Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19K5.R9
True Name	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac CircoFLEX AD - No distributor specified
Date of Compilation Summary	March 21, 2025

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>Demonstration of a 2-week onset of immunity against PCV2a</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine.</td></tr>
<tr><td>Study Animals</td><td>Cesarean-derived, colostrum deprived pigs vaccinated at 22 days old and randomly divided into 3 groups:

Group 1 Control vaccine (n=25)
Group 2 Test vaccine (n=26)
Group 3 Non-treated, non-challenged controls (NTX) (n=4)</td></tr>
<tr><td>Challenge Description</td><td>Porcine Circovirus, Type 2a challenge virus administered 2 weeks following vaccination (Study Day 15).</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 21 days for clinical signs (Study Day 16-36 or Day 1-21 Post-Challenge). Lymphoid tissues were taken 21 days after challenge (Study Day 36) and examined.</td></tr>
<tr><td>Results</td><td>A pig is considered positive for lymphoid depletion if the histopathology score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig is considered positive for lymphoid colonization if the immunohistochemistry score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

Summary of Lymphoid Tissue Efficacy Results
<table>
<tr><th>Group</th><th>Lymphoid Depletion*</th><th>Lymphoid Colonization (IHC)*</th></tr>
<tr><td>Control Vaccine</td><td>25/25 (100%)</td><td>25/25 (100%)</td></tr>
<tr><td>Test Vaccine</td><td>10/26 (38%)</td><td>10/26 (38%)</td></tr>
</table>
*All non-vaccinated, non-challenged control (NTX) pigs were negative for lymphoid depletion and lymphoid colonization on Study Day 14

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<tr><td>USDA Approval Date</td><td>August 28, 2023</td></tr>
</table>

Lymphoid Colonization and Depletion Scores

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	10	0	0	0	0	0	0	0	0
NTX	27	0	0	0	0	0	0	0	0
NTX	35	0	0	0	0	0	0	0	0
NTX	50	0	0	0	0	0	0	0	0
Control	3	1	2	2	3	1	2	0	2
Control	4	3	3	3	3	1	3	2	3
Control	5	3	3	3	3	0	2	1	2
Control	8	1	2	2	2	2	3	2	3
Control	9	2	2	2	3	1	2	0	2
Control	13	1	2	1	2	0	1	0	1
Control	14	2	2	2	2	0	1	0	1
Control	16	3	2	2	2	1	2	2	1
Control	17	3	3	3	3	1	2	2	2
Control	19	3	3	3	3	0	1	2	2
Control	20	1	2	2	2	1	2	2	2
Control	23	3	3	3	3	1	2	1	2
Control	28	3	2	2	2	0	2	1	2
Control	30	3	3	3	3	0	0	0	2
Control	33*	0	0	0	0	0	0	0	0
Control	34	3	3	3	3	2	2	2	2
Control	36	3	3	3	3	1	0	0	2
Control	38	3	3	3	3	1	2	1	2
Control	39	1	2	0	2	0	2	1	2
Control	40	2	1	2	1	1	2	1	2
Control	41	3	2	3	2	1	2	1	2
Control	47	3	3	3	3	2	1	1	2
Control	49	3	3	3	3	1	2	2	3
Control	52	2	2	3	1	1	0	0	1
Control	53	2	3	3	3	2	0	0	1
Control	55	2	3	1	3	0	2	1	2
Test	1	0	0	0	0	0	0	0	0
Test	2	0	0	0	1	0	0	0	1
Test	6	0	0	0	0	0	0	0	0
Test	7	0	0	0	0	0	0	0	1
Test	11	0	0	0	1	0	0	0	1
Test	12	0	0	0	0	0	0	0	0
Test	15	0	0	0	0	0	0	0	0
Test	18	0	0	0	0	0	0	0	0
Test	21	0	0	0	0	0	0	0	0
Test	22	0	0	0	0	0	0	0	0
Test	24	0	1	0	1	0	1	0	1
Test	25	0	0	0	1	0	0	0	0
Test	26	0	0	0	1	0	0	0	0
Test	29	0	1	0	0	0	0	0	0
Test	31	0	0	0	0	0	0	0	1
Test	32	1	0	0	0	0	1	0	0
Test	37	0	0	0	0	0	0	0	0
Test	42	0	0	0	0	0	1	0	0
Test	43	0	0	0	1	0	0	0	0
Test	44	0	0	0	0	0	1	0	0
Test	45	0	0	0	0	0	0	0	0
Test	46	1	0	0	0	0	0	1	0
Test	48	0	0	0	0	0	0	0	0
Test	51	0	0	0	0	0	0	0	0
Test	54	0	0	0	0	0	0	0	0
Test	56	0	0	1	0	0	0	1	0

NTX=non-treated, non-challenged control; MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry; N.A.=tissue was not available to be scored

Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

*Pig 33 died prior to challenge and was not included in statistical analysis; the pig was negative for both PCV2 and PCV3 by molecular diagnostics and there was no obvious evidence of infection on necropsy or histopathology

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Circovirus Type 2d (PCV2d)</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of a 2-week onset of immunity against PCV2d</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine.</td></tr>
<tr><td>Study Animals</td><td>Cesarean-derived, colostrum deprived pigs vaccinated at 22 days old and randomly divided into 3 groups:

Group 1 Control vaccine (n=25)
Group 2 Test vaccine (n=25)
Group 3 Non-treated, non-challenged controls (NTX) (n=6)</td></tr>
<tr><td>Challenge Description</td><td>Porcine Circovirus, Type 2d challenge virus administered 2 weeks following vaccination (Study Day 15)</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 21 days for clinical signs (Study Day 16-36 or Day 1-21 Post-Challenge). Lymphoid tissues were taken 21 days after challenge (Study Day 36) and examined.</td></tr>
<tr><td>Results</td><td>A pig is considered positive for lymphoid depletion if the histopathology score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig is considered positive for lymphoid colonization if the immunohistochemistry score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

Summary of Lymphoid Tissue Efficacy Results
<table>
<tr><th>Group</th><th>Lymphoid Depletion*</th><th>Lymphoid Colonization (IHC)*</th></tr>
<tr><td>Control Vaccine</td><td>25/25 (100%)</td><td>25/25 (100%)</td></tr>
<tr><td>Test Vaccine</td><td>11/25 (44%)</td><td>8/25 (32%)</td></tr>
</table>
*All non-vaccinated, non-challenged control (NTX) pigs were negative for lymphoid depletion and lymphoid colonization on Study Day 14

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<tr><td>USDA Approval Date</td><td>August 30, 2023</td></tr>
</table>

Lymphoid Colonization and Depletion Scores

Group	Pig ID	Depletion (Histology)				Colonization (IHC)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	**60**	0	0	0	0	0	0	0	0
NTX	**69**	0	0	0	0	0	0	0	0
NTX	**71**	0	0	0	0	0	0	0	0
NTX	**84**	0	0	0	0	0	0	0	0
NTX	**85**	0	0	0	0	0	0	0	0
NTX	**103**	0	0	0	0	0	0	0	0
Control	**57**	2	2	3	3	3	2	2	2
Control	**59***	2	3	3	2	3	3	3	3
Control	**62**	3	3	3	3	3	3	3	3
Control	**64**	1	0	0	1	3	0	1	2
Control	**66**	3	3	3	3	3	2	3	3
Control	**67**	1	1	1	2	2	2	2	1
Control	**72**	3	3	3	3	3	3	3	3
Control	**74**	3	2	3	3	3	3	3	2
Control	**75**	3	3	3	3	3	2	3	3
Control	**78**	1	1	1	1	3	3	2	3
Control	**79**	3	3	3	3	3	3	3	3
Control	**81**	3	3	3	3	3	3	3	3
Control	**87**	1	0	1	2	2	2	2	2
Control	**88**	1	1	0	0	2	1	1	2
Control	**89**	3	2	2	2	3	1	2	2
Control	**92**	2	1	1	2	3	1	1	2
Control	**94**	1	1	1	1	3	2	2	3
Control	**95**	3	3	3	3	3	2	2	3
Control	**99**	3	3	2	3	3	3	2	3
Control	**102**	0	0	1	1	1	2	1	0
Control	**104**	1	1	1	1	3	0	1	2
Control	**105**	3	3	3	3	3	3	3	3
Control	**106**	3	3	2	3	3	3	3	3
Control	**110***	3	3	3	3	3	3	3	3
Control	**111**	0	1	0	2	3	1	2	1
Test	**58**	0	0	0	0	0	0	0	0
Test	**61**	0	0	0	1	0	0	0	1
Test	**63**	0	0	0	0	0	0	0	0
Test	**65**	0	0	0	0	0	0	0	0
Test	**68**	0	0	0	1	0	1	0	1
Test	**70**	0	0	0	0	1	0	0	0
Test	**73**	0	0	0	0	0	1	0	0
Test	**76**	0	1	0	0	1	0	0	2
Test	**77**	0	0	0	0	0	0	0	0
Test	**80**	0	0	0	0	0	0	0	0
Test	**82**	0	0	0	0	0	0	0	0
Test	**83**	0	0	0	0	0	0	0	0
Test	**86**	0	1	0	0	0	0	0	0
Test	**90**	0	1	0	0	0	0	0	0
Test	**91**	0	0	0	1	0	0	0	0
Test	**93**	0	0	0	1	0	1	0	0
Test	**96**	0	0	0	0	0	0	0	0
Test	**97**	0	0	0	0	0	0	0	0
Test	**98**	1	0	0	0	0	0	0	0
Test	**100**	0	1	0	0	0	0	0	0
Test	**101**	0	0	0	0	0	0	0	0
Test	**107**	0	0	0	0	0	0	0	0
Test	**108**	0	1	0	0	0	0	0	0
Test	**109**	0	0	1	0	0	1	0	1
Test	**112**	0	0	0	0	1	0	0	0

NTX=non-treated, non-challenged control; MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry; N.A.=tissue was not available to be scored

Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

*Died prior to scheduled necropsy; lymphoid depletion and PCV2 colonization were observed in each animal. This met the study criteria for inclusion for analysis and association with PCV2 disease.

