



## Summary of Studies Supporting USDA Product Licensure

|   |   |
|---|---|
| Establishment Name  | Boehringer Ingelheim Animal Health USA Inc.   |
| USDA Vet Biologics Establishment Number                                   | 124   |
| Product Code  | 18P5.R0                                       |
| True Name   | Parvovirus Vaccine, Killed Baculovirus Vector |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) |   |
| Date of Compilation Summary   | April 30, 2019                                |

**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.**

| <b>Study Type</b>                        | Efficacy  |              |  |                |            |                  |            |
|--|---|--------------|--|----------------|------------|------------------|------------|
| <b>Pertaining to</b>                     | Porcine Parvovirus (PPV)  |              |  |                |            |                  |            |
| <b>Study Purpose</b>                     | Demonstration of efficacy against porcine parvovirus induced reproductive failure   |              |  |                |            |                  |            |
| <b>Product Administration</b>            | 2 intramuscular doses of vaccine at 3 weeks apart prior to breeding   |              |  |                |            |                  |            |
| <b>Study Animals</b>                     | 5- to 6-month-old healthy gilts not previously vaccinated against PPV:<br>T01 Placebo control group: 10 gilts<br>T05 Vaccinate group: 12 gilts  |              |  |                |            |                  |            |
| <b>Challenge Description</b>             | PPV serotype 1 challenge virus was at approximately 40 days of gestation.   |              |  |                |            |                  |            |
| <b>Interval observed after challenge</b> | Fetuses were delivered from gilts via cesarean at approximately 90 days of gestation. Fetuses were evaluated for fetal condition (normal, necrotic/stillborn, mummy, or aborted).   |              |  |                |            |                  |            |
| <b>Results</b>                           | <p><b>A gilt was considered affected by PPV if at least one fetus in the litter was mummified/necrotic or stillborn or aborted.</b></p> <p><b>Summary of PPV Affected Gilts:</b></p> <table border="1"> <thead> <tr> <th><b>Group</b></th> <th><b>Number Affected/Total<br/>(Percent Affected )</b></th> </tr> </thead> <tbody> <tr> <td><b>Control</b></td> <td>9/10 (90%)</td> </tr> <tr> <td><b>Vaccinate</b></td> <td>4/12 (33%)</td> </tr> </tbody> </table> | <b>Group</b> | <b>Number Affected/Total<br/>(Percent Affected )</b> | <b>Control</b> | 9/10 (90%) | <b>Vaccinate</b> | 4/12 (33%) |
| <b>Group</b>                             | <b>Number Affected/Total<br/>(Percent Affected )</b>  |              |  |                |            |                  |            |
| <b>Control</b>                           | 9/10 (90%)  |              |  |                |            |                  |            |
| <b>Vaccinate</b>                         | 4/12 (33%)  |              |  |                |            |                  |            |
| <b>USDA Approval Date</b>                | August 18, 2017   |              |  |                |            |                  |            |

### Summary of Fetal Status

| Group | Gilt | Total Fetuses | Fetuses Abnormal | Percent Abnormal | Gilt Status     | Frequency of Positive Gilts | Percent of Positive Gilts |
|-------|------|---------------|------------------|------------------|-----------------|-----------------------------|---------------------------|
| T01   | 2    | 14            | 6                | 42.9%            | <b>Affected</b> |                             |                           |
| T01   | 11   | 15            | 1                | 6.7%             | <b>Affected</b> |                             |                           |
| T01   | 14   | 12            | 12               | 100%             | <b>Affected</b> |                             |                           |
| T01   | 24   | 17            | 11               | 64.7%            | <b>Affected</b> |                             |                           |
| T01   | 34   | 15            | 12               | 80.0%            | <b>Affected</b> |                             |                           |
| T01   | 35   | 14            | 14               | 100%             | <b>Affected</b> |                             |                           |
| T01   | 53   | 12            | 12               | 100%             | <b>Affected</b> |                             |                           |
| T01   | 54   | 16            | 0                | 0.0%             | Negative        |                             |                           |
| T01   | 56   | 15            | 9                | 60.0%            | <b>Affected</b> |                             |                           |
| T01   | 62   | 16            | 14               | 87.5%            | <b>Affected</b> |                             |                           |
| T05   | 12   |               |                  | 100.0%           | <b>Affected</b> |                             |                           |
| T05   | 1    | 10            | 0                | 0.0%             | Negative        |                             |                           |
| T05   | 4    | 15            | 0                | 0.0%             | Negative        |                             |                           |
| T05   | 8    | 17            | 0                | 0.0%             | Negative        |                             |                           |
| T05   | 17   | 11            | 0                | 0.0%             | Negative        |                             |                           |
| T05   | 19   | 3             | 0                | 0.0%             | Negative        |                             |                           |
| T05   | 22   | 16            | 6                | 37.5%            | <b>Affected</b> |                             |                           |
| T05   | 40   | 17            | 0                | 0.0%             | Negative        |                             |                           |
| T05   | 41   | 17            | 1                | 5.9%             | <b>Affected</b> |                             |                           |
| T05   | 46   | 13            | 0                | 0.0%             | Negative        |                             |                           |
| T05   | 57   | 15            | 1                | 6.7%             | <b>Affected</b> |                             |                           |
| T05   | 61   | 14            | 0                | 0.0%             | Negative        |                             |                           |

