



Clinical trial results:

A Phase III, Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Immunogenicity of Three Consistency Lots and a High Dose Lot of rVSV-ZEBOV-GP (V920 Ebola Vaccine) in Healthy Adults

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2015-001658-14 |
| Trial protocol | ES |
| Global end of trial date | 29 September 2017 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 |
| This version publication date | 26 September 2018 |
| First version publication date | 26 September 2018 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | V920-012 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02503202 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|----------------------------------------------------------------------------------------------|
| Sponsor organisation name | Merck Sharp & Dohme Corp. |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033 |
| Public contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |
| Scientific contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |

Notes:

Paediatric regulatory details

| | |
|----------------------------------------------------------------------|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|------------------------------------------------------|-------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 29 September 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 29 September 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The study evaluated the safety and immunogenicity of 3 consistency lots and a high-dose lot of rVSV-ZEBOV-GP (V920 Ebola Vaccine) in healthy adults. The primary purpose of this study was to demonstrate consistency in the immune responses of participants receiving 3 separate lots of V920 through 28 days postvaccination. In addition to the 3 lot groups, a high-dose group and a placebo group were studied. A subset of participants representative of all treatment groups continued through 24 months postvaccination in the extension study for the evaluation of long-term safety. The primary hypothesis states that the geometric mean titer of anti-Zaire ebolavirus envelope (ZEBOV) glycoprotein antibody at 28 days postvaccination is equivalent across the three consistency lots.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

| | |
|-----------------------------------------------------------|----------------|
| Actual start date of recruitment | 17 August 2015 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|---------------------|
| Country: Number of subjects enrolled | Canada: 24 |
| Country: Number of subjects enrolled | Spain: 40 |
| Country: Number of subjects enrolled | United States: 1133 |
| Worldwide total number of subjects | 1197 |
| EEA total number of subjects | 40 |

Notes:

Subjects enrolled per age group

| | |
|-------------------------------------------|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |

| | |
|---------------------------|------|
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 1186 |
| From 65 to 84 years | 11 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study enrolled healthy male and female adults.

Pre-assignment

Screening details:

A total of 1261 participants were screened and 1197 were randomized.

Period 1

| | |
|------------------------------|---------------------------------|
| Period 1 title | Base Study: Up to Month 6 |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Subject, Assessor |

Arms

| | |
|------------------------------|------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | V920 Consistency Lot A |

Arm description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot A on Day 1

| | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | V920 Consistency Lot A |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency Lot A, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Nominal $\geq 2 \times 10^7$ plaque-forming units in 1 mL for intramuscular injection

| | |
|------------------|------------------------|
| Arm title | V920 Consistency Lot B |
|------------------|------------------------|

Arm description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot B on Day 1

| | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | V920 Consistency Lot B |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency Lot B, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Nominal $\geq 2 \times 10^7$ plaque-forming units in 1 mL for intramuscular injection

| | |
|------------------|------------------------|
| Arm title | V920 Consistency Lot C |
|------------------|------------------------|

Arm description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot C on Day 1

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Investigational medicinal product name | V920 Consistency Lot C |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency Lot C, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Nominal $\geq 2 \times 10^7$ plaque-forming units in 1 mL for intramuscular injection | |
| Arm title | V920 High-dose Lot |
| Arm description: | |
| Participants received a 1.0-mL intramuscular injection of V920 high-dose lot on Day 1 | |
| Arm type | Experimental |
| Investigational medicinal product name | V920 High-dose Lot |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency high-dose lot, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Nominal $\geq 1 \times 10^8$ plaque-forming units in 1 mL for intramuscular injection | |
| Arm title | Placebo |
| Arm description: | |
| Participants received a 1.0-mL intramuscular injection of placebo on Day 1 | |
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | Normal saline (0.9%) |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| 1 mL for intramuscular injection | |

| Number of subjects in period 1 | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C |
|--------------------------------|------------------------|------------------------|------------------------|
| Started | 266 | 265 | 267 |
| Vaccinated | 266 | 265 | 266 |
| Completed | 248 | 253 | 252 |
| Not completed | 18 | 12 | 15 |
| Adverse event, serious fatal | 1 | 1 | - |
| Consent withdrawn by subject | 6 | 3 | 4 |
| Physician decision | - | - | - |
| Randomized not vaccinated | - | - | 1 |
| Lost to follow-up | 11 | 8 | 10 |

