Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	19A5.28
True Name	Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	PneumoSTAR SIV Complete - Elanco Canada Limited - Elanco US Inc. PneumoSTAR SIV Complete - Elanco Philippines, Inc PneumoSTAR SIV Complete - Elanco Philippines, Inc - Elanco US Inc. PneumoSTAR SIV Complete - No distributor specified
Date of Compilation Summary	June 07, 2023

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>Swine Influenza virus strain H1N1 (SIV H1N1)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate effectiveness against Swine Influenza virus strain H1N1</td></tr>
<tr><td>Product Administration</td><td>1 doses, given intramuscularly</td></tr>
<tr><td>Study Animals</td><td>47 piglets seronegative for SIV, 3 weeks of age. 24 vaccinates and 23 controls.</td></tr>
<tr><td>Challenge Description</td><td>SIV H1N1 isolate A/SW/IN/1726/88, administered 10 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>The pigs were observed daily for five days for clinical signs of influenza. Lungs were evaluated 5 days after challenge.</td></tr>
<tr><td>Results</td><td>The primary outcome of the study was the percent of the lung mass that was abnormal (consolidated).

5-number summary for lung consolidation (%)

<table>
<tr><th>Treatment</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr>
<tr><td>Controls</td><td>10.1</td><td>22.3</td><td>30.4</td><td>41.1</td><td>56.2</td></tr>
<tr><td>Vaccinates</td><td>0.6</td><td>1.5</td><td>3.0</td><td>6.4</td><td>15.4</td></tr>
</table>

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>June 27, 2011</td></tr>
</table>

Lung Consolidation Scores (%) in order of rank	
Vaccinate	Control
0.6	10.1
1.0	13.6
1.3	13.7
1.4	20.7
1.4	22.2
1.4	22.3
1.6	23.0
1.8	23.3
1.8	23.7
2.1	25.8
2.3	26.1
2.7	30.4
3.3	32.1
5.0	33.4
5.1	34.1
5.3	34.4
5.5	37.6
5.6	41.1
7.2	42.0
7.9	43.1
8.2	45.1
8.3	47.2
10.0	56.2
15.4	

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Swine Influenza virus strain H1N2 (SIV H1N2)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate effectiveness against Swine Influenza virus strain H1N2</td></tr>
<tr><td>Product Administration</td><td>1 dose, given intramuscularly</td></tr>
<tr><td>Study Animals</td><td>53 piglets seronegative for SIV, 3 weeks of age. 26 vaccinates and 27 controls.</td></tr>
<tr><td>Challenge Description</td><td>SIV H1N2 isolate D03-049561, administered 10 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>The pigs were observed daily for five days for clinical signs of influenza. Lungs were evaluated 5 days after challenge.</td></tr>
<tr><td>Results</td><td>The primary outcome of the study was the percent of the lung mass that was abnormal (consolidated).

5-number summary for lung consolidation (%)

<table>
<tr><th>Treatment</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr>
<tr><td>Controls</td><td>.325</td><td>4.7</td><td>11.0</td><td>23.1</td><td>41.1</td></tr>
<tr><td>Vaccinates</td><td>.1</td><td>1.4</td><td>2.55</td><td>7.7</td><td>15.3</td></tr>
</table>

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<tr><td>USDA Approval Date</td><td>February 1, 2011</td></tr>
</table>

Lung Consolidation Scores (%) in order of rank	
Vaccinate	Control
0.1	0.325
0.1	0.4
0.3	1.9
0.6	2.4125
0.7	2.5
1.1	4.0
1.4	4.7
1.4	5.2
1.7	5.6
1.8	5.6
2.2	8.4
2.3	8.6
2.4	10.8
2.7	11.0
3.1	11.8
3.2	14.1
4.2	14.1
4.8	14.5
5.3	15.9
7.7	21.1
9.2	23.1
9.8	23.075
10.6	27.8
11.6	29.2
11.8	33.8
15.3	40.8
	41.1

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Swine Influenza virus strain H3N2 (SIV H3N2)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate effectiveness against Swine Influenza virus strain H3N2</td></tr>
<tr><td>Product Administration</td><td>1 dose, intramuscularly</td></tr>
<tr><td>Study Animals</td><td>50 piglets, seronegative for SIV, 3 weeks of age. 26 vaccinates and 24 controls.</td></tr>
<tr><td>Challenge Description</td><td>SIV H3N2 isolate SW/TX/1/98, administered approximately 11 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>The pigs were observed daily for five days for clinical signs of influenza. Lungs were evaluated 5 days after challenge.</td></tr>
<tr><td>Results</td><td>The primary outcome of the study was the percent lung consolidation.

5-number summary for lung consolidation (%)

<table>
<tr><th>Treatment</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr>
<tr><td>Controls</td><td>0.3</td><td>1.15</td><td>2.4</td><td>3.2</td><td>25</td></tr>
<tr><td>Vaccinates</td><td>0.1</td><td>0.4</td><td>0.9</td><td>1.9</td><td>5.5</td></tr>
</table>

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>July 11, 2011</td></tr>
</table>

Lung Consolidation Scores (%) in order of rank	
Vaccinate	Control
0.1	0.3
0.2	0.5
0.2	0.8
0.3	0.9
0.4	1.0
0.4	1.0
0.4	1.3
0.4	1.6
0.5	1.8
0.5	2.1
0.6	2.2
0.775	2.3
0.8	2.5
1.0	2.5
1.1	2.6
1.2	2.7
1.2	2.8
1.4	3.0
1.7	3.3
1.9	4.7
2.0	5.7
2.6	6.5
2.9	9.6
3.175	25.0
4.0	
5.5	

<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>To demonstrate safety under typical field conditions</td></tr>
<tr><td>Product Administration</td><td>One Dose</td></tr>
<tr><td>Study Animals</td><td>656, 3-4 week old pigs</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed on the day of each vaccination for 2 hours, 24 hours, 48 hours, 1 week, 2 weeks, and 3 weeks after vaccination.</td></tr>
<tr><td>Results</td><td>Frequency of events:

<table>
<tr><th>Clinical Observation</th><th># of pigs</th></tr>
<tr><td>No Reaction</td><td>626</td></tr>
<tr><td>Injection site reaction/lesions <2 inches diameter</td><td>9*</td></tr>
<tr><td>Anaphylactic reaction resolved without treatment</td><td>1</td></tr>
<tr><td>Rough hair / weight loss</td><td>9</td></tr>
<tr><td>Greasy Pig</td><td>6</td></tr>
<tr><td>Bad leg</td><td>1</td></tr>
<tr><td>Death</td><td>4**</td></tr>
</table>

*8/9 injection site reactions resolved within 21 days.
**Deaths affirmed by licensee as not attributed to the vaccine</td></tr>
<tr><td>USDA Approval Date</td><td>March 1, 2011</td></tr>
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