T01 Placebo control group; T05 Vaccinate group

T05 Gilt # 12 identified as not pregnant at the time of cesarean.

### Placebo Control Group Fetus Raw Data

| Fetus ID | Gilt ID | Group | Fetus Condition |
|----------|---------|-------|-----------------|
| 11L1     | 11      | T01   | Normal          |
| 11L2     | 11      | T01   | Normal          |
| 11L3     | 11      | T01   | Normal          |
| 11L4     | 11      | T01   | Normal          |
| 11L5     | 11      | T01   | Normal          |
| 11L6     | 11      | T01   | Normal          |
| 11L7     | 11      | T01   | Normal          |
| 11R1     | 11      | T01   | Normal          |
| 11R2     | 11      | T01   | Mummy           |
| 11R3     | 11      | T01   | Normal          |
| 11R4     | 11      | T01   | Normal          |
| 11R5     | 11      | T01   | Normal          |
| 11R6     | 11      | T01   | Normal          |
| 11R7     | 11      | T01   | Normal          |
| 11R8     | 11      | T01   | Normal          |
| 14L1     | 14      | T01   | Mummy           |
| 14L2     | 14      | T01   | Mummy           |
| 14L3     | 14      | T01   | Mummy           |
| 14L4     | 14      | T01   | Mummy           |
| 14L5     | 14      | T01   | Mummy           |
| 14L6     | 14      | T01   | Mummy           |
| 14L7     | 14      | T01   | Mummy           |
| 14R1     | 14      | T01   | Mummy           |
| 14R2     | 14      | T01   | Necrotic        |
| 14R3     | 14      | T01   | Mummy           |
| 14R4     | 14      | T01   | Mummy           |
| 14R5     | 14      | T01   | Mummy           |
| 24L1     | 24      | T01   | Mummy           |
| 24L10    | 24      | T01   | Normal          |
| 24L2     | 24      | T01   | Mummy           |
| 24L3     | 24      | T01   | Mummy           |
| 24L4     | 24      | T01   | Necrotic        |
| 24L5     | 24      | T01   | Normal          |
| 24L6     | 24      | T01   | Normal          |
| 24L7     | 24      | T01   | Normal          |
| 24L8     | 24      | T01   | Normal          |
| 24L9     | 24      | T01   | Normal          |
| 24R1     | 24      | T01   | Mummy           |
| 24R2     | 24      | T01   | Mummy           |
| 24R3     | 24      | T01   | Mummy           |
| 24R4     | 24      | T01   | Mummy           |
| 24R5     | 24      | T01   | Mummy           |
| 24R6     | 24      | T01   | Mummy           |
| 24R7     | 24      | T01   | Mummy           |
| 2L1      | 2       | T01   | Necrotic        |
| 2L2      | 2       | T01   | Necrotic        |
| 2L3      | 2       | T01   | Normal          |

