# Summary of Studies Supporting USDA Product Licensure

| | |
|---|---|
| Establishment Name | Zoetis Inc. |
| USDA Vet Biologics Establishment Number | 190 |
| Product Code | 14W5.22 |
| True Name | Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | West Nile Innovator + EW - No distributor specified |
| Date of Compilation Summary | December 06, 2022 |

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Eastern Equine Encephalomyelitis Virus (EEE) |
| **Study Purpose** | Efficacy against EEE |
| **Product Administration** | Each product serial is tested in accordance with 9 CFR 113.207(b)(2) requirements |
| **Study Animals** | Guinea pigs |
| **Challenge Description** | NA |
| **Interval observed after challenge** | NA |
| **Results** | Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.207(b)(2). |
| **USDA Approval Date** | NA |

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Western Equine Encephalomyelitis Virus (WEE) |
| **Study Purpose** | Efficacy against WEE |
| **Product Administration** | Each product serial is tested in accordance with 9 CFR 113.207(b)(2) requirements |
| **Study Animals** | Guinea pigs |
| **Challenge Description** | NA |
| **Interval observed after challenge** | NA |
| **Results** | Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.207(b)(2). |
| **USDA Approval Date** | NA |

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>West Nile Virus (WNV)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate effectiveness and duration of immunity against WNV</td></tr>
<tr><td>Product Administration</td><td>Two doses, administered intramuscularly 3 weeks apart</td></tr>
<tr><td>Study Animals</td><td>Thirty-two, 9-11 month (at vaccination) old mixed breed horses that were WNV sero-negative: 19 vaccinates, 11 controls (3 added at challenge)</td></tr>
<tr><td>Challenge Description</td><td>Challenged 12 months after vaccination with WNV</td></tr>
<tr><td>Interval observed after challenge</td><td>After challenge, animals were monitored twice daily for 14 days, and then once daily for an additional week</td></tr>
<tr><td>Results</td><td>The primary outcome was prevention of WNV viremia. Serum samples were collected from each animal twice daily from challenge for 2 weeks, and once thereafter.<br><br>Table 1. Virernia detected in vaccinated and control horses after experimental challenge with West Nile Virus<br><br>
<table>
<tr><th>Treatment group</th><th>Number of viremic horses/horses challenged horses</th></tr>
<tr><td>Vaccinates</td><td>1/19</td></tr>
<tr><td>Controls</td><td>9/11</td></tr>
</table>
<br>The raw data is shown on the attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>August 13, 2002</td></tr>
</table>

**Table 2: Number of Viremia incidences detected in vaccinated and control horses after experimental challenge with West Nile virus (WNV)**

| ID number | Group | Days Post Challenge | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 | 4.5 |
| 4271041A29 | Controls | - | - | - | - | - | + | - | + | - | - |
| 4273363D4C | | - | - | + | + | - | + | + | + | + | + |
| 422C651E1C | | - | - | - | - | - | - | - | - | - | + |
| 524A3B6477/5317501016 | | - | - | - | - | - | - | - | - | - | + |
| 421B355400/53190B764A | | - | - | - | - | - | - | - | - | - | + |
| 42735D5E73 | | - | - | - | - | - | - | - | - | - | - |
| 421A056A0A | | - | - | - | - | - | - | - | - | - | - |
| 421E51781D | | - | - | - | - | + | - | + | + | + | - |
| 421E4F723F | | - | - | - | - | - | + | - | + | + | + |
| 421B2C3C13 | | - | - | + | - | - | + | + | + | + | - |
| 421E565A55 | | - | - | - | - | + | - | + | + | - | - |
| 421A002D66 | Vaccinates | - | - | - | - | - | - | - | - | - | - |
| 5308581947 | | - | - | - | - | - | - | - | - | - | - |
| 422C63576B | | - | - | - | - | - | - | - | - | - | - |
| 417B242E4D | | - | - | - | - | - | - | - | - | - | - |
| 422C301B30 | | - | - | - | - | - | - | - | - | - | - |
| 422C643F28 | | - | - | - | - | - | + | - | - | - | - |
| 421E77405A | | - | - | - | - | - | - | - | - | - | - |
| 421E712746 | | - | - | - | - | - | - | - | - | - | - |
| 421E78465C | | - | - | - | - | - | - | - | - | - | - |
| 421E5C0856 | | - | - | - | - | - | - | - | - | - | - |
| 421E6C706F | | - | - | - | - | - | - | - | - | - | - |
| 422C74131B | | - | - | - | - | - | - | - | - | - | - |
| 52491F2C40 | | - | - | - | - | - | - | - | - | - | - |
| 422C63330B | | - | - | - | - | - | - | - | - | - | - |
| 421945065E | | - | - | - | - | - | - | - | - | - | - |
| 422C5A5E36 | | - | - | - | - | - | - | - | - | - | - |
| 421E606E22 | | - | - | - | - | - | - | - | - | - | - |
| 421E5B025B | | - | - | - | - | - | - | - | - | - | - |
| 421E6A2314 | | - | - | - | - | - | - | - | - | - | - |