| Number of subjects in period 1 | V920 High-dose Lot | Placebo |
|--------------------------------|--------------------|---------|
| Started | 266 | 133 |

| | | |
|------------------------------|-----|-----|
| Vaccinated | 264 | 133 |
| Completed | 255 | 130 |
| Not completed | 11 | 3 |
| Adverse event, serious fatal | - | - |
| Consent withdrawn by subject | 4 | 1 |
| Physician decision | - | 1 |
| Randomized not vaccinated | 2 | - |
| Lost to follow-up | 5 | 1 |

Period 2

| | |
|------------------------------|---------------------------------|
| Period 2 title | Extension: Month 6 to 24 |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Assessor |

Arms

| | |
|------------------------------|------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | V920 Consistency Lot A |

Arm description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot A on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension.

| | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | V920 Consistency Lot A |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency Lot A, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Nominal $\geq 2 \times 10^7$ plaque-forming units in 1 mL for intramuscular injection on Day 1 in the Base Study. No vaccine was administered in the study extension.

| | |
|------------------|------------------------|
| Arm title | V920 Consistency Lot B |
|------------------|------------------------|

Arm description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot B on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension.

| | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | V920 Consistency Lot B |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency Lot B, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Nominal $\geq 2 \times 10^7$ plaque-forming units in 1 mL for intramuscular injection on Day 1 in the Base Study. No vaccine was administered in the study extension.

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Arm title | V920 Consistency Lot C |
| Arm description: Participants received a 1.0-mL intramuscular injection of V920 consistency Lot C on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |
| Arm type | Experimental |
| Investigational medicinal product name | V920 Consistency Lot C |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency Lot C, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: Nominal $\geq 2 \times 10^7$ plaque-forming units in 1 mL for intramuscular injection on Day 1 in the Base Study. No vaccine was administered in the study extension. | |
| Arm title | V920 High-dose Lot |
| Arm description: Participants received a 1.0-mL intramuscular injection of V920 high-dose lot on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |
| Arm type | Experimental |
| Investigational medicinal product name | V920 High-dose Lot |
| Investigational medicinal product code | |
| Other name | V920 (rVSVZEBOV-GP) Ebola Zaire vaccine consistency high-dose lot, live, attenuated, sterile solution for intramuscular injection |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: Nominal $\geq 1 \times 10^8$ plaque-forming units in 1 mL for intramuscular injection on Day 1 in the Base Study. No vaccine was administered in the study extension. | |
| Arm title | Placebo |
| Arm description: Participants received a 1.0-mL intramuscular injection of placebo on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | Normal saline (0.9%) |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: 1 mL for intramuscular injection on Day 1 in the Base Study. No placebo was administered in the study extension. | |

| Number of subjects in period 2^[1] | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C |
|-----------------------------------------------------|------------------------|------------------------|------------------------|
| Started | 119 | 130 | 112 |
| Completed | 108 | 114 | 103 |
| Not completed | 11 | 16 | 9 |
| Adverse event, serious fatal | 1 | - | - |
| Physician decision | 1 | - | 1 |
| Consent withdrawn by subject | 5 | 8 | 2 |
| Lost to follow-up | 4 | 8 | 6 |
| Protocol deviation | - | - | - |

| Number of subjects in period 2^[1] | V920 High-dose Lot | Placebo |
|-----------------------------------------------------|--------------------|---------|
| Started | 137 | 68 |
| Completed | 119 | 67 |
| Not completed | 18 | 1 |
| Adverse event, serious fatal | - | - |
| Physician decision | 3 | - |
| Consent withdrawn by subject | 4 | - |
| Lost to follow-up | 10 | 1 |
| Protocol deviation | 1 | - |

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants from selected US sites were invited to enroll in the study extension. Participation in the study extension was voluntary.