| <b>Fetus ID</b> | <b>Gilt ID</b> | <b>Group</b> | <b>Fetus Condition</b> |
|-----------------|----------------|--------------|------------------------|
| 2L4             | 2              | T01          | Normal                 |
| 2L5             | 2              | T01          | Normal                 |
| 2L6             | 2              | T01          | Normal                 |
| 2R1             | 2              | T01          | Normal                 |
| 2R2             | 2              | T01          | Normal                 |
| 2R3             | 2              | T01          | Normal                 |
| 2R4             | 2              | T01          | Normal                 |
| 2R5             | 2              | T01          | Necrotic               |
| 2R6             | 2              | T01          | Mummy                  |
| 2R7             | 2              | T01          | Mummy                  |
| 2R8             | 2              | T01          | Mummy                  |
| 34L1            | 34             | T01          | Mummy                  |
| 34L2            | 34             | T01          | Mummy                  |
| 34L3            | 34             | T01          | Mummy                  |
| 34L4            | 34             | T01          | Mummy                  |
| 34L5            | 34             | T01          | Mummy                  |
| 34L6            | 34             | T01          | Mummy                  |
| 34L7            | 34             | T01          | Mummy                  |
| 34R1            | 34             | T01          | Mummy                  |
| 34R2            | 34             | T01          | Mummy                  |
| 34R3            | 34             | T01          | Mummy                  |
| 34R4            | 34             | T01          | Mummy                  |
| 34R5            | 34             | T01          | Necrotic               |
| 34R6            | 34             | T01          | Normal                 |
| 34R7            | 34             | T01          | Normal                 |
| 34R8            | 34             | T01          | Normal                 |
| 35L1            | 35             | T01          | Mummy                  |
| 35L2            | 35             | T01          | Mummy                  |
| 35L3            | 35             | T01          | Mummy                  |
| 35L4            | 35             | T01          | Mummy                  |
| 35L5            | 35             | T01          | Mummy                  |
| 35L6            | 35             | T01          | Mummy                  |
| 35L7            | 35             | T01          | Mummy                  |
| 35R1            | 35             | T01          | Mummy                  |
| 35R2            | 35             | T01          | Mummy                  |
| 35R3            | 35             | T01          | Mummy                  |
| 35R4            | 35             | T01          | Mummy                  |
| 35R5            | 35             | T01          | Mummy                  |
| 35R6            | 35             | T01          | Mummy                  |
| 35R7            | 35             | T01          | Mummy                  |
| 53L1            | 53             | T01          | Mummy                  |
| 53L2            | 53             | T01          | Mummy                  |
| 53L3            | 53             | T01          | Mummy                  |
| 53L4            | 53             | T01          | Mummy                  |
| 53L5            | 53             | T01          | Mummy                  |
| 53L6            | 53             | T01          | Mummy                  |
| 53L7            | 53             | T01          | Mummy                  |
| 53R1            | 53             | T01          | Mummy                  |

| <b>Fetus ID</b> | <b>Gilt ID</b> | <b>Group</b> | <b>Fetus Condition</b> |
|-----------------|----------------|--------------|------------------------|
| 53R2            | 53             | T01          | Mummy                  |
| 53R3            | 53             | T01          | Mummy                  |
| 53R4            | 53             | T01          | Mummy                  |
| 53R5            | 53             | T01          | Mummy                  |
| 54L1            | 54             | T01          | Normal                 |
| 54L2            | 54             | T01          | Normal                 |
| 54L3            | 54             | T01          | Normal                 |
| 54L4            | 54             | T01          | Normal                 |
| 54L5            | 54             | T01          | Normal                 |
| 54L6            | 54             | T01          | Normal                 |
| 54L7            | 54             | T01          | Normal                 |
| 54R1            | 54             | T01          | Normal                 |
| 54R2            | 54             | T01          | Normal                 |
| 54R3            | 54             | T01          | Normal                 |
| 54R4            | 54             | T01          | Normal                 |
| 54R5            | 54             | T01          | Normal                 |
| 54R6            | 54             | T01          | Normal                 |
| 54R7            | 54             | T01          | Normal                 |
| 54R8            | 54             | T01          | Normal                 |
| 54R9            | 54             | T01          | Normal                 |
| 56L1            | 56             | T01          | Normal                 |
| 56L2            | 56             | T01          | Necrotic               |
| 56L3            | 56             | T01          | Mummy                  |
| 56L4            | 56             | T01          | Mummy                  |
| 56L5            | 56             | T01          | Mummy                  |
| 56L6            | 56             | T01          | Mummy                  |
| 56L7            | 56             | T01          | Mummy                  |
| 56R1            | 56             | T01          | Normal                 |
| 56R2            | 56             | T01          | Mummy                  |
| 56R3            | 56             | T01          | Mummy                  |
| 56R4            | 56             | T01          | Mummy                  |
| 56R5            | 56             | T01          | Normal                 |
| 56R6            | 56             | T01          | Normal                 |
| 56R7            | 56             | T01          | Normal                 |
| 56R8            | 56             | T01          | Normal                 |
| 62L1            | 62             | T01          | Mummy                  |
| 62L2            | 62             | T01          | Mummy                  |
| 62L3            | 62             | T01          | Mummy                  |
| 62L4            | 62             | T01          | Mummy                  |
| 62L5            | 62             | T01          | Mummy                  |
| 62L6            | 62             | T01          | Mummy                  |
| 62L7            | 62             | T01          | Necrotic               |
| 62R1            | 62             | T01          | Necrotic               |
| 62R2            | 62             | T01          | Mummy                  |
| 62R3            | 62             | T01          | Mummy                  |
| 62R4            | 62             | T01          | Mummy                  |
| 62R5            | 62             | T01          | Mummy                  |
| 62R6            | 62             | T01          | Mummy                  |
| 62R7            | 62             | T01          | Mummy                  |
| 62R8            | 62             | T01          | Normal                 |
| 62R9            | 62             | T01          | Normal                 |