+ Positive for WNV
- Negative for WNV

**Table 2 (continued)**

| ID number | Group | Days Post Challenge | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 5.0 | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.5 |
| 4271041A29 | Controls | - | - | - | - | - | - | - | - | - | - |
| 4273363D4C | | - | - | - | - | - | - | - | - | - | - |
| 422C651E1C | | - | - | - | - | - | - | - | - | - | - |
| 524A3B6477/5317501016 | | | + | - | - | - | - | - | - | - | - |
| 421B355400/53190B764A | | + | + | - | - | - | - | - | - | - | - |
| 42735D5E73 | | - | - | - | - | - | - | - | - | - | - |
| 421A056A0A | | - | - | - | - | - | - | - | - | - | - |
| 421E51781D | | - | - | - | - | - | - | - | - | - | - |
| 421E4F723F | | - | + | - | - | - | - | - | - | - | - |
| 421B2C3C13 | | - | - | - | - | - | - | - | - | - | - |
| 421E565A55 | | - | - | - | - | - | - | - | - | - | - |
| 421A002D66 | Vaccinates | - | - | - | - | - | - | - | - | - | - |
| 5308581947 | | - | - | - | - | - | - | - | - | - | - |
| 422C63576B | | - | - | - | - | - | - | - | - | - | - |
| 417B242E4D | | - | - | - | - | - | - | - | - | - | - |
| 422C301B30 | | - | - | - | - | - | - | - | - | - | - |
| 422C643F28 | | - | - | - | - | - | - | - | - | - | - |
| 421E77405A | | - | - | - | - | - | - | - | - | - | - |
| 421E712746 | | - | - | - | - | - | - | - | - | - | - |
| 421E78465C | | - | - | - | - | - | - | - | - | - | - |
| 421E5C0856 | | - | - | - | - | - | - | - | - | - | - |
| 421E6C706F | | - | - | - | - | - | - | - | - | - | - |
| 422C74131B | | - | - | - | - | - | - | - | - | - | - |
| 52491F2C40 | | - | - | - | - | - | - | - | - | - | - |
| 422C63330B | | - | - | - | - | - | - | - | - | - | - |
| 421945065E | | - | - | - | - | - | - | - | - | - | - |
| 422C5A5E36 | | - | - | - | - | - | - | - | - | - | - |
| 421E606E22 | | - | - | - | - | - | - | - | - | - | - |
| 421E5B025B | | - | - | - | - | - | - | - | - | - | - |
| 421E6A2314 | | - | - | - | - | - | - | - | - | - | - |

+ Positive for WNV
- Negative for WNV

**Table 2 (continued)**

| ID number | Group | Days Post Challenge | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 10.0 | 10.5 | 11.0 | 11.5 | 12.0 | 12.5 | 13.0 | 13.5 | 14.0 | 14.5 | 21.0 |
| 4271041A29 | Controls | - | - | - | - | - | - | - | - | - | - | - |
| 4273363D4C | | - | - | - | - | - | - | - | - | - | - | - |
| 422C651E1C | | - | - | - | - | - | - | - | - | - | - | - |
| 524A3B6477/5317501016 | | - | - | - | - | - | - | - | - | - | - | - |
| 421B355400/53190B764A | | - | - | - | - | - | - | - | - | - | - | - |
| 42735D5E73 | | - | - | - | - | - | - | - | - | - | - | - |
| 421A056A0A | | - | - | - | - | - | - | - | - | - | - | - |
| 421E51781D | | - | - | - | - | - | - | - | - | - | - | - |
| 421E4F723F | | - | - | - | - | - | - | - | - | - | - | - |
| 421B2C3C13 | | - | - | - | - | - | - | - | - | - | - | - |
| 421E565A55 | | - | - | - | - | - | - | - | - | - | - | - |
| 421A002D66 | Vaccinates | - | - | - | - | - | - | - | - | - | - | - |
| 5308581947 | | - | - | - | - | - | - | - | - | - | - | - |
| 422C63576B | | - | - | - | - | - | - | - | - | - | - | - |
| 417B242E4D | | - | - | - | - | - | - | - | - | - | - | - |
| 422C301B30 | | - | - | - | - | - | - | - | - | - | - | - |
| 422C643F28 | | - | - | - | - | - | - | - | - | - | - | - |
| 421E77405A | | - | - | - | - | - | - | - | - | - | - | - |
| 421E712746 | | - | - | - | - | - | - | - | - | - | - | - |
| 421E78465C | | - | - | - | - | - | - | - | - | - | - | - |
| 421E5C0856 | | - | - | - | - | - | - | - | - | - | - | - |
| 421E6C706F | | - | - | - | - | - | - | - | - | - | - | - |
| 422C74131B | | - | - | - | - | - | - | - | - | - | - | - |
| 52491F2C40 | | - | - | - | - | - | - | - | - | - | - | - |
| 422C63330B | | - | - | - | - | - | - | - | - | - | - | - |
| 421945065E | | - | - | - | - | - | - | - | - | - | - | - |
| 422C5A5E36 | | - | - | - | - | - | - | - | - | - | - | - |
| 421E606E22 | | - | - | - | - | - | - | - | - | - | - | - |
| 421E5B025B | | - | - | - | - | - | - | - | - | - | - | - |
| 421E6A2314 | | - | - | - | - | - | - | - | - | - | - | - |

