tbody> </table> <p>*Lesion scores were calculated as the percentage of total lung area</p> <p>Raw data are shown below.</p>	<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>	<i>Vaccinate</i>	20	0.7	1.4	2.3	3.5	9.2	<i>Placebo</i>	20	4	5.7	10.5	13.7	21.2
<i>Group</i>	<i>Number</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>																
<i>Vaccinate</i>	20	0.7	1.4	2.3	3.5	9.2																
<i>Placebo</i>	20	4	5.7	10.5	13.7	21.2																
USDA Approval Date	September 24, 2020																					

Table 1: Lung Lesion Scoring (LLS) by 1st Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
3111	Placebo	0.00	19.00	5.00	1.00	13.00	6.00	1.50	8.50	2.50	0.00	8.00	4.50	1.00	70.00	5.93
3114	Placebo	0.00	16.50	1.00	0.00	10.00	1.50	1.00	10.00	0.50	0.00	6.50	1.00	0.00	48.00	4.06
3116	Placebo	0.00	4.50	1.50	0.00	13.00	3.00	0.00	7.00	1.00	0.00	8.00	4.50	3.50	46.00	3.90
3120	Placebo	1.00	23.00	10.50	5.00	22.00	5.00	4.50	20.00	13.00	3.50	21.00	4.50	3.00	136.00	11.52
3121	Placebo	9.50	31.50	2.50	7.00	22.50	13.00	9.00	30.00	2.50	17.00	37.00	15.50	8.00	205.00	17.36
3122	Placebo	0.00	29.00	7.00	0.00	13.50	7.50	0.00	17.00	5.50	0.00	16.50	6.00	2.00	104.00	8.81
3126	Placebo	1.00	29.00	4.50	0.00	23.50	6.00	6.00	25.50	7.50	0.00	38.00	4.00	1.00	146.00	12.36
3128	Placebo	1.50	23.50	4.00	4.50	34.00	9.00	8.00	22.50	2.00	5.50	28.50	10.00	9.00	162.00	13.72
3132	Placebo	6.00	27.00	38.00	4.50	27.00	28.00	12.00	24.00	20.00	3.50	34.00	22.00	5.50	251.50	21.30
3133	Placebo	0.00	22.00	17.50	0.00	23.00	9.00	3.00	19.00	12.00	0.00	12.00	11.00	2.50	131.00	11.09
3142	Placebo	0.00	8.50	7.50	2.00	7.00	3.00	1.00	6.00	5.00	1.50	4.50	3.50	0.00	49.50	4.19
3143	Placebo	1.00	7.00	6.00	1.00	13.00	5.00	0.50	8.00	4.50	1.00	12.00	3.00	0.00	62.00	5.25
3156	Placebo	5.50	28.50	6.50	13.50	27.00	21.50	3.00	23.50	4.50	21.00	55.00	17.00	14.00	240.50	20.36
3159	Placebo	2.00	21.50	16.50	2.00	25.00	8.00	2.50	16.50	9.00	4.00	17.50	4.00	1.50	130.00	11.01
3163	Placebo	0.00	23.50	9.00	1.00	9.00	3.00	1.00	16.00	7.00	1.50	8.00	4.00	3.00	86.00	7.28
3164	Placebo	0.00	11.00	6.50	1.00	12.00	2.50	2.00	8.50	3.50	0.50	10.00	3.00	2.00	62.50	5.29