### Vaccinate Group Fetus Raw Data

| <b>Fetus ID</b> | <b>Gilt ID</b> | <b>Group</b> | <b>Fetus Condition</b> |
|-----------------|----------------|--------------|------------------------|
| 17L1            | 17             | T05          | Normal                 |
| 17L2            | 17             | T05          | Normal                 |
| 17L3            | 17             | T05          | Normal                 |
| 17L4            | 17             | T05          | Normal                 |
| 17L5            | 17             | T05          | Normal                 |
| 17R1            | 17             | T05          | Normal                 |
| 17R2            | 17             | T05          | Normal                 |
| 17R3            | 17             | T05          | Normal                 |
| 17R4            | 17             | T05          | Normal                 |
| 17R5            | 17             | T05          | Normal                 |
| 17R6            | 17             | T05          | Normal                 |
| 19R1            | 19             | T05          | Normal                 |
| 19R2            | 19             | T05          | Normal                 |
| 19R3            | 19             | T05          | Normal                 |
| 1L1             | 1              | T05          | Normal                 |
| 1L2             | 1              | T05          | Normal                 |
| 1L3             | 1              | T05          | Normal                 |
| 1L4             | 1              | T05          | Normal                 |
| 1L5             | 1              | T05          | Normal                 |
| 1R1             | 1              | T05          | Normal                 |
| 1R2             | 1              | T05          | Normal                 |
| 1R3             | 1              | T05          | Normal                 |
| 1R4             | 1              | T05          | Normal                 |
| 1R5             | 1              | T05          | Normal                 |
| 22L1            | 22             | T05          | Normal                 |
| 22L2            | 22             | T05          | Mummy                  |
| 22L3            | 22             | T05          | Mummy                  |
| 22L4            | 22             | T05          | Mummy                  |
| 22L5            | 22             | T05          | Mummy                  |
| 22L6            | 22             | T05          | Mummy                  |
| 22L7            | 22             | T05          | Mummy                  |
| 22L8            | 22             | T05          | Normal                 |
| 22R1            | 22             | T05          | Normal                 |
| 22R2            | 22             | T05          | Normal                 |
| 22R3            | 22             | T05          | Normal                 |
| 22R4            | 22             | T05          | Normal                 |
| 22R5            | 22             | T05          | Normal                 |
| 22R6            | 22             | T05          | Normal                 |
| 22R7            | 22             | T05          | Normal                 |
| 22R8            | 22             | T05          | Normal                 |

| <b>Fetus ID</b> | <b>Gilt ID</b> | <b>Group</b> | <b>Fetus Condition</b> |
|-----------------|----------------|--------------|------------------------|
| 40L1            | 40             | T05          | Normal                 |
| 40L2            | 40             | T05          | Normal                 |
| 40L3            | 40             | T05          | Normal                 |
| 40L4            | 40             | T05          | Normal                 |
| 40L5            | 40             | T05          | Normal                 |
| 40L6            | 40             | T05          | Normal                 |
| 40L7            | 40             | T05          | Normal                 |
| 40L8            | 40             | T05          | Normal                 |
| 40L9            | 40             | T05          | Normal                 |
| 40R1            | 40             | T05          | Normal                 |
| 40R2            | 40             | T05          | Normal                 |
| 40R3            | 40             | T05          | Normal                 |
| 40R4            | 40             | T05          | Normal                 |
| 40R5            | 40             | T05          | Normal                 |
| 40R6            | 40             | T05          | Normal                 |
| 40R7            | 40             | T05          | Normal                 |
| 40R8            | 40             | T05          | Normal                 |
| 41L1            | 41             | T05          | Normal                 |
| 41L2            | 41             | T05          | Normal                 |
| 41L3            | 41             | T05          | Normal                 |
| 41L4            | 41             | T05          | Normal                 |
| 41L5            | 41             | T05          | Mummy                  |
| 41L6            | 41             | T05          | Normal                 |
| 41L7            | 41             | T05          | Normal                 |
| 41L8            | 41             | T05          | Normal                 |
| 41L9            | 41             | T05          | Normal                 |
| 41R1            | 41             | T05          | Normal                 |
| 41R2            | 41             | T05          | Normal                 |
| 41R3            | 41             | T05          | Normal                 |
| 41R4            | 41             | T05          | Normal                 |
| 41R5            | 41             | T05          | Normal                 |
| 41R6            | 41             | T05          | Normal                 |
| 41R7            | 41             | T05          | Normal                 |
| 41R8            | 41             | T05          | Normal                 |
| 46L1            | 46             | T05          | Normal                 |
| 46L2            | 46             | T05          | Normal                 |
| 46L3            | 46             | T05          | Normal                 |
| 46L4            | 46             | T05          | Normal                 |
| 46L5            | 46             | T05          | Normal                 |
| 46L6            | 46             | T05          | Normal                 |
| 46L7            | 46             | T05          | Normal                 |
| 46L8            | 46             | T05          | Normal                 |
| 46R1            | 46             | T05          | Normal                 |
| 46R2            | 46             | T05          | Normal                 |
| 46R3            | 46             | T05          | Normal                 |
| 46R4            | 46             | T05          | Normal                 |
| 46R5            | 46             | T05          | Normal                 |
| 4L1             | 4              | T05          | Normal                 |