+ Positive for WNV
- Negative for WNV

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | West Nile Virus (WNV) |
| **Study Purpose** | Demonstrate efficacy against West Nile Virus (WNV) |
| **Product Administration** | 2 doses, administered intramuscularly, 3 weeks apart |
| **Study Animals** | 30 horses, mixed breeds, male/female, 17-20 months of age. 20 horses in the vaccinated group and 10 horses in the control group. |
| **Challenge Description** | |
| **Interval observed after challenge** | |
| **Results** | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| **USDA Approval Date** | May 13, 2002 |

| | |
|---|---|
| **Study Type** | Safety |
| **Pertaining to** | All fractions |
| **Study Purpose** | Demonstrate safety under typical field conditions |
| **Product Administration** | 2 doses, 3 to 4 weeks apart |
| **Study Animals** | 654 Male/female horses |
| **Challenge Description** | |
| **Interval observed after challenge** | |
| **Results** | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| **USDA Approval Date** | October 2, 2003 |

<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>Determine safety of product in typical field conditions</td></tr>
<tr><td>Product Administration</td><td>2 doses administered intramuscularly 3 to 4 weeks apart</td></tr>
<tr><td>Study Animals</td><td>214 foals approximately 3 months of age were enrolled at 3 different geographical sites</td></tr>
<tr><td>Challenge Description</td><td>N/A</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for immediate post-vaccination reactions 30 minutes after vaccination, and observed daily for 21 days post-second vaccination</td></tr>
<tr><td>Results</td><td>Two hundred and eleven horses (98.6%) completed the study. Three (3) horses did not complete the study for reasons unrelated to the vaccine. There were no immediate systemic or local reactions using 427 doses of product.<br><br><u>Table 1: Frequency Distribution of Abnormal Health Events in Vaccinates:</u><br><br>
<table>
<tr><th>Number of Vaccinations</th><th>Abnormal Health Event</th><th>Number (Percent of Vaccinations)</th></tr>
<tr><td rowspan="11">427 Vaccinations</td><td>Abnormal Breathing</td><td>1 (0.23%)</td></tr>
<tr><td>Death</td><td>3 (0.70%)</td></tr>
<tr><td>Depression</td><td>1 (0.23%)</td></tr>
<tr><td>Diarrhea</td><td>1 (0.23%)</td></tr>
<tr><td>Dyspnea</td><td>1 (0.23%)</td></tr>
<tr><td>Injection Site Swelling (1.5-5.0 cm)</td><td>1 (0.23%)</td></tr>
<tr><td>Lameness</td><td>1 (0.23%)</td></tr>
<tr><td>Loss of Condition</td><td>1 (0.23%)</td></tr>
<tr><td>Joint Pain</td><td>1 (0.23%)</td></tr>
<tr><td>Skin Lesion NOS*</td><td>1 (0.23%)</td></tr>
<tr><td>Weakness</td><td>1 (0.23%)</td></tr>
</table>
*Not otherwise specified<br><br>Additional data is provided on the next page.</td></tr>
<tr><td>USDA Approval Date</td><td>July 13, 2015</td></tr>
</table>