<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>Demonstration of a 6-month duration of immunity against PCV2a</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine.</td></tr>
<tr><td>Study Animals</td><td>Cesarean-derived, colostrum deprived pigs vaccinated at 22 days old and randomly divided into 3 groups:

Group 1 Control vaccine (n=31)
Group 2 Test vaccine (n=30)
Group 3 Non-treated, non-challenged controls (NTX) (n=7)</td></tr>
<tr><td>Challenge Description</td><td>Challenged with Porcine Circovirus, Type 2a challenge virus 6 months following vaccination (Study Day 183)</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 21 days for clinical signs. Blood samples were collected twice weekly in the post-challenge period. Lymphoid tissues were taken 21 days after challenge and examined.</td></tr>
<tr><td>Results</td><td>A pig is considered positive for lymphoid depletion if the histopathology score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig is considered positive for lymphoid colonization if the immunohistochemistry score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig was considered positive for viremia if PCV2 DNA was detected by qPCR in the serum during any of the sampling points post-challenge.

Summary of Lymphoid Tissue and Viremia Efficacy Results
<table>
<tr><th>Group</th><th>Lymphoid Depletion*</th><th>Lymphoid Colonization (IHC)*</th><th>Viremia**</th></tr>
<tr><td>Control Vaccine</td><td>27/31 (87%)</td><td>31/31 (100%)</td><td>31/31 (100%)</td></tr>
<tr><td>Test Vaccine</td><td>4/30 (13%)</td><td>4/30 (13%)</td><td>3/30 (10%)</td></tr>
</table>
*All NTX pigs were negative for lymphoid colonization and depletion in all tissues.
**All NTX pigs were negative for viremia.

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<tr><td>USDA Approval Date</td><td>October 17, 2024</td></tr>
</table>

Lymphoid Colonization and Depletion Scores

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Control	1	1	0	2	0	0	0	1	0
Control	4	3	2	3	2	0	1	1	0
Control	6	2	0	1	0	1	0	0	0
Control	7	0	0	0	1	0	0	0	0
Control	9	1	1	1	0	0	0	0	0
Control	12	3	2	2	2	1	2	1	1
Control	18	2	2	2	2	0	1	1	1
Control	23	2	2	2	0	1	0	1	0
Control	24	3	0	1	0	0	0	0	0
Control	25	2	0	1	1	0	1	0	1
Control	26	2	0	1	2	0	1	1	0
Control	27	3	2	3	3	1	2	2	1
Control	32	3	1	3	2	0	1	1	1
Control	33	2	2	2	2	1	2	1	1
Control	34	1	0	2	3	0	1	0	0
Control	39	3	2	3	3	1	0	0	1
Control	40	1	0	1	0	0	1	0	0
Control	41	3	2	3	1	0	1	0	1
Control	42	3	2	3	2	0	1	2	1
Control	50	0	0	2	1	0	0	0	0
Control	51	3	2	3	2	0	1	0	1
Control	52	3	1	1	1	0	1	1	1
Control	53	3	3	3	3	1	1	1	1
Control	54	0	1	2	1	0	1	0	1
Control	56	3	3	1	3	0	0	0	1
Control	57	0	0	1	0	0	1	0	0
Control	61	0	2	2	1	0	1	1	0
Control	63	3	3	3	3	1	0	2	0
Control	65	3	2	3	2	0	1	1	0
Control	67	3	2	3	2	0	1	1	0
Control	70	3	3	3	3	1	1	2	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

Lymphoid Colonization and Depletion Scores (Continued)