| <b>Fetus ID</b> | <b>Gilt ID</b> | <b>Group</b> | <b>Fetus Condition</b> |
|-----------------|----------------|--------------|------------------------|
| 4L2             | 4              | T05          | Normal                 |
| 4L3             | 4              | T05          | Normal                 |
| 4L4             | 4              | T05          | Normal                 |
| 4L5             | 4              | T05          | Normal                 |
| 4L6             | 4              | T05          | Normal                 |
| 4L7             | 4              | T05          | Normal                 |
| 4R1             | 4              | T05          | Normal                 |
| 4R2             | 4              | T05          | Normal                 |
| 4R3             | 4              | T05          | Normal                 |
| 4R4             | 4              | T05          | Normal                 |
| 4R5             | 4              | T05          | Normal                 |
| 4R6             | 4              | T05          | Normal                 |
| 4R7             | 4              | T05          | Normal                 |
| 4R8             | 4              | T05          | Normal                 |
| 57L1            | 57             | T05          | Normal                 |
| 57L2            | 57             | T05          | Normal                 |
| 57L3            | 57             | T05          | Normal                 |
| 57L4            | 57             | T05          | Normal                 |
| 57L5            | 57             | T05          | Normal                 |
| 57L6            | 57             | T05          | Normal                 |
| 57L7            | 57             | T05          | Normal                 |
| 57L8            | 57             | T05          | Normal                 |
| 57L9            | 57             | T05          | Normal                 |
| 57R1            | 57             | T05          | Mummy                  |
| 57R2            | 57             | T05          | Normal                 |
| 57R3            | 57             | T05          | Normal                 |
| 57R4            | 57             | T05          | Normal                 |
| 57R5            | 57             | T05          | Normal                 |
| 57R6            | 57             | T05          | Normal                 |
| 61L1            | 61             | T05          | Normal                 |
| 61L2            | 61             | T05          | Normal                 |
| 61L3            | 61             | T05          | Normal                 |
| 61L4            | 61             | T05          | Normal                 |
| 61L5            | 61             | T05          | Normal                 |
| 61L6            | 61             | T05          | Normal                 |
| 61L7            | 61             | T05          | Normal                 |
| 61R1            | 61             | T05          | Normal                 |
| 61R2            | 61             | T05          | Normal                 |
| 61R3            | 61             | T05          | Normal                 |
| 61R4            | 61             | T05          | Normal                 |
| 61R5            | 61             | T05          | Normal                 |
| 61R6            | 61             | T05          | Normal                 |
| 61R7            | 61             | T05          | Normal                 |
| 8L1             | 8              | T05          | Normal                 |
| 8L2             | 8              | T05          | Normal                 |
| 8L3             | 8              | T05          | Normal                 |
| 8L4             | 8              | T05          | Normal                 |
| 8L5             | 8              | T05          | Normal                 |

| <b>Fetus ID</b> | <b>Gilt ID</b> | <b>Group</b> | <b>Fetus Condition</b> |
|-----------------|----------------|--------------|------------------------|
| 8L6             | 8              | T05          | Normal                 |
| 8L7             | 8              | T05          | Normal                 |
| 8L8             | 8              | T05          | Normal                 |
| 8L9             | 8              | T05          | Normal                 |
| 8R1             | 8              | T05          | Normal                 |
| 8R2             | 8              | T05          | Normal                 |
| 8R3             | 8              | T05          | Normal                 |
| 8R4             | 8              | T05          | Normal                 |
| 8R5             | 8              | T05          | Normal                 |
| 8R6             | 8              | T05          | Normal                 |
| 8R7             | 8              | T05          | Normal                 |
| 8R8             | 8              | T05          | Normal                 |