Baseline characteristics

Reporting groups

| | |
|-------------------------------------------------------------------------------------------|------------------------|
| Reporting group title | V920 Consistency Lot A |
| Reporting group description: | |
| Participants received a 1.0-mL intramuscular injection of V920 consistency Lot A on Day 1 | |
| Reporting group title | V920 Consistency Lot B |
| Reporting group description: | |
| Participants received a 1.0-mL intramuscular injection of V920 consistency Lot B on Day 1 | |
| Reporting group title | V920 Consistency Lot C |
| Reporting group description: | |
| Participants received a 1.0-mL intramuscular injection of V920 consistency Lot C on Day 1 | |
| Reporting group title | V920 High-dose Lot |
| Reporting group description: | |
| Participants received a 1.0-mL intramuscular injection of V920 high-dose lot on Day 1 | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Participants received a 1.0-mL intramuscular injection of placebo on Day 1 | |

| Reporting group values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C |
|------------------------|------------------------|------------------------|------------------------|
| Number of subjects | 266 | 265 | 267 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 263 | 263 | 263 |
| From 65-84 years | 3 | 2 | 4 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 41.3 | 41.5 | 40.9 |
| standard deviation | ± 13.4 | ± 12.4 | ± 13.1 |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 143 | 135 | 138 |
| Male | 123 | 130 | 129 |

| Reporting group values | V920 High-dose Lot | Placebo | Total |
|------------------------|--------------------|---------|-------|
| Number of subjects | 266 | 133 | 1197 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 265 | 132 | 1186 |
| From 65-84 years | 1 | 1 | 11 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 41.7 | 41.1 | - |
| standard deviation | ± 13.4 | ± 13.7 | - |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 149 | 72 | 637 |
| Male | 117 | 61 | 560 |

End points

End points reporting groups

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Reporting group title | V920 Consistency Lot A |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 consistency Lot A on Day 1 | |
| Reporting group title | V920 Consistency Lot B |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 consistency Lot B on Day 1 | |
| Reporting group title | V920 Consistency Lot C |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 consistency Lot C on Day 1 | |
| Reporting group title | V920 High-dose Lot |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 high-dose lot on Day 1 | |
| Reporting group title | Placebo |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of placebo on Day 1 | |
| Reporting group title | V920 Consistency Lot A |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 consistency Lot A on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |
| Reporting group title | V920 Consistency Lot B |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 consistency Lot B on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |
| Reporting group title | V920 Consistency Lot C |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 consistency Lot C on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |
| Reporting group title | V920 High-dose Lot |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of V920 high-dose lot on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |
| Reporting group title | Placebo |
| Reporting group description: Participants received a 1.0-mL intramuscular injection of placebo on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension. | |

Primary: Geometric Mean Titer of Anti-ZEBOV Glycoprotein Antibody

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| End point title | Geometric Mean Titer of Anti-ZEBOV Glycoprotein Antibody |
| End point description: Serum was collected for determination of geometric mean titer (GMT) of anti-Zaire ebolavirus envelope (ZEBOV) glycoprotein antibodies using an enzyme-linked immunosorbent assay (GP-ELISA). The unit of measure is ELISA units/mL (EU/mL). The lower limit of quantification for the assay was 36.11 EU/mL. A value of 36.11 in the table means that the geometric mean and CIs were <36.11 EU/mL. The population analyzed was participants who were compliant with the protocol, received vaccination, were seronegative at Day 1, and had a serum sample collected within the acceptable day range. | |

| | |
|------------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Day 28 postvaccination | |

| End point values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C | V920 High-dose Lot |
|------------------------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 239 | 231 | 226 | 219 |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | 1183.9 (1038.7 to 1349.4) | 1266.0 (1108.2 to 1446.2) | 1346.0 (1176.6 to 1539.9) | 1291.9 (1126.9 to 1481.2) |

| End point values | Placebo | | | |
|------------------------------------------|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124 | | | |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | 36.11 (36.11 to 36.11) | | | |

Statistical analyses

| Statistical analysis title | Equivalence |
|-----------------------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 470 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 ^[1] |
| Method | ANOVA |
| Parameter estimate | GMT ratio (Lot A / Lot B) |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.77 |
| upper limit | 1.14 |

Notes:

[1] - Primary analysis: a p-value <0.025 supported the conclusion of equivalence. As equivalence was established for the 3 pairwise comparisons, the lots were considered to be consistent.

| Statistical analysis title | Equivalence |
|----------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |

| | |
|-----------------------------------------|---------------------------|
| Number of subjects included in analysis | 465 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 ^[2] |
| Method | ANOVA |
| Parameter estimate | GMT ratio (Lot A / Lot C) |
| Point estimate | 0.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.71 |
| upper limit | 1.09 |

Notes:

[2] - Primary analysis: a p-value <0.025 supported the conclusion of equivalence. As equivalence was established for the 3 pairwise comparisons, the lots were considered to be consistent.

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Equivalence |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 457 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 ^[3] |
| Method | ANOVA |
| Parameter estimate | GMT ratio (Lot B / Lot C) |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.77 |
| upper limit | 1.15 |

Notes:

[3] - Primary analysis: a p-value <0.025 supported the conclusion of equivalence. As equivalence was established for the 3 pairwise comparisons, the lots were considered to be consistent.

Primary: Percentage of Participants Reporting Serious Adverse Events

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|
| End point title | Percentage of Participants Reporting Serious Adverse Events |
| End point description: | |
| An adverse event (AE) is defined as any untoward medical occurrence in a participant which does not necessarily have to have a causal relationship with this treatment. A serious AE (SAE) is an AE that results in death, is life threatening, results in persistent or significant disability or incapacity, results in or prolongs a hospitalization, is a congenital anomaly or birth defect, is any other important medical event, is a cancer, or is associated with an overdose. The population analyzed was randomized participants who received vaccination and had follow-up data for the outcome measure. | |
| End point type | Primary |
| End point timeframe: | |
| Up to Month 6 postvaccination | |

| End point values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C | V920 High-dose Lot |
|-----------------------------------|------------------------|------------------------|------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 265 | 263 | 263 | 260 |
| Units: Percentage of participants | | | | |
| number (not applicable) | 2.6 | 1.5 | 2.7 | 1.2 |

| End point values | Placebo | | | |
|-----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 133 | | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 0.0 | | | |

Statistical analyses

| Statistical analysis title | Risk Difference |
|-----------------------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.368 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.5 |
| upper limit | 4 |

| Statistical analysis title | Risk Difference |
|-----------------------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.989 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.1 |
| upper limit | 3 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.361 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.1 |
| upper limit | 1.5 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.214 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.7 |
| upper limit | 3.3 |

Primary: Percentage of Participants with Injection-site Adverse Events Prompted on the Vaccination Report Card

| | |
|-----------------|-------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants with Injection-site Adverse Events Prompted on the Vaccination Report Card |
|-----------------|-------------------------------------------------------------------------------------------------------|

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a participant which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or protocol-specified procedure, whether or not considered related to the study vaccine or

protocol-specified procedure. Any worsening of a preexisting condition that is temporally associated with the use of the study vaccine or protocol-specified procedure is also an adverse event. Injection-site AEs prompted on the Vaccination Report Card (VRC) were erythema, pain, and swelling. The population analyzed was randomized participants who received vaccination and had follow-up data for the outcome measure.

| | |
|-----------------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to Day 5 postvaccination | |

| End point values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C | V920 High-dose Lot |
|-----------------------------------|------------------------|------------------------|------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 265 | 263 | 263 | 260 |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Injection-site erythema | 14.7 | 10.6 | 14.8 | 7.3 |
| Injection-site pain | 66.8 | 73.0 | 70.3 | 67.7 |
| Injection-site swelling | 17.7 | 13.7 | 18.3 | 16.2 |

| End point values | Placebo | | | |
|-----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 133 | | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Injection-site erythema | 1.5 | | | |
| Injection-site pain | 12.8 | | | |
| Injection-site swelling | 3.0 | | | |