3172	Placebo	2.00	12.00	2.50	1.50	22.00	8.00	3.00	10.50	2.50	1.50	26.00	4.00	3.50	99.00	8.38
3182	Placebo	1.50	35.50	10.00	4.00	24.00	6.50	6.00	30.00	5.50	6.00	26.00	7.00	9.00	171.00	14.48
3185	Placebo	1.00	19.00	4.00	10.00	27.00	6.50	5.00	16.00	3.00	13.00	35.50	7.00	4.50	151.50	12.83
3191	Placebo	1.00	22.00	9.50	3.00	18.50	9.00	1.00	18.00	8.50	3.50	18.00	6.50	8.00	126.50	10.71
3113	Vaccinate	0.00	2.00	2.00	0.00	1.00	0.00	0.00	1.00	1.00	0.00	1.00	0.00	0.00	8.00	0.68
3115	Vaccinate	0.00	0.00	3.00	0.50	0.50	0.50	0.00	2.00	3.50	1.00	1.00	2.00	0.50	14.50	1.23
3117	Vaccinate	0.00	2.50	1.50	1.00	1.50	2.50	0.00	3.50	3.00	0.00	1.50	2.00	0.00	19.00	1.61
3118	Vaccinate	0.00	2.00	0.50	0.50	3.00	1.00	0.00	1.50	0.00	0.00	4.00	1.00	1.50	15.00	1.27
3123	Vaccinate	1.50	10.50	4.50	0.50	6.00	3.00	1.50	8.00	0.00	0.00	3.50	3.00	0.50	42.50	3.60
3127	Vaccinate	0.00	1.50	3.00	0.00	1.50	2.50	0.00	1.50	1.00	0.00	1.00	1.00	0.00	13.00	1.10
3129	Vaccinate	0.00	2.50	1.00	0.00	1.00	1.50	0.00	1.50	0.00	0.00	1.00	0.00	0.00	8.50	0.72
3130	Vaccinate	0.00	11.00	13.00	1.00	12.00	19.00	0.00	8.50	12.00	1.00	10.00	12.00	2.50	102.00	8.64
3136	Vaccinate	0.00	1.00	2.50	0.00	2.00	1.50	0.00	1.50	0.00	0.00	3.00	1.00	0.00	12.50	1.06
3140	Vaccinate	0.00	4.50	1.50	1.00	9.00	6.00	0.00	3.00	3.00	1.50	7.50	5.00	1.50	43.50	3.68
3144	Vaccinate	0.00	6.00	4.00	0.50	3.00	1.50	0.00	5.00	2.00	0.00	4.50	1.50	0.50	28.50	2.41
3145	Vaccinate	0.00	3.00	3.50	2.00	4.00	1.50	0.00	4.00	5.00	3.00	5.00	1.50	1.00	33.50	2.84
3154	Vaccinate	0.50	4.50	2.00	1.50	4.00	0.50	0.50	3.00	1.50	1.00	4.50	1.00	0.50	25.00	2.12
3155	Vaccinate	0.00	2.50	1.00	0.50	5.00	1.00	1.00	5.00	1.00	1.00	5.00	1.50	0.00	24.50	2.07
3162	Vaccinate	0.00	2.50	2.00	0.00	2.50	0.00	0.00	3.00	1.00	0.00	2.00	0.00	0.00	13.00	1.10
3166	Vaccinate	4.50	14.50	7.00	3.50	11.50	5.00	3.00	14.00	7.00	3.00	14.00	10.50	8.00	105.50	8.93
3179	Vaccinate	0.00	2.00	4.00	3.00	6.00	4.00	0.50	3.00	1.50	3.00	2.00	3.00	1.00	33.00	2.79
3180	Vaccinate	0.00	16.00	4.50	1.00	9.00	1.00	1.00	11.00	6.00	1.00	11.00	2.00	1.50	65.00	5.50
3186	Vaccinate	0.50	2.50	3.50	1.50	4.00	1.00	1.50	2.00	2.00	1.50	3.00	1.00	1.00	25.00	2.12
3188	Vaccinate	0.50	2.50	3.50	2.00	2.00	0.00	0.50	2.50	2.50	2.50	2.00	0.00	1.00	21.50	1.82