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Vaccine	2	0	0	0	0	0	0	0	0
Vaccine	3	0	0	0	0	0	0	0	0
Vaccine	5	0	0	0	0	0	0	0	0
Vaccine	8	0	0	0	0	0	0	0	0
Vaccine	10	0	0	0	0	0	0	0	0
Vaccine	11	0	0	0	0	0	0	0	0
Vaccine	14	0	0	0	0	0	0	0	0
Vaccine	15	0	0	1	0	0	0	0	0
Vaccine	16	0	0	0	0	0	0	0	0
Vaccine	17	0	0	0	0	0	0	0	0
Vaccine	19	0	0	1	0	0	0	0	0
Vaccine	21	0	0	0	0	0	0	0	0
Vaccine	28	0	0	0	0	0	0	1	0
Vaccine	29	0	0	0	0	0	0	0	0
Vaccine	30	0	0	0	0	0	0	0	0
Vaccine	35	0	0	0	0	0	0	0	0
Vaccine	36	0	0	0	0	0	0	0	0
Vaccine	37	0	0	1	0	0	0	0	0
Vaccine	38	0	0	0	0	0	0	0	0
Vaccine	43	0	0	0	0	0	0	0	0
Vaccine	45	0	0	1	0	0	0	0	0
Vaccine	46	0	0	0	0	0	1	0	0
Vaccine	49	0	0	0	0	0	0	0	0
Vaccine	55	0	0	0	0	0	1	0	0
Vaccine	59	0	0	0	0	0	0	0	0
Vaccine	60	0	0	0	0	0	1	0	0
Vaccine	62	0	0	0	0	0	0	0	0
Vaccine	66	0	0	0	0	0	0	0	0
Vaccine	68	0	0	0	0	0	0	0	0
Vaccine	69	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

Lymphoid Colonization and Depletion Scores of NTX pigs

Group	Pig ID	Depletion (Histology)				Colonization (IHC)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	13	0	0	0	0	0	0	0	0
NTX	22	0	0	0	0	0	0	0	0
NTX	31	0	0	0	0	0	0	0	0
NTX	44	0	0	0	0	0	0	0	0
NTX	47	0	0	0	0	0	0	0	0
NTX	58	0	0	0	0	0	0	0	0
NTX	64	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

Viremia (Serum qPCR results, genomic equivalent/mL)

Group	Pig ID	Day 182	Day 187	Day 190	Day 194	Day 197	Day 201	Day 204
Control	1	.	.	16,860	37,257	32,301	8,486	4,486
Control	4	.	.	54,496	1,148,451	1,244,955	620,528	1,005,584
Control	6	.	.	.	138,184	41,489	124,453	63,055
Control	7	.	.	2,341	52,866	11,075	8,577	3,168
Control	9	.	.	839	285,414	185,769	142,134	74,440
Control	12	.	.	11,037	629,912	734,863	127,889	328,944
Control	18	.	.	9,123	722,687	1,171,136	430,541	164,079
Control	23	.	3,325	408,604	338,738	147,284	148,287	202,820,320
Control	24	.	.	6,247	1,067,517	228,588	119,670	189,502
Control	25	.	.	3,361	561,454	49,037	34,100	30,491
Control	26	.	.	6,112	342,905	180,557	47,519	47,516
Control	27	.	.	.	355,521	756,692	519,658	297,325
Control	32	.	.	.	235,666	170,475	89,806	121,348
Control	33	.	.	97,564	1,947,082	853,233	221,151	119,573
Control	34	.	.	1,025	23,223	25,604	34,830	7,668
Control	39	.	.	263,863	4,652,635	1,681,979	1,495,014	1,350,485
Control	40	.	.	1,640	40,655	24,505	11,890	10,008
Control	41	.	.	1,141	108,329	220,431	164,179	705,567
Control	42	.	.	4,936	4,578,966	2,664,020	6,622,901	6,068,579
Control	50	.	.	.	30,584	25,429	21,619	14,243
Control	51	.	.	4,090	70,705	72,028	34,512	312,120
Control	52	.	.	6,669	1,026,841	815,278	445,715	93,104
Control	53	.	.	16,058	599,321	355,980	326,651	5,584,876
Control	54	.	.	.	8,479	5,632	6,713	20,817
Control	56	.	.	.	103,693	239,620	211,500	90,732
Control	57	.	.	.	54,167	2,561	4,035	4,516
Control	61	.	.	37,237	168,666	86,068	19,026	8,679
Control	63	.	.	.	510,077	390,666	579,980	255,764
Control	65	.	.	2,482	750,652	142,899	417,269	602,177
Control	67	.	.	5,201	989,662	957,984	325,278	190,509
Control	70	.	.	2,550	833,870	862,087	421,571	494,926