**Table 2: Abnormal Health Events and Relation to Investigational Veterinary Product (IVP) for Individual Animals**

| Animal # | Start Day | End Day | Abnormal Health Event | Outcome | Related to IVP[a] |
|---|---|---|---|---|---|
| W602 | 21 | 21 | Skin Lesion NOS | Resolved | No |
| B061 | 22 | 22 | Weakness | Removed from Study | No |
| B061 | 22 | 22 | Loss of Condition | Removed from Study | No |
| B061 | 22 | 22 | Death | Removed from Study | No |
| B061 | 13 | 16 | Lameness | Resolved | No |
| B061 | 13 | 18 | Abnormal Breathing | Resolved | No |
| B061 | 13 | 18 | Dyspnea | Resolved | No |
| B061 | 22 | 22 | Depression | Removed from Study | No |
| B118 | 31 | 31 | Death | Removed from Study | No |
| B007 | 15 | 17 | Joint Pain | Resolved | No |
| R598 | 2 | 3 | Injection Site Swelling (1.5 – 5.0 cm) | Resolved | Yes |
| R599 | 3 | 8 | Diarrhea | Removed from Study | No |
| R599 | 8 | 8 | Death | Removed from Study | No |

[a] Investigational Veterinary Product

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety in pregnant mares in the third trimester under field conditions.</td></tr>
<tr><td>Product Administration</td><td>Single dose administered intramuscularly during the third trimester of pregnancy.</td></tr>
<tr><td>Study Animals</td><td>A total of 282 healthy pregnant mares in their third trimester were enrolled in one of two treatment groups in two distinct geographical locations. The animals were distributed as follows: Controls, n = 57, Vaccinated, n = 225.</td></tr>
<tr><td>Challenge Description</td><td>N/A</td></tr>
<tr><td>Interval observed after last treatment</td><td>Clinical observations were performed on all mares for at least 30 minutes following vaccination. Pregnant mares were also observed at least once daily for general health for 21 days following vaccination and at least once weekly until foaling.<br><br>Mares were observed during foaling and foals were observed at least once weekly for general health until they were at least 21 days of age.</td></tr>
<tr><td>Results</td><td>
Mare Abnormal Health Events
<table>
<tr><th colspan="2">Number of Mares</th><th rowspan="2">Mares with no AE* (%)</th><th rowspan="2">Mares with AE* (%)</th></tr>
<tr><th>Total Enrolled</th><td>282</td></tr>
<tr><td>Controls</td><td>57</td><td>54 (94.7%)</td><td>3 (5.3%)</td></tr>
<tr><td>Vaccinated</td><td>225</td><td>214 (95.1%)</td><td>11 (4.9%)</td></tr>
</table>
*AE= Adverse Events
<table>
<tr><th>Treatment / Number of Vaccinations</th><th>Mare Abnormal Health Events</th><th>Number of Mares / Percent of Vaccinations</th></tr>
<tr><td rowspan="4">Controls (57 animals)</td><td>Agalactia</td><td>1 / 1.75%</td></tr>
<tr><td>Death[1]</td><td>1 / 1.75%</td></tr>
<tr><td>Dystocia</td><td>1 / 1.75%</td></tr>
<tr><td>Fracture</td><td>1 / 1.75%</td></tr>
<tr><td rowspan="10">Vaccinated (Product Code 48R5.20; 225 animals)</td><td>Abdominal Pain</td><td>1 / 0.44%</td></tr>
<tr><td>Decreased Appetite</td><td>1 / 0.44%</td></tr>
<tr><td>Dystocia</td><td>3 / 1.33%</td></tr>
<tr><td>Fracture</td><td>1 / 0.44%</td></tr>
<tr><td>Injection Site Swelling</td><td>1 / 0.44%</td></tr>
<tr><td>Laceration</td><td>1 / 0.44%</td></tr>
<tr><td>Lameness</td><td>2 / 0.89%</td></tr>
<tr><td>Nasal Discharge</td><td>1 / 0.44%</td></tr>
<tr><td>Placental Abnormality</td><td>1 / 0.44%</td></tr>
<tr><td>Retained Placenta</td><td>1 / 0.44%</td></tr>
</table>
[1] Mare died due to septic shock as a result of a difficult foaling.
</td></tr>
</table>

<table>
<tr><td></td><td>There was only one adverse event that was attributable to IVP which was an injection site reaction in a vaccinate that was observed the day after vaccination and resolved the following day.<br><br>Birth Outcome Summary from Vaccinated Mares
<table>
<tr><th colspan="2">Number of Foals</th><th>Live Foals</th><th>Foal died during or immediately post-parturition</th></tr>
<tr><td>Total Foals</td><td>280[1]</td><td>273 (97.50%)</td><td>7 (2.50%)</td></tr>
<tr><td>Controls</td><td>56</td><td>53 (94.64%)</td><td>3 (5.36%)</td></tr>
<tr><td>Vaccinated</td><td>224</td><td>220 (98.21%)</td><td>4 (1.79%)</td></tr>
</table>
[1] Two mares (one vaccinate and one control) were removed prior to foaling due to fractured legs.</td></tr>
<tr><td>USDA Approval Date</td><td>March 02, 2022</td></tr>
</table>