Statistical analyses

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site erythema | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.16 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 4.1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 9.9 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site erythema | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.971 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -0.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.2 |
| upper limit | 6 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site erythema | |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.151 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -4.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10 |
| upper limit | 1.5 |

| | |
|-----------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site erythema | |
| Comparison groups | V920 High-dose Lot v Placebo |

| | |
|-----------------------------------------|----------------------|
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.016 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 5.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.4 |
| upper limit | 9.9 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site pain | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.12 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -6.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -14 |
| upper limit | 1.6 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site pain | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.38 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -3.5 |
| Confidence interval | |
| level | Other: 94 % |
| sides | 2-sided |
| lower limit | -11.4 |
| upper limit | 4.4 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site pain | |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.499 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 2.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.1 |
| upper limit | 10.4 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site pain | |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 54.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 46.2 |
| upper limit | 62.3 |

| | |
|-----------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site swelling | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |

| | |
|-----------------------------------------|----------------------|
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.202 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.2 |
| upper limit | 10.3 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site swelling | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.878 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.1 |
| upper limit | 6.1 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site swelling | |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.154 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -4.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.9 |
| upper limit | 1.7 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Injection site swelling | |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 13.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.4 |
| upper limit | 18.6 |

Primary: Percentage of Participants with Elevated Maximum Temperature

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| End point title | Percentage of Participants with Elevated Maximum Temperature |
| End point description: | |
| Participants were instructed on the VRC to take and record their oral (or oral equivalent) temperature daily from the day of vaccination through Day 42. Elevated temperature was defined as $\geq 38.0^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$). The population analyzed was randomized participants who received vaccination and had follow-up data for the outcome measure. | |
| End point type | Primary |
| End point timeframe: | |
| Up to Day 42 postvaccination | |

| End point values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C | V920 High-dose Lot |
|-----------------------------------|------------------------|------------------------|------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 262 | 263 | 263 | 258 |
| Units: Percentage of participants | | | | |
| number (not applicable) | 21.4 | 16.7 | 22.4 | 32.2 |

| End point values | Placebo | | | |
|-----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 132 | | | |
| Units: Percentage of participants | | | | |

| | | | | |
|-------------------------|-----|--|--|--|
| number (not applicable) | 0.8 | | | |
|-------------------------|-----|--|--|--|

Statistical analyses

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 525 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.176 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 4.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.1 |
| upper limit | 11.4 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |
| Number of subjects included in analysis | 525 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.769 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.2 |
| upper limit | 6 |

| | |
|-----------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |

| | |
|-----------------------------------------|----------------------|
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.1 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -5.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.5 |
| upper limit | 1.1 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 390 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 31.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 25.6 |
| upper limit | 37.5 |

Primary: Percentage of Participants with Arthralgia or Arthritis Adverse Events Prompted on the Vaccination Report Card

| | |
|-----------------|----------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants with Arthralgia or Arthritis Adverse Events Prompted on the Vaccination Report Card |
|-----------------|----------------------------------------------------------------------------------------------------------------|

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a participant which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. Any worsening of a preexisting condition that is temporally associated with the use of the study vaccine or protocol-specified procedure is also an adverse event. Adverse events of arthralgia and arthritis were prompted on the VRC. The population analyzed was randomized participants who received vaccination and had follow-up data for the outcome measure.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 5 to Day 42 postvaccination

| End point values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C | V920 High-dose Lot |
|-----------------------------------|------------------------|------------------------|------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 265 | 263 | 263 | 260 |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Arthralgia AEs | 5.7 | 5.7 | 6.5 | 7.7 |
| Arthritis AEs | 4.5 | 3.8 | 2.7 | 3.1 |

| End point values | Placebo | | | |
|-----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 133 | | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Arthralgia AEs | 1.5 | | | |
| Arthritis AEs | 0.0 | | | |

Statistical analyses

| Statistical analysis title | Risk Difference |
|-------------------------------------------------|-------------------------------------------------|
| Statistical analysis description: Arthralgia | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.983 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.2 |
| upper limit | 4.1 |

| Statistical analysis title | Risk Difference |
|-------------------------------------------------|-------------------------------------------------|
| Statistical analysis description: Arthralgia | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |

| | |
|-----------------------------------------|----------------------|
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.699 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.1 |
| upper limit | 3.4 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Arthralgia | |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.716 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.1 |
| upper limit | 3.5 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Arthralgia | |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.012 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 6.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.8 |
| upper limit | 10.4 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Arthritis | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.677 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.9 |
| upper limit | 4.4 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Arthritis | |
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.25 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 1.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.4 |
| upper limit | 5.4 |

| | |
|-----------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Arthritis | |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |

| | |
|-----------------------------------------|----------------------|
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.46 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.1 |
| upper limit | 4.5 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Statistical analysis description: | |
| Arthritis | |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.041 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 3.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 6 |