| <b>Study Type</b>                          | Safety  |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
|--|---|--|---------------------|---------------------|----------------------|---------------------|----------------------|---------------------------|--|------------|------------|------------|------------|----------|--|---|---|----|----|----------------------|--|---|---|---|----|-----------------------------|---|---|---|----|---------------------------------|---|---|---|----|--|---|---|----|----|----------|---|---|---|---|-----------------------|--|---|---|----|----|----------|--|---|---|---|---|------------------|--|---|---|---|---|----------------|--|---|---|---|---|------------|--|---|---|---|---|----------|--|---|---|---|---|-------------------------|--|---|---|---|---|--------------------------------|--|---|---|---|
| <b>Pertaining to</b>                       | All   |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>Study Purpose</b>                       | Demonstrate safety in breeding age animals prior to breeding and at all stages of gestation.  |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>Product Administration</b>              | Two doses, 3 weeks apart  |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>Study Animals</b>                       | 775 breeding age gilts and sows (319 vaccinated prior to breeding, 228 vaccinated in early gestation, 228 vaccinated in mid- to late gestation)   |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>Challenge Description</b>               | N/A   |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>Interval observed after vaccination</b> | Observed through farrowing including loss of pregnancy and mortality.   |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>Results</b>                             | Results of the study are summarized as follows:<br><b>All Sites and Gestational Phases</b>  |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
|  | <table border="1"> <thead> <tr> <th colspan="2"><b>Clinical Observations<sup>†</sup></b></th> <th><b>IL<br/>N=229</b></th> <th><b>MO<br/>N=296</b></th> <th><b>SD<br/>N=250</b></th> <th><b>All<br/>N=775</b></th> </tr> </thead> <tbody> <tr> <td colspan="2"><b>Normal<sup>1</sup></b></td> <td><b>210</b></td> <td><b>249</b></td> <td><b>138</b></td> <td><b>597</b></td> </tr> <tr> <td colspan="2">Lameness</td> <td>2</td> <td>1</td> <td>29</td> <td>32</td> </tr> <tr> <td rowspan="5">Reproductive Failure</td> <td>Abortion/pre-mature farrowing<sup>2</sup></td> <td>2</td> <td>9</td> <td>1</td> <td>12</td> </tr> <tr> <td>Did not farrow<sup>3</sup></td> <td>3</td> <td>9</td> <td>3</td> <td>15</td> </tr> <tr> <td>Conception failure<sup>4</sup></td> <td>7</td> <td>8</td> <td>6</td> <td>21</td> </tr> <tr> <td>Not selected for breeding<sup>5</sup></td> <td>0</td> <td>9</td> <td>37</td> <td>46</td> </tr> <tr> <td>Dystocia</td> <td>0</td> <td>0</td> <td>1</td> <td>1</td> </tr> <tr> <td colspan="2">Injection Site Lesion</td> <td>0</td> <td>0</td> <td>24</td> <td>24</td> </tr> <tr> <td colspan="2">Anorexia</td> <td>3</td> <td>0</td> <td>1</td> <td>4</td> </tr> <tr> <td colspan="2">Vaginal prolapse</td> <td>1</td> <td>3</td> <td>0</td> <td>4</td> </tr> <tr> <td colspan="2">Vulvovaginitis</td> <td>0</td> <td>0</td> <td>4</td> <td>4</td> </tr> <tr> <td colspan="2">Recumbency</td> <td>0</td> <td>2</td> <td>0</td> <td>2</td> </tr> <tr> <td colspan="2">Fracture</td> <td>0</td> <td>1</td> <td>0</td> <td>1</td> </tr> <tr> <td colspan="2">Injection site erythema</td> <td>0</td> <td>0</td> <td>1</td> <td>1</td> </tr> <tr> <td colspan="2">Mortality (Death)<sup>6</sup></td> <td>1</td> <td>5</td> <td>5</td> <td>11</td> </tr> </tbody> </table> <p>N = number<br/> <sup>†</sup> sows/gilts may be represented in multiple observation categories.<br/> <sup>1</sup>for “normal” a sow or gilt had to be observed to be without adverse events for the entire study<br/> <sup>2</sup>sows/gilts with observed abortion/premature farrowing<br/> <sup>3</sup>pregnant sows/gilts that did not farrow, but no abortion was observed<br/> <sup>4</sup>gilts that were inseminated, but did not conceive<br/> <sup>5</sup>gilts that were never inseminated/not selected by the sites for inclusion in the breeding herd<br/> <sup>6</sup>Mortalities were due to dystocia or orthopedic disease</p> <p>Additional data located in the tables below</p> | <b>Clinical Observations<sup>†</sup></b> |                     | <b>IL<br/>N=229</b> | <b>MO<br/>N=296</b>  | <b>SD<br/>N=250</b> | <b>All<br/>N=775</b> | <b>Normal<sup>1</sup></b> |  | <b>210</b> | <b>249</b> | <b>138</b> | <b>597</b> | Lameness |  | 2 | 1 | 29 | 32 | Reproductive Failure | Abortion/pre-mature farrowing <sup>2</sup> | 2 | 9 | 1 | 12 | Did not farrow <sup>3</sup> | 3 | 9 | 3 | 15 | Conception failure <sup>4</sup> | 7 | 8 | 6 | 21 | Not selected for breeding <sup>5</sup> | 0 | 9 | 37 | 46 | Dystocia | 0 | 0 | 1 | 1 | Injection Site Lesion |  | 0 | 0 | 24 | 24 | Anorexia |  | 3 | 0 | 1 | 4 | Vaginal prolapse |  | 1 | 3 | 0 | 4 | Vulvovaginitis |  | 0 | 0 | 4 | 4 | Recumbency |  | 0 | 2 | 0 | 2 | Fracture |  | 0 | 1 | 0 | 1 | Injection site erythema |  | 0 | 0 | 1 | 1 | Mortality (Death) <sup>6</sup> |  | 1 | 5 | 5 |
| <b>Clinical Observations<sup>†</sup></b>   |   | <b>IL<br/>N=229</b>                      | <b>MO<br/>N=296</b> | <b>SD<br/>N=250</b> | <b>All<br/>N=775</b> |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>Normal<sup>1</sup></b>                  |   | <b>210</b>                               | <b>249</b>          | <b>138</b>          | <b>597</b>           |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Lameness                                   |   | 2  | 1                   | 29                  | 32                   |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Reproductive Failure                       | Abortion/pre-mature farrowing <sup>2</sup>  | 2  | 9                   | 1                   | 12                   |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
|  | Did not farrow <sup>3</sup>   | 3  | 9                   | 3                   | 15                   |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
|  | Conception failure <sup>4</sup>   | 7  | 8                   | 6                   | 21                   |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
|  | Not selected for breeding <sup>5</sup>  | 0  | 9                   | 37                  | 46                   |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
|  | Dystocia  | 0  | 0                   | 1                   | 1                    |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Injection Site Lesion                      |   | 0  | 0                   | 24                  | 24                   |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Anorexia                                   |   | 3  | 0                   | 1                   | 4                    |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Vaginal prolapse                           |   | 1  | 3                   | 0                   | 4                    |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Vulvovaginitis                             |   | 0  | 0                   | 4                   | 4                    |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Recumbency                                 |   | 0  | 2                   | 0                   | 2                    |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Fracture                                   |   | 0  | 1                   | 0                   | 1                    |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Injection site erythema                    |   | 0  | 0                   | 1                   | 1                    |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| Mortality (Death) <sup>6</sup>             |   | 1  | 5                   | 5                   | 11                   |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |
| <b>USDA Approval Date</b>                  | December 7, 2018  |  |                     |                     |                      |                     |                      |                           |  |            |            |            |            |          |  |   |   |    |    |                      |  |   |   |   |    |                             |   |   |   |    |                                 |   |   |   |    |  |   |   |    |    |          |   |   |   |   |                       |  |   |   |    |    |          |  |   |   |   |   |                  |  |   |   |   |   |                |  |   |   |   |   |            |  |   |   |   |   |          |  |   |   |   |   |                         |  |   |   |   |   |                                |  |   |   |   |