. =result was negative; NA=no sample collected

Viremia (Serum qPCR results, genomic equivalent/mL) Continued

Group	Pig	Day 182	Day 187	Day 190	Day 194	Day 197	Day 201	Day 204
Vaccine	2	.	.	.	.	.	.	.
Vaccine	3	.	.	.	.	.	.	.
Vaccine	5	.	.	.	.	.	.	.
Vaccine	8	.	.	.	.	.	.	.
Vaccine	10	.	.	.	.	.	.	.
Vaccine	11	.	.	.	934,655	.	.	.
Vaccine	14	.	.	.	.	.	.	.
Vaccine	15	.	.	.	.	.	.	.
Vaccine	16	.	.	.	.	.	.	.
Vaccine	17	.	.	.	.	.	.	.
Vaccine	19	.	.	.	.	.	827	.
Vaccine	21	.	.	.	.	.	.	.
Vaccine	28	.	.	.	.	.	.	.
Vaccine	29	.	.	.	.	.	.	.
Vaccine	30	.	.	.	.	.	.	218,523
Vaccine	35	.	.	.	.	.	.	.
Vaccine	36	.	.	.	.	.	.	.
Vaccine	37	.	.	.	.	.	.	.
Vaccine	38	.	.	.	.	.	.	.
Vaccine	43	.	.	.	.	.	.	.
Vaccine	45	.	.	.	.	.	.	.
Vaccine	46	.	.	.	.	.	.	.
Vaccine	49	.	.	.	.	.	.	.
Vaccine	55	.	.	.	.	.	.	.
Vaccine	59	.	.	.	.	.	.	.
Vaccine	60	.	.	.	.	.	.	.
Vaccine	62	.	.	.	.	.	.	.
Vaccine	66	.	.	.	.	.	.	.
Vaccine	68	.	.	.	.	.	.	.
Vaccine	69	.	.	.	.	.	.	.

. =result was negative

Viremia (Serum qPCR results, genomic equivalent/mL) Continued

Group	Pig ID	Day 182
NTX	13	Negative
NTX	22	Negative
NTX	31	Negative
NTX	44	Negative
NTX	47	Negative
NTX	58	Negative
NTX	64	Negative

<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>Demonstration of efficacy against PCV2a</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine.</td></tr>
<tr><td>Study Animals</td><td>Cesarean-derived, colostrum deprived pigs vaccinated at 15 days old and randomly divided into 3 groups:

Group 1 Control vaccine (n=28)
Group 2 Test vaccine (n=28)
Group 3 Non-treated, non-challenged controls (NTX) (n=8)</td></tr>
<tr><td>Challenge Description</td><td>Challenged with Porcine Circovirus, Type 2a challenge virus 4 weeks following vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 21 days for clinical signs. Blood samples were collected twice weekly in the post-challenge period. Lymphoid tissues were taken 21 days after challenge and examined.</td></tr>
<tr><td>Results</td><td>A pig is considered positive for lymphoid depletion if the histopathology score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig is considered positive for lymphoid colonization if the immunohistochemistry score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

Summary of Lymphoid Tissue Efficacy Results
<table>
<tr><th>Group</th><th>Lymphoid Depletion*</th><th>Lymphoid Colonization (IHC)*</th></tr>
<tr><td>Control Vaccine</td><td>24/28 (86%)</td><td>24/28 (86%)</td></tr>
<tr><td>Test Vaccine</td><td>6/28 (21%)</td><td>6/28 (21%)</td></tr>
</table>
*All NTX pigs were negative for lymphoid depletion and colonization in all tissues.

Raw data on attached page</td></tr>
<tr><td>USDA Approval Date</td><td>December 2, 2024</td></tr>
</table>

Lymphoid Colonization and Depletion Scores

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Control	1	3	2	2	1	1	1	2	1
Control	5	2	0	0	1	1	0	1	1
Control	7	0	0	0	0	0	0	0	0
Control	10	1	0	0	0	1	0	0	0
Control	11	3	3	3	3	2	3	2	3
Control	12	2	1	3	1	1	1	2	0
Control	13	1	0	0	0	1	2	1	1
Control	19	3	2	3	2	2	2	2	2
Control	20	1	2	1	3	1	2	1	2
Control	22	0	0	0	0	0	0	0	0
Control	25	3	3	3	3	3	3	3	3
Control	27	3	3	3	3	2	3	3	3
Control	29	2	2	1	1	1	2	1	1
Control	30	.	.	.	.	.	.	.	.
Control	31	0	0	0	0	0	0	0	0
Control	35	1	1	1	0	1	0	1	0
Control	36	2	2	3	3	2	2	2	2
Control	40	0	0	0	0	0	0	0	0
Control	41	3	3	3	3	2	3	2	3
Control	44	2	1	2	1	1	1	1	1
Control	46	2	1	1	2	1	1	1	1
Control	54	3	3	3	2	1	2	2	2
Control	55	2	1	1	0	1	2	2	1
Control	56	3	3	3	3	3	3	3	3
Control	57	3	3	3	3	3	3	3	3
Control	58	2	2	3	2	2	3	3	3
Control	62	3	3	3	3	2	3	2	3
Control	64	2	2	1	3	1	2	1	2
Control	66	1	1	1	2	1	2	1	1

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)
. = no sample available (pig removed from study prior to challenge and not included in statistical analysis)

Lymphoid Colonization and Depletion Scores (Continued)

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Vaccine	3	0	0	0	0	0	0	0	0
Vaccine	4	0	0	0	0	0	0	0	0
Vaccine	6	2	1	1	1	1	1	1	1
Vaccine	8	3	3	3	3	1	2	2	3
Vaccine	9	0	0	0	0	0	0	0	0
Vaccine	14	1	3	1	3	1	2	1	2
Vaccine	15	0	0	0	0	0	0	0	0
Vaccine	16	0	0	0	0	0	0	0	0
Vaccine	18	0	0	0	0	0	0	0	0
Vaccine	23	1	1	1	1	1	0	0	1
Vaccine	24	0	0	0	0	0	0	0	0
Vaccine	26	0	0	0	0	0	0	0	0
Vaccine	28	0	0	0	0	0	0	0	0
Vaccine	33	0	0	0	0	0	0	0	0
Vaccine	34	0	0	0	0	0	0	0	0
Vaccine	37	0	0	0	0	0	0	0	0
Vaccine	38	0	0	0	0	0	0	0	0
Vaccine	39	1	1	1	0	1	1	1	1
Vaccine	43	0	0	0	0	0	0	0	0
Vaccine	45	.	.	.	.	.	.	.	.
Vaccine	48	0	0	0	0	0	0	0	0
Vaccine	49	0	0	0	0	0	0	0	0
Vaccine	50	0	0	0	0	0	0	0	0
Vaccine	52	0	0	0	0	0	0	0	0
Vaccine	53	1	0	0	0	1	1	1	1
Vaccine	59	0	0	0	0	0	0	0	0
Vaccine	60	0	0	0	0	0	0	0	0
Vaccine	63	0	0	0	0	0	0	0	0
Vaccine	65	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)
. = no sample available (pig removed from study prior to challenge and not included in statistical analysis)

Lymphoid Colonization and Depletion Scores of NTX pigs

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	2	0	0	0	0	0	0	0	0
NTX	17	0	0	0	0	0	0	0	0
NTX	21	0	0	0	0	0	0	0	0
NTX	32	0	0	0	0	0	0	0	0
NTX	42	0	0	0	0	0	0	0	0
NTX	47	0	0	0	0	0	0	0	0
NTX	51	0	0	0	0	0	0	0	0
NTX	61	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Circovirus Type 2d (PCV2d)</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of efficacy against PCV2d</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine.</td></tr>
<tr><td>Study Animals</td><td>Cesarean-derived, colostrum deprived pigs vaccinated at 15 days old and randomly divided into 3 groups:

Group 1 Control vaccine (n=27)
Group 2 Test vaccine (n=27)
Group 3 Non-treated, non-challenged controls (NTX) (n=6)</td></tr>
<tr><td>Challenge Description</td><td>Challenged with Porcine Circovirus, Type 2d challenge virus 4 weeks following vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 21 days for clinical signs. Blood samples were collected twice weekly in the post-challenge period. Lymphoid tissues were taken 21 days after challenge and examined.</td></tr>
<tr><td>Results</td><td>A pig is considered positive for lymphoid depletion if the histopathology score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig is considered positive for lymphoid colonization if the immunohistochemistry score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

Summary of Lymphoid Tissue Efficacy Results
<table>
<tr><th>Group</th><th>Lymphoid Depletion*</th><th>Lymphoid Colonization (IHC)*</th></tr>
<tr><td>Control Vaccine</td><td>26/27 (96%)</td><td>27/27 (100%)</td></tr>
<tr><td>Test Vaccine</td><td>1/27 (4%)</td><td>3/27 (11%)</td></tr>
</table>
* All NTX pigs were negative for lymphoid depletion and colonization in all tissues.

Raw data on attached page</td></tr>
<tr><td>USDA Approval Date</td><td>December 2, 2024</td></tr>
</table>

Lymphoid Colonization and Depletion Scores

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Control	5	3	1	2	2	1	1	2	0
Control	7	2	1	0	0	1	0	1	0
Control	8	1	0	1	0	0	0	0	0
Control	9	3	1	2	1	2	2	2	1
Control	11	2	0	1	0	1	0	0	1
Control	12	3	3	3	2	0	2	2	2
Control	13	3	1	3	1	0	2	2	2
Control	16	1	1	1	1	0	1	1	0
Control	20	2	2	3	2	3	2	3	2
Control	23	3	3	3	3	3	3	3	3
Control	24	3	3	3	3	3	3	3	3
Control	25	3	3	3	2	3	3	3	3
Control	29	3	3	3	3	3	3	3	3
Control	30	3	3	3	3	3	3	3	3
Control	31	1	1	0	0	1	3	1	3
Control	32	1	1	3	0	1	2	2	0
Control	35	3	1	3	0	3	1	3	1
Control	38	3	2	3	2	2	2	3	2
Control	39	3	2	3	3	3	3	3	3
Control	41	3	2	3	1	2	1	1	0
Control	42	3	3	3	3	3	3	3	3
Control	45	2	3	2	0	2	3	3	1
Control	52	2	2	2	2	0	0	1	0
Control	54	3	3	2	2	1	1	2	1
Control	56	3	3	3	0	0	0	1	0
Control	57	1	1	1	0	1	1	0	0
Control	59	3	3	3	3	3	3	3	2

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

Lymphoid Colonization and Depletion Scores (Continued)

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Vaccine	1	0	0	0	0	0	0	0	0
Vaccine	2	0	0	0	0	0	0	0	0
Vaccine	3	1	0	0	0	0	0	0	0
Vaccine	6	0	0	0	0	0	0	0	0
Vaccine	10	1	0	0	0	0	0	0	0
Vaccine	15	0	0	0	0	0	0	0	0
Vaccine	17	0	0	0	0	0	0	0	0
Vaccine	18	0	0	0	0	0	0	0	0
Vaccine	19	0	0	0	0	0	0	0	0
Vaccine	21	0	0	0	0	0	1	0	0
Vaccine	22	0	0	0	0	0	0	0	0
Vaccine	26	0	0	0	0	0	0	0	0
Vaccine	27	0	0	0	0	0	0	0	0
Vaccine	33	1	0	0	0	0	0	0	0
Vaccine	34	0	0	0	0	0	0	0	0
Vaccine	36	0	0	0	0	0	0	0	0
Vaccine	37	0	0	0	0	0	0	0	0
Vaccine	40	0	0	0	0	0	0	0	0
Vaccine	43	0	0	0	0	0	0	0	0
Vaccine	44	0	0	0	0	0	0	0	0
Vaccine	47	0	0	0	0	0	0	0	0
Vaccine	48	0	0	0	0	0	0	0	0
Vaccine	50	0	0	0	0	0	0	0	0
Vaccine	51	0	0	0	0	0	0	0	0
Vaccine	53	0	0	0	0	0	0	0	0
Vaccine	58	0	0	0	0	0	0	0	0
Vaccine	60	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

Lymphoid Colonization and Depletion Scores of NTX pigs

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	4	0	0	0	0	0	0	0	0
NTX	14	0	0	0	0	0	0	0	0
NTX	28	0	0	0	0	0	0	0	0
NTX	46	0	0	0	0	0	0	0	0
NTX	49	0	0	0	0	0	0	0	0
NTX	55	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Circovirus Type 2d (PCV2d)</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of a 6-month duration of immunity against PCV2d</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine.</td></tr>
<tr><td>Study Animals</td><td>Cesarean-derived, colostrum deprived pigs vaccinated at 22 days old and randomly divided into 3 groups:

Group 1 Control vaccine (n=19)
Group 2 Test vaccine (n=16)
Group 3 Non-treated, non-challenged controls (NTX) (n=4)</td></tr>
<tr><td>Challenge Description</td><td>Challenged with Porcine Circovirus, Type 2d challenge virus 6 months following vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 21 days for clinical signs. Blood samples were collected twice weekly in the post-challenge period. Lymphoid tissues were taken 21 days after challenge and examined.</td></tr>
<tr><td>Results</td><td>A pig is considered positive for lymphoid depletion if the histopathology score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig is considered positive for lymphoid colonization if the immunohistochemistry score is > 0 for one or more of the four lymphoid tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node, or iliac lymph node).

A pig was considered positive for viremia if PCV2 DNA was detected by qPCR in the serum during any of the sampling points post-challenge.

Summary of Lymphoid Tissue and Viremia Efficacy Results
<table>
<tr><th>Group</th><th>Lymphoid Depletion*</th><th>Lymphoid Colonization (IHC)*</th><th>Viremia**</th></tr>
<tr><td>Control Vaccine</td><td>11/19 (58%)</td><td>17/19 (90%)</td><td>19/19 (100%)</td></tr>
<tr><td>Test Vaccine</td><td>2/16 (13%)</td><td>1/16 (6%)</td><td>3/16 (19%)</td></tr>
</table>
*All NTX pigs were all negative for lymphoid colonization in all tissues.
** All NTX pigs were negative for viremia.

Raw data on attached page</td></tr>
<tr><td>USDA Approval Date</td><td>January 22, 2025</td></tr>
</table>

Lymphoid Colonization and Depletion Scores

Group	Pig ID	Colonization (IHC)				Depletion (Histology)			
		Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	10	0	0	0	0	0	0	0	0
	15	0	0	0	0	0	0	0	0
	26	0	0	0	0	0	0	0	0
	38	0	0	0	0	0	0	0	0
Control	5	0	0	0	0	0	0	0	0
	12	0	0	0	0	0	0	0	0
	14	0	0	1	0	0	0	2	0
	16	1	0	0	0	0	0	0	0
	17	1	1	1	0	0	0	0	0
	20	1	0	0	0	0	0	0	0
	21	0	0	1	0	0	0	0	0
	25	1	0	1	0	0	0	0	0
	28	1	0	1	0	1	0	1	0
	39	1	1	1	1	1	1	1	0
	41	2	2	1	2	1	1	1	1
	42	1	0	2	1	1	2	1	0
	48	2	0	2	1	1	0	1	1
	49	2	0	1	0	1	0	1	0
	51	0	0	1	0	0	0	1	0
	55	1	0	1	0	1	0	1	0
	60	1	1	1	0	1	0	1	0
	61	3	3	3	3	3	2	3	2
	63	1	0	1	0	1	0	1	0
Vaccine	2	0	0	0	0	0	0	0	0
	11	0	0	0	0	0	0	0	0
	13	0	0	0	0	0	0	0	0
	18	0	0	1	0	0	0	1	0
	19	0	0	0	0	0	0	0	0
	24	0	0	0	0	0	0	0	0
	27	0	0	0	0	0	0	0	0
	30	0	0	0	0	0	0	0	0
	37	0	0	0	0	0	0	0	0
	45	0	0	0	0	0	0	0	0
	46	0	0	0	0	0	0	0	1
	47	0	0	0	0	0	0	0	0
	50	0	0	0	0	0	0	0	0
	52	0	0	0	0	0	0	0	0
	53	0	0	0	0	0	0	0	0
	62	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.
Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)
Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

Viremia (Serum qPCR results, genomic equivalent/mL)

Group	Pig ID	Day 182	Day 187	Day 190	Day 194	Day 196	Day 201	Day 204
NTX	10	.	NA	NA	NA	NA	NA	NA
	15	.	NA	NA	NA	NA	NA	NA
	26	.	NA	NA	NA	NA	NA	NA
	38	.	NA	NA	NA	NA	NA	NA
Control	5	.	.	1,529	95,240	40,344	21,956	34,505
	12	.	1,307	27,249	232,297	631,454	149,735	156,599
	14	.	.	37,333	50,456	146,884	195,755	215,751
	16	.	1,196	66,229	48,606	103,644	23,864	138,316
	17	.	.	170,533	622,385	635,887	195,835	302,725
	20	.	.	10,244	3,282	29,807	47,973	134,098
	21	.	.	1,241	24,848	69,482	263,111	111,903
	25	.	.	5,915	962,615	1,320,554	1,799,449	1,190,948
	28	.	1,659	101,429	118,925	1,261,381	833,417	764,336
	39	.	.	6,605	198,365	628,587	282,118	666,215
	41	.	.	65,722	552,301	3,977,072	313,501	309,902
	42	.	.	16,143	131,117	685,120	354,364	248,403
	48	.	1,874	82,368	166,504	2,380,309	198,594	196,875
	49	.	.	.	.	7,764	214,087	171,345
	51	.	.	59,684	37,519	370,207	125,898	204,382
	55	.	.	6,256	106,599	1,055,263	753,768	613,905
	60	.	.	26,468	47,613	330,085	287,613	351,368
	61	.	12,289	1,525,269	5,113,265	912,823,866	433,475,224	162,196,100
	63	.	.	25,413	60,784	67,130	174,386	284,736
Vaccine	2	.	.	.	.	.	.	.
	11	.	.	.	.	.	.	.
	13	.	.	.	.	.	.	.
	18	.	.	.	.	.	.	.
	19	.	.	.	.	.	.	.
	24	.	.	1,740	.	1,088	.	.
	27	.	.	.	.	.	.	.
	30	.	.	.	.	.	.	.
	37	.	.	.	.	.	.	.
	45	.	.	.	.	.	.	.
	46	.	.	.	.	.	1,704	.
	47	.	.	.	.	.	.	.
	50	.	.	.	.	.	.	.
	52	.	.	.	.	.	782	928
	53	.	.	.	.	.	.	.
	62	.	.	.	.	.	.	.

. =result was negative; NA=no sample collected

<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>Single intramuscular administration of vaccine</td></tr>
<tr><td>Study Animals</td><td>750 pigs at 7 to 14 days of age</td></tr>
<tr><td>Challenge Description</td><td>Not Applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were observed daily for 14 days following vaccination</td></tr>
<tr><td>Results</td><td>No injection site reactions were observed.

Number of pigs with any listed clinical observations occurring at least once during the 14 day study duration.
<table>
<tr><th>Clinical Observation</th><th>Number in 750 doses</th></tr>
<tr><td>Normal*</td><td>726</td></tr>
<tr><td>Lameness</td><td>9</td></tr>
<tr><td>Lethargy</td><td>5</td></tr>
<tr><td>Ataxia</td><td>3</td></tr>
<tr><td>Anorexia</td><td>1</td></tr>
<tr><td>Emesis</td><td>1</td></tr>
<tr><td>Central nervous system disorder</td><td>1</td></tr>
<tr><td>Recumbency</td><td>1</td></tr>
<tr><td>Death**</td><td>9</td></tr>
</table>
*For “normal” a pig had to be observed to be without adverse events for the entire observation period of the study.
**All deaths were investigated and none of the observed deaths were determined to have been likely due to vaccine administration.</td></tr>
<tr><td>USDA Approval Date</td><td>January 22, 2025</td></tr>
</table>