Primary: Percentage of Participants with Rash Adverse Events Prompted on the Vaccination Report Card

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants with Rash Adverse Events Prompted on the Vaccination Report Card |
| End point description: | |
| <p>An adverse event (AE) is defined as any untoward medical occurrence in a participant which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. Any worsening of a preexisting condition that is temporally associated with the use of the study vaccine or protocol-specified procedure is also an adverse event. Rash AEs prompted on the VRC were petechial rash, purpuric rash, and vesicular-type rash. The analysis population was randomized participants who received vaccination and had follow-up data for the outcome measure.</p> | |
| End point type | Primary |
| End point timeframe: | |
| Up to Day 42 postvaccination | |

| End point values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C | V920 High-dose Lot |
|-----------------------------------|------------------------|------------------------|------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 265 | 263 | 263 | 260 |
| Units: Percentage of participants | | | | |
| number (not applicable) | 3.0 | 4.6 | 3.8 | 3.8 |

| End point values | Placebo | | | |
|-----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 133 | | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 1.5 | | | |

Statistical analyses

| Statistical analysis title | Risk Difference |
|-----------------------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.353 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.1 |
| upper limit | 1.9 |

| Statistical analysis title | Risk Difference |
|-----------------------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.62 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -0.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.2 |
| upper limit | 2.5 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.663 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.9 |
| upper limit | 4.5 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.202 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 2.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.8 |
| upper limit | 5.7 |

Primary: Percentage of Participants with Vesicular Lesion Adverse Events Prompted on the Vaccination Report Card

| | |
|-----------------|---------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants with Vesicular Lesion Adverse Events Prompted on the Vaccination Report Card |
|-----------------|---------------------------------------------------------------------------------------------------------|

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a participant which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or protocol-specified procedure, whether or not considered related to the study vaccine or

protocol-specified procedure. Any worsening of a preexisting condition that is temporally associated with the use of the study vaccine or protocol-specified procedure is also an adverse event. Vesicular lesion AEs prompted on the VRC included blister and rash vesicular. The population analyzed was randomized participants who received vaccination and had follow-up data for the outcome measure.

| | |
|------------------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to Day 42 postvaccination | |

| End point values | V920 Consistency Lot A | V920 Consistency Lot B | V920 Consistency Lot C | V920 High-dose Lot |
|-----------------------------------|------------------------|------------------------|------------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 265 | 263 | 263 | 260 |
| Units: Percentage of participants | | | | |
| number (not applicable) | 1.9 | 1.1 | 1.5 | 1.5 |

| End point values | Placebo | | | |
|-----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 133 | | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 0.0 | | | |

Statistical analyses

| Statistical analysis title | Risk Difference |
|-----------------------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot B |
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.483 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 3.3 |

| Statistical analysis title | Risk Difference |
|----------------------------|-------------------------------------------------|
| Comparison groups | V920 Consistency Lot A v V920 Consistency Lot C |

| | |
|-----------------------------------------|----------------------|
| Number of subjects included in analysis | 528 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.746 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.2 |
| upper limit | 3 |

| | |
|-----------------------------------------|-------------------------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 Consistency Lot B v V920 Consistency Lot C |
| Number of subjects included in analysis | 526 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.704 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -0.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.8 |
| upper limit | 2 |

| | |
|-----------------------------------------|------------------------------|
| Statistical analysis title | Risk Difference |
| Comparison groups | V920 High-dose Lot v Placebo |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.151 |
| Method | Miettinen & Nurminen |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.3 |
| upper limit | 3.9 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Month 24

Adverse event reporting additional description:

The at-risk population was randomized participants who received vaccination and had follow-up safety data available.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 20.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | V920 Lot A |
|-----------------------|------------|

Reporting group description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot A on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension.

| | |
|-----------------------|------------|
| Reporting group title | V920 Lot B |
|-----------------------|------------|

Reporting group description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot B on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension.

| | |
|-----------------------|----------------|
| Reporting group title | V920 High Dose |
|-----------------------|----------------|

Reporting group description:

Participants received a 1.0-mL intramuscular injection of V920 high-dose lot on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension.

| | |
|-----------------------|------------|
| Reporting group title | V920 Lot C |
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Reporting group description:

Participants received a 1.0-mL intramuscular injection of V920 consistency Lot C on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No vaccine was administered in the study extension.