Code

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DRA = Dorsal Right Apical Lobe	VRA = Ventral Right Apical Lobe
DRC = Dorsal Right Cardiac Lobe	VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe	VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe	

Table 2: Lung Lesion Scoring (LLS) by 2nd Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
3111	Placebo	0.00	12.50	3.00	1.00	10.00	4.50	1.50	9.50	4.50	1.00	10.50	4.50	2.00	64.50	5.46
3114	Placebo	0.00	13.00	1.50	0.00	7.00	1.50	1.00	12.50	0.50	0.50	6.00	1.00	1.00	45.50	3.85
3116	Placebo	1.00	9.00	2.50	0.00	12.00	2.50	1.50	8.50	4.00	0.00	20.00	5.00	4.00	70.00	5.93
3120	Placebo	1.00	21.50	9.50	3.00	22.00	3.50	4.00	19.50	9.50	3.00	21.00	3.50	2.00	123.00	10.41
3121	Placebo	9.00	38.50	2.50	14.00	26.00	12.00	10.00	27.00	2.00	12.00	45.00	15.50	7.00	220.50	18.67
3122	Placebo	0.50	28.50	5.00	0.50	13.50	7.50	0.50	19.00	3.50	1.00	13.00	4.50	2.00	99.00	8.38
3126	Placebo	4.50	30.00	6.00	0.00	28.50	7.00	10.00	24.00	9.50	0.00	41.00	7.00	3.50	171.00	14.48
3128	Placebo	4.50	24.00	5.00	3.50	23.00	24.50	9.50	25.00	3.50	5.50	28.00	20.00	11.50	187.50	15.88
3132	Placebo	8.00	33.00	31.00	4.00	20.50	18.00	12.00	27.50	19.50	4.50	42.00	18.00	10.50	248.50	21.04
3133	Placebo	1.50	21.00	16.00	0.50	11.00	5.00	4.50	20.00	8.50	0.00	15.00	6.00	1.50	110.50	9.36
3142	Placebo	0.00	14.00	6.00	2.00	6.50	3.00	0.50	8.00	4.50	2.50	4.00	5.00	0.50	56.50	4.78
3143	Placebo	0.50	12.50	4.00	1.00	15.00	4.50	1.00	7.00	4.50	2.00	15.00	4.50	0.50	72.00	6.10
3156	Placebo	5.00	50.00	22.00	6.00	34.00	8.00	11.00	29.50	11.50	4.00	36.50	5.50	7.00	230.00	19.48
3159	Placebo	2.00	23.50	10.50	3.50	24.00	9.00	3.00	25.00	11.00	4.00	16.00	5.00	1.50	138.00	11.69
3163	Placebo	0.50	22.50	11.00	2.00	15.00	5.00	1.50	17.00	8.50	3.00	11.50	6.00	5.00	108.50	9.19
3164	Placebo	0.00	8.50	4.50	0.50	12.50	9.00	2.00	8.00	3.50	0.50	14.00	6.00	1.50	70.50	5.97
3172	Placebo	1.50	14.00	2.50	2.00	24.00	4.00	5.00	11.50	2.50	2.50	21.00	5.00	5.00	100.50	8.51
3182	Placebo	2.50	31.00	6.00	5.00	27.50	6.50	4.00	21.00	6.50	9.00	38.00	6.00	6.50	169.50	14.35
3185	Placebo	1.00	21.50	6.50	6.50	25.00	5.50	4.00	17.50	2.50	8.00	28.50	8.00	6.00	140.50	11.90
3191	Placebo	1.00	21.00	8.50	4.50	18.00	5.50	3.00	17.50	7.00	4.50	23.00	5.50	8.00	127.00	10.75
3113	Vaccinate	0.00	3.00	1.00	0.00	1.50	0.50	0.00	2.00	1.00	0.00	0.50	0.00	0.00	9.50	0.80
3115	Vaccinate	0.50	3.00	2.00	0.50	1.00	0.50	1.00	2.00	4.00	0.50	2.50	3.00	1.00	21.50	1.82
3117	Vaccinate	0.00	3.00	0.00	0.50	1.50	2.00	0.00	3.00	3.00	0.00	3.00	2.50	0.00	18.50	1.57
3118	Vaccinate	0.50	2.50	1.00	1.00	3.00	0.50	0.00	2.50	0.00	0.50	4.00	2.00	1.50	19.00	1.61
3123	Vaccinate	2.00	13.00	3.00	1.50	5.00	4.00	1.50	9.00	2.00	0.00	4.50	3.00	0.50	49.00	4.15
3127	Vaccinate	0.00	4.50	2.50	0.00	2.00	2.00	0.00	4.00	0.50	0.00	3.00	1.00	0.50	20.00	1.69
3129	Vaccinate	0.00	2.50	2.00	0.00	1.50	1.00	0.00	3.00	1.00	0.00	2.50	1.00	0.50	15.00	1.27
3130	Vaccinate	0.00	11.50	11.00	1.00	11.50	13.00	0.00	11.00	9.50	2.00	14.00	13.50	2.50	100.50	8.51
3136	Vaccinate	0.00	1.00	1.50	0.00	2.00	0.50	0.00	2.00	0.50	0.00	2.50	1.00	0.00	11.00	0.93
3140	Vaccinate	0.00	6.50	3.50	3.00	6.00	5.50	0.00	7.00	4.00	4.00	6.00	5.00	1.50	52.00	4.40
3144	Vaccinate	0.50	5.50	4.00	1.00	3.50	2.00	1.00	4.00	2.00	2.00	5.50	1.50	0.50	33.00	2.79
3145	Vaccinate	0.00	2.50	4.50	2.00	5.50	1.50	0.00	3.00	4.50	2.00	6.00	2.50	0.50	34.50	2.92
3154	Vaccinate	1.00	5.50	2.00	1.50	7.00	0.50	2.00	6.00	2.00	0.00	6.00	0.50	1.00	35.00	2.96
3155	Vaccinate	1.50	6.00	2.00	0.50	7.50	2.50	1.00	5.00	1.50	1.50	7.00	2.00	0.50	38.50	3.26
3162	Vaccinate	0.00	1.50	1.00	0.00	2.00	0.50	0.50	2.00	1.00	0.00	3.00	0.00	0.00	11.50	0.97
3166	Vaccinate	3.00	12.50	5.50	3.50	13.00	7.50	8.00	15.00	7.00	6.00	14.00	10.00	7.00	112.00	9.48
3179	Vaccinate	0.50	4.00	4.00	4.00	8.00	3.50	1.00	4.50	3.00	3.50	5.50	4.00	1.00	46.50	3.94
3180	Vaccinate	1.50	12.00	5.00	1.50	15.00	1.50	1.50	3.00	6.00	2.00	13.50	4.50	2.00	69.00	5.84
3186	Vaccinate	1.00	3.00	2.50	1.00	2.00	1.50	1.50	3.00	2.00	1.00	2.00	1.00	0.00	21.50	1.82
3188	Vaccinate	0.00	5.00	2.50	2.00	3.50	0.00	0.50	3.50	2.00	3.00	2.00	0.50	0.50	25.00	2.12