### Injection Site Reactions by Gestation Phase

| Gestation Phase       | Vaccination | <2cm size | 2cm size | 3cm size | 8cm size |
|-----------------------|-------------|-----------|----------|----------|----------|
| Prior to Breeding     | 1           | 5         | 1        | 2        | 0        |
| Prior to Breeding     | 2           | 9         | 0        | 0        | 0        |
| Early Gestation       | 1           | 2         | 0        | 2        | 2        |
| Early Gestation       | 2           | 2         | 0        | 0        | 0        |
| Mid to late Gestation | 1           | 1         | 0        | 0        | 0        |
| Mid to late Gestation | 2           | 1         | 0        | 0        | 0        |

### Five Number Summary of Duration of Injection Site Reactions by Gestation Period

| Gestation Phase       | Vaccination | Min | Q1  | Median | Q3   | Max  |
|-----------------------|-------------|-----|-----|--------|------|------|
| Prior to Breeding     | 1           | 1.0 | 1.5 | 2.0    | 3.0  | 16.0 |
| Prior to Breeding     | 2           | 1.0 | 3.0 | 3.0    | 4.0  | 7.0  |
| Early Gestation       | 1           | 3.0 | 4.0 | 4.0    | 11.0 | 11.0 |
| Early Gestation       | 2           | 2.0 | 2.0 | 3.5    | 5.0  | 5.0  |
| Mid to late Gestation | 1           | 2.0 | 2.0 | 2.0    | 2.0  | 2.0  |
| Mid to late Gestation | 2           | 2.0 | 2.0 | 2.0    | 2.0  | 2.0  |