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|-----------------------|---------|
| Reporting group title | Placebo |
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Reporting group description:

Participants received a 1.0-mL intramuscular injection of placebo A on Day 1. A subset of participants was followed beyond Month 6 through approximately Month 24 to assess long-term safety. No placebo was administered in the study extension.

| Serious adverse events | V920 Lot A | V920 Lot B | V920 High Dose |
|---------------------------------------------------------------------|------------------|------------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 12 / 265 (4.53%) | 12 / 263 (4.56%) | 8 / 260 (3.08%) |
| number of deaths (all causes) | 2 | 1 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Breast cancer | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Breast cancer stage III | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oropharyngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ruptured ectopic pregnancy | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Reproductive system and breast disorders | | | |
| Menometrorrhagia | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemothorax | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Schizophrenia | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Craniocerebral injury | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rib fracture | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Scapula fracture | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Migraine | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Radicular pain | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| Conductive deafness | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorder | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Incarcerated umbilical hernia | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic failure | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal failure | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Endocrine disorders | | | |
| Autoimmune thyroiditis | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperthyroidism | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exostosis | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foot deformity | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal column stenosis | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Appendicitis | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mastitis | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis aseptic | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 265 (0.38%) | 0 / 263 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | | |
| subjects affected / exposed | 0 / 265 (0.00%) | 1 / 263 (0.38%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | V920 Lot C | Placebo | |
|---------------------------------------------------------------------|------------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 11 / 263 (4.18%) | 4 / 133 (3.01%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer stage III | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 1 / 133 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 1 / 133 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ruptured ectopic pregnancy | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Menometrorrhagia | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 1 / 133 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Schizophrenia | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 1 / 133 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|--|
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 1 / 133 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scapula fracture | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Migraine | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radicular pain | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|--|
| Conductive deafness | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 1 / 133 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorder | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated umbilical hernia | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|--|
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Autoimmune thyroiditis | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exostosis | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot deformity | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column stenosis | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Appendicitis | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 1 / 263 (0.38%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastitis | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis aseptic | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 263 (0.00%) | 1 / 133 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | | |
| subjects affected / exposed | 0 / 263 (0.00%) | 0 / 133 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | V920 Lot A | V920 Lot B | V920 High Dose |
|-------------------------------------------------------|--------------------|--------------------|--------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 211 / 265 (79.62%) | 211 / 263 (80.23%) | 208 / 260 (80.00%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 61 / 265 (23.02%) | 51 / 263 (19.39%) | 67 / 260 (25.77%) |
| occurrences (all) | 72 | 56 | 83 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 14 / 265 (5.28%) | 16 / 263 (6.08%) | 27 / 260 (10.38%) |
| occurrences (all) | 14 | 16 | 27 |