Code

DLA = Dorsal Left Apical Lobe	VLA = Ventral Left Apical Lobe
DLC = Dorsal Left Cardiac Lobe	VLC = Ventral Left Cardiac Lobe
DLD = Dorsal Left Diaphragmatic Lobe	VLD = Ventral Left Diaphragmatic Lobe
DRA = Dorsal Right Apical Lobe	VRA = Ventral Right Apical Lobe
DRC = Dorsal Right Cardiac Lobe	VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe	VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe	

Study Type	Safety																																																																				
Pertaining to	All																																																																				
Study Purpose	Demonstrate safety of product under typical use conditions.																																																																				
Product Administration	2 doses administered intramuscularly (IM) 3 weeks apart.																																																																				
Study Animals	748 pigs, 3-5 days of age, distributed among 3 study sites.																																																																				
Challenge Description	Not applicable																																																																				
Interval observed after challenge	Animals were observed for systemic and/or local injection site reactions, and various adverse events (AEs) per VeDDRA guidance for 21 days after each vaccination, or until resolution.																																																																				
Results	<table border="1"> <thead> <tr> <th rowspan="2">Site</th> <th rowspan="2">Total Number animals</th> <th colspan="3">Max. Size of injection site reaction</th> <th rowspan="2">1st or 2nd Vaccination</th> <th rowspan="2">Injection site reactions not observed</th> </tr> <tr> <th><1.5 cm</th> <th>1.5 to 5 cm</th> <th>5 to 10 cm</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>240</td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> <td>240</td> </tr> <tr> <td>226</td> <td>33</td> <td>19</td> <td>1</td> <td>2</td> <td>173</td> </tr> <tr> <td rowspan="2">2</td> <td>247</td> <td>8</td> <td>0</td> <td>0</td> <td>1</td> <td>239</td> </tr> <tr> <td>235</td> <td>22</td> <td>5</td> <td>0</td> <td>2</td> <td>208</td> </tr> <tr> <td rowspan="2">3</td> <td>259</td> <td>20</td> <td>2</td> <td>0</td> <td>1</td> <td>237</td> </tr> <tr> <td>253</td> <td>7</td> <td>2</td> <td>0</td> <td>2</td> <td>244</td> </tr> <tr> <td rowspan="2">Total All Sites</td> <td>746</td> <td>28</td> <td>2</td> <td>0</td> <td>1</td> <td>716</td> </tr> <tr> <td>714</td> <td>62</td> <td>26</td> <td>1</td> <td>2</td> <td>625</td> </tr> </tbody> </table>							Site	Total Number animals	Max. Size of injection site reaction			1st or 2nd Vaccination	Injection site reactions not observed	<1.5 cm	1.5 to 5 cm	5 to 10 cm	1	240	0	0	0	1	240	226	33	19	1	2	173	2	247	8	0	0	1	239	235	22	5	0	2	208	3	259	20	2	0	1	237	253	7	2	0	2	244	Total All Sites	746	28	2	0	1	716	714	62	26	1	2	625
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	VeDDRA Code	Total Animals	Percent of All Animals
	No adverse events	525	70.20%
	Anorexia	55	7.40%
	Death	24	3.20%
	Lameness	20	2.70%
	Loss of Condition	12	1.60%
	Diarrhea	11	1.50%
	Unthrifty	7	0.90%
	Anaphylaxis [^]	3	0.40%
	Central Nervous System Disorder*	3	0.40%
	Lethargy	3	0.40%
	Respiratory Tract Infection*	3	0.40%
	Arthritis	2	0.30%
	Meningitis	2	0.30%
	Musculoskeletal Disorder*	2	0.30%
	Trauma*	2	0.30%
	Abdominal Caviry Hernia	1	0.10%
	Abscess*	1	0.10%
	*Not otherwise specified		
	[^] Related to IVP		
USDA Approval Date	December 13, 2021		