### All Sites Gilts Vaccinated Prior to Breeding

| Clinical Observations <sup>†</sup> |  | IL<br>N=119 | MO<br>N=60 | SD<br>N=140 | All<br>N=319 |
|------------------------------------|--|-------------|------------|-------------|--------------|
| <b>Normal<sup>1</sup></b>          |  | <b>112</b>  | <b>56</b>  | <b>90</b>   | <b>258</b>   |
| Lameness                           |  | 1           | 0          | 26          | 27           |
| Reproductive Failure               | Abortion/pre-mature farrowing <sup>2</sup> | 2           | 2          | 0           | 4            |
|                                    | Did not farrow <sup>3</sup>                | 2           | 3          | 3           | 8            |
|                                    | Conception failure <sup>4</sup>            | 7           | 8          | 6           | 21           |
|                                    | Not selected for breeding <sup>5</sup>     | 0           | 9          | 37          | 46           |
| Injection Site Lesion              |  | 0           | 0          | 15          | 15           |
| Mortality (Death)                  |  | 1           | 0          | 2           | 3            |

N = number

<sup>1</sup>For “normal” a sow or gilt had to be observed to be without adverse events for the entire study

<sup>2</sup>sows/gilts with observed abortion/premature farrowing

<sup>3</sup>pregnant sows/gilts that did not farrow, but no abortion was observed

<sup>4</sup>gilts that were inseminated, but did not conceive

<sup>5</sup>gilts that were never inseminated/not selected by the sites for inclusion in the breeding herd

<sup>†</sup> sows/gilts may be represented in multiple observation categories. Observations occurring with <1% frequency are omitted from this table, and included recumbency, fracture, anorexia, vaginal prolapse, or injection site erythema.

**All Sites Sows/Gilts Vaccinated in Early (~35 days) Gestation**

| <b>Clinical Observations<sup>†</sup></b> |  | <b>IL<br/>N=55</b> | <b>MO<br/>N=118</b> | <b>SD<br/>N=55</b> | <b>All<br/>N=228</b> |
|--|--|--------------------|---------------------|--------------------|----------------------|
| <b>Normal<sup>1</sup></b>                |  | <b>53</b>          | <b>107</b>          | <b>47</b>          | <b>207</b>           |
| Lameness                                 |  | 1                  | 0                   | 1                  | 2                    |
| Reproductive Failure                     | Abortion/pre-mature farrowing <sup>2</sup> | 0                  | 3                   | 1                  | 4                    |
|  | Did not farrow <sup>3</sup>                | 1                  | 4                   | 0                  | 5                    |
| Injection Site Lesion                    |  | 0                  | 0                   | 7                  | 7                    |
| Mortality (Death)                        |  | 0                  | 4                   | 2                  | 6                    |

N = number

<sup>1</sup>For “normal” a sow or gilt had to be observed to be without adverse events for the entire study

<sup>2</sup>sows/gilts with observed abortion/premature farrowing

<sup>3</sup>pregnant sows/gilts that did not farrow, but no abortion was observed

<sup>†</sup> sows/gilts may be represented in multiple observation categories. Observations occurring with <1% frequency are omitted from this table, and included recumbency, fracture, anorexia, vaginal prolapse, or injection site erythema.

**All Sites Sows/Gilts Vaccinated in Mid to Late (~70 days) Gestation**

| <b>Clinical Observations<sup>†</sup></b> |  | <b>IL<br/>N=55</b> | <b>MO<br/>N=117</b> | <b>SD<br/>N=55</b> | <b>All<br/>N=228</b> |
|--|--|--------------------|---------------------|--------------------|----------------------|
| <b>Normal<sup>1</sup></b>                |  | <b>55</b>          | <b>110</b>          | <b>50</b>          | <b>215</b>           |
| Lameness                                 |  | 0                  | 1                   | 2                  | 3                    |
| Reproductive Failure                     | Abortion/pre-mature farrowing <sup>2</sup> | 0                  | 4                   | 0                  | 4                    |
|  | Did not farrow <sup>3</sup>                | 0                  | 2                   | 0                  | 2                    |
| Injection Site Lesion                    |  | 0                  | 0                   | 2                  | 2                    |
| Mortality (Death)                        |  | 0                  | 1                   | 1                  | 2                    |

N = number

<sup>1</sup>For “normal” a sow or gilt had to be observed to be without adverse events for the entire study

<sup>2</sup>sows/gilts with observed abortion/premature farrowing

<sup>3</sup>pregnant sows/gilts that did not farrow, but no abortion was observed

<sup>†</sup> sows/gilts may be represented in multiple observation categories. Observations occurring with <1% frequency are omitted from this table, and included recumbency, fracture, anorexia, vaginal prolapse, or injection site erythema.

### **Piglet Morbidity and Mortality (All Sites Combined)**

|                                    |                   |
|------------------------------------|-------------------|
| Weak born (Morbidity)              | 1.7% (144/8474)*  |
| Stillborn or Mummified (Mortality) | 11% (1009/9483)** |

\*number affected/total live born

\*\*number affected/total born