| | | | |
|-------------------------------------------------|--------------------|--------------------|--------------------|
| Fatigue | | | |
| subjects affected / exposed | 21 / 265 (7.92%) | 15 / 263 (5.70%) | 20 / 260 (7.69%) |
| occurrences (all) | 22 | 15 | 21 |
| Influenza like illness | | | |
| subjects affected / exposed | 14 / 265 (5.28%) | 12 / 263 (4.56%) | 9 / 260 (3.46%) |
| occurrences (all) | 14 | 13 | 9 |
| Injection site erythema | | | |
| subjects affected / exposed | 39 / 265 (14.72%) | 30 / 263 (11.41%) | 19 / 260 (7.31%) |
| occurrences (all) | 43 | 30 | 23 |
| Injection site pain | | | |
| subjects affected / exposed | 179 / 265 (67.55%) | 192 / 263 (73.00%) | 176 / 260 (67.69%) |
| occurrences (all) | 198 | 215 | 192 |
| Injection site swelling | | | |
| subjects affected / exposed | 47 / 265 (17.74%) | 36 / 263 (13.69%) | 42 / 260 (16.15%) |
| occurrences (all) | 51 | 40 | 42 |
| Pain | | | |
| subjects affected / exposed | 34 / 265 (12.83%) | 23 / 263 (8.75%) | 32 / 260 (12.31%) |
| occurrences (all) | 34 | 23 | 33 |
| Pyrexia | | | |
| subjects affected / exposed | 58 / 265 (21.89%) | 47 / 263 (17.87%) | 76 / 260 (29.23%) |
| occurrences (all) | 66 | 47 | 83 |
| Gastrointestinal disorders | | | |
| Nausea | | | |
| subjects affected / exposed | 12 / 265 (4.53%) | 13 / 263 (4.94%) | 14 / 260 (5.38%) |
| occurrences (all) | 12 | 13 | 15 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 47 / 265 (17.74%) | 41 / 263 (15.59%) | 53 / 260 (20.38%) |
| occurrences (all) | 72 | 74 | 79 |
| Myalgia | | | |
| subjects affected / exposed | 17 / 265 (6.42%) | 11 / 263 (4.18%) | 23 / 260 (8.85%) |
| occurrences (all) | 19 | 13 | 23 |

| | | | |
|-------------------------------------------------------|--------------------|-------------------|--|
| Non-serious adverse events | V920 Lot C | Placebo | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 208 / 263 (79.09%) | 35 / 133 (26.32%) | |

| | | | |
|------------------------------------------------------|--------------------|-------------------|--|
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 55 / 263 (20.91%) | 15 / 133 (11.28%) | |
| occurrences (all) | 68 | 18 | |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 20 / 263 (7.60%) | 1 / 133 (0.75%) | |
| occurrences (all) | 20 | 1 | |
| Fatigue | | | |
| subjects affected / exposed | 9 / 263 (3.42%) | 3 / 133 (2.26%) | |
| occurrences (all) | 9 | 3 | |
| Influenza like illness | | | |
| subjects affected / exposed | 18 / 263 (6.84%) | 1 / 133 (0.75%) | |
| occurrences (all) | 19 | 1 | |
| Injection site erythema | | | |
| subjects affected / exposed | 39 / 263 (14.83%) | 2 / 133 (1.50%) | |
| occurrences (all) | 42 | 2 | |
| Injection site pain | | | |
| subjects affected / exposed | 185 / 263 (70.34%) | 18 / 133 (13.53%) | |
| occurrences (all) | 212 | 19 | |
| Injection site swelling | | | |
| subjects affected / exposed | 49 / 263 (18.63%) | 4 / 133 (3.01%) | |
| occurrences (all) | 52 | 4 | |
| Pain | | | |
| subjects affected / exposed | 29 / 263 (11.03%) | 2 / 133 (1.50%) | |
| occurrences (all) | 30 | 2 | |
| Pyrexia | | | |
| subjects affected / exposed | 63 / 263 (23.95%) | 1 / 133 (0.75%) | |
| occurrences (all) | 70 | 4 | |
| Gastrointestinal disorders | | | |
| Nausea | | | |
| subjects affected / exposed | 15 / 263 (5.70%) | 1 / 133 (0.75%) | |
| occurrences (all) | 16 | 1 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |

| | | | |
|-----------------------------|-------------------|-----------------|--|
| subjects affected / exposed | 50 / 263 (19.01%) | 4 / 133 (3.01%) | |
| occurrences (all) | 75 | 7 | |
| Myalgia | | | |
| subjects affected / exposed | 12 / 263 (4.56%) | 1 / 133 (0.75%) | |
| occurrences (all) | 12 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01 July 2015 | Amendment 1: Modified Inclusion Criteria to indicate that male subjects of reproductive potential must avoid impregnating a partner for 2 months following study vaccination by complying with the outlined contraception methods. |
| 28 January 2016 | Amendment 2: Modified sections to reflect a subset of approximately 600 subjects who will continue in the study through Month 24 in a study extension. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported