# Clinical trial results:
# A phase 2b, randomized, controlled, observer-blind, multi-center, non-inferiority immunogenicity and safety study of two formulations of GSK Biologicals' Meningococcal ACWY conjugate vaccine (GSK3536820A and Menveo) administered to healthy adults 18 to 40 years of age.

## Summary

| | |
|---|---|
| EudraCT number | 2017-003692-61 |
| Trial protocol | DE EE BE IT |
| Global end of trial date | 22 September 2020 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 25 February 2021 |
| First version publication date | 25 February 2021 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | 205343 |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | Rue de l'Institut 89, Rixensart, Belgium, B-1330 |
| Public contact | GSK Response Center, GlaxoSmithKline, 044 2089-904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 044 2089-904466, GSKClinicalSupportHD@gsk.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 | 27 October 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 17 January 2019 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 September 2020 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate non-inferiority of the MenACWY liquid vaccine with approximately 30% Men A Free Saccharide (FS) to that of currently licensed MenACWY vaccine, as measured by the human serum bactericidal assay (hSBA) Geometric Mean Titers (GMTs) directed against N. meningitidis serogroup A at Day 29 after a single dose vaccination. Criterion to demonstrate non-inferiority: Non-inferiority will be concluded if the lower limit of the two-sided 95% confidence interval (CI) for the ratio of hSBA GMTs against serogroup A between the liquid formulation and the licensed formulation is greater than 0.5.

Protection of trial subjects:

All subjects were observed closely for at least 30 minutes following the administration of the vaccine, with appropriate medical treatment readily available in case of anaphylaxis. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccine. Safety was monitored for 6 months after vaccination.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 07 September 2018 |
| 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 | Australia: 184 |
| Country: Number of subjects enrolled | Belgium: 175 |
| Country: Number of subjects enrolled | Canada: 285 |
| Country: Number of subjects enrolled | Germany: 200 |
| Country: Number of subjects enrolled | Italy: 152 |
| Worldwide total number of subjects | 996 |
| EEA total number of subjects | 527 |

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) | 996 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Enrolment from 8 centers in Australia,2 in Belgium,10 in Canada,6 in Germany,4 in Italy.Planned age range in this study was 18-40 years.But 1 subject aged 44 years not meeting inclusion criteria was enrolled & vaccinated in GSK3536820A ACWY_Liq Group & therefore was considered for all analyses except per protocol set for immunogenicity analyses

### Pre-assignment

Screening details:

Among 996 enrolled subjects,16 subjects did not receive any treatment and ICF documentation was not retrievable for 1 subject.

### Pre-assignment period milestones

| | |
|---|---|
| Number of subjects started | 996 |
| Number of subjects completed | 979 |

### Pre-assignment subject non-completion reasons

| | |
|---|---|
| Reason: Number of subjects | Did not receive any study treatment: 16 |
| Reason: Number of subjects | ICF documentation not retrievable: 1 |

### Period 1

| | |
|---|---|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Carer, Data analyst, Assessor |

Blinding implementation details:

This was an observer blind study

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | GSK3536820A ACWY_Liq Group |

Arm description:

Healthy adults, 18 to 44 years of age, receiving at Day 1 a single dose of investigational MenACWY liquid vaccine (GSK3536820A) formulation with approximately 30% Men A FS.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | MenACWY liquid vaccine with approximately 30% MenA FS (GSK3536820A) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single dose administered at Day 1, by intramuscular injection in the deltoid of the non-dominant arm

| | |
|---|---|
| **Arm title** | ACWY Group |

Arm description:

Healthy adults, 18 to 40 years of age, receiving at Day 1 a single dose of licensed GSK's MenACWY vaccine formulation (Menveo).

| | |
|---|---|
| Arm type | Active comparator |

| | |
|---|---|
| Investigational medicinal product name | Licensed GSK MenACWY vaccine |
| Investigational medicinal product code | |
| Other name | Menveo |
| Pharmaceutical forms | Powder and solution for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single dose administered at Day 1, by intramuscular injection in the deltoid of the non-dominant arm

| **Number of subjects in period 1[1]** | GSK3536820A ACWY_Liq Group | ACWY Group |
|---|---|---|
| Started | 490 | 489 |
| Completed | 486 | 484 |
| Not completed | 4 | 5 |
| Consent withdrawn by subject | 3 | 5 |
| Lost to follow-up | 1 | - |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The number of subjects reported in the baseline period are the number vaccinated and therefore differ from the worldwide enrolled number.

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | GSK3536820A ACWY_Liq Group |
| Reporting group description: | |
| Healthy adults, 18 to 44 years of age, receiving at Day 1 a single dose of investigational MenACWY liquid vaccine (GSK3536820A) formulation with approximately 30% Men A FS. | |
| Reporting group title | ACWY Group |
| Reporting group description: | |
| Healthy adults, 18 to 40 years of age, receiving at Day 1 a single dose of licensed GSK's MenACWY vaccine formulation (Menveo). | |

| Reporting group values | GSK3536820A ACWY_Liq Group | ACWY Group | Total |
|---|---|---|---|
| Number of subjects | 490 | 489 | 979 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 490 | 489 | 979 |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 31.7 | 31.9 | |
| standard deviation | ± 5.8 | ± 5.8 | - |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 309 | 305 | 614 |
| Male | 181 | 184 | 365 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| American Indian Or Alaska Native | 4 | 0 | 4 |
| Asian | 40 | 27 | 67 |
| Black Or African American | 4 | 8 | 12 |
| Native Hawaiian Or Other Pacific Islander | 2 | 2 | 4 |
| Other | 13 | 13 | 26 |
| White | 427 | 439 | 866 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | GSK3536820A ACWY_Liq Group |
| Reporting group description: | |
| Healthy adults, 18 to 44 years of age, receiving at Day 1 a single dose of investigational MenACWY liquid vaccine (GSK3536820A) formulation with approximately 30% Men A FS. | |
| Reporting group title | ACWY Group |
| Reporting group description: | |
| Healthy adults, 18 to 40 years of age, receiving at Day 1 a single dose of licensed GSK's MenACWY vaccine formulation (Menveo). | |

### Primary: Adjusted Human Serum Bactericidal Activity (hSBA) Geometric Mean Titers (GMTs) against N. meningitidis serogroup A for each vaccine group, and between-group ratios

| | |
|---|---|
| End point title | Adjusted Human Serum Bactericidal Activity (hSBA) Geometric Mean Titers (GMTs) against N. meningitidis serogroup A for each vaccine group, and between-group ratios |
| End point description: | |
| hSBA titers against N.meningitidis serogroup A were calculated in terms of GMTs adjusted for pre-vaccination titer. Analysis was performed on the per protocol set for immunogenicity that includes subjects who received the vaccine, did not have any protocol deviation leading to exclusion, who were not excluded due to other reasons defined prior to unblinding or analysis and had available immuno data for any serogroup and time point considered. | |
| End point type | Primary |
| End point timeframe: | |
| At Day 29 | |

| End point values | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 386 | 404 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 185.16 (147.90 to 231.81) | 211.33 (169.61 to 263.32) | | |

### Statistical analyses

| Statistical analysis title | hSBA GMT ratio for serogroup A at day 29 |
|---|---|
| Statistical analysis description: | |
| To demonstrate non-inferiority of the investigational MenACWY liquid vaccine with approximately 30% Men A FS (GSK3536820A ACWY_Liq Group) to that of currently licensed MenACWY vaccine (ACWY Group), as measured by the adjusted human serum bactericidal assay (hSBA) Geometric Mean Titers (GMTs) directed against N. meningitidis serogroup A at Day 29 after a single dose vaccination | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |

| | |
|---|---|
| Number of subjects included in analysis | 790 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | ANCOVA |
| Parameter estimate | GMT ratio |
| Point estimate | 0.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.64 |
| upper limit | 1.2 |

## Secondary: hSBA GMTs against each of the N.meningitidis serogroups A, C, W and Y for each vaccine group, and between-group ratios

| | |
|---|---|
| End point title | hSBA GMTs against each of the N.meningitidis serogroups A, C, W and Y for each vaccine group, and between-group ratios |

End point description:

hSBA titers were calculated in terms of GMTs, at Day 1 and Day 29, against each of the N. meningitidis serogroups A, C, W and Y. Analysis was performed on the per protocol set for immunogenicity that includes subjects who received the vaccine, did not have any protocol deviation leading to exclusion, who were not excluded due to other reasons defined prior to unblinding or analysis and had available immuno data for any serogroup and time point considered.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

At Day 1 and Day 29

| **End point values** | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 459 | 467 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Meningitis A, Day 1(N=446,446) | 2.79 (2.52 to 3.10) | 2.97 (2.68 to 3.29) | | |
| Meningitis A, Day 29(N=386,404) | 182.96 (145.11 to 230.68) | 213.42 (170.11 to 267.77) | | |
| Meningitis C, Day 1(N=459,467) | 11.41 (9.81 to 13.27) | 12.05 (10.38 to 14.00) | | |
| Meningitis C, Day 29(N=437,441) | 153.95 (115.03 to 206.04) | 139.63 (104.56 to 186.47) | | |
| Meningitis W, Day 1(N=455,457) | 9.6 (8.05 to 11.45) | 10.92 (9.16 to 13.02) | | |
| Meningitis W, Day 29(N=445,443) | 59.74 (47.67 to 74.86) | 54.12 (43.17 to 67.86) | | |
| Meningitis Y, Day 1(N=458,463) | 4.14 (3.63 to 4.71) | 4.75 (4.17 to 5.40) | | |
| Meningitis Y, Day 29(N=452,455) | 60.29 (48.67 to 74.68) | 54.99 (44.44 to 68.06) | | |

## Statistical analyses

| **Statistical analysis title** | hSBA GMT ratio for serogroup C |
|---|---|

Statistical analysis description:

To compare the immunogenicity of the investigational MenACWY liquid vaccine with approximately 30% Men A FS (GSK3536820A ACWY_Liq Group) and the currently licensed MenACWY vaccine (ACWY Group), as measured by the adjusted hSBA GMTs directed against N. meningitidis serogroup C at Day 29

| | |
|---|---|
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 926 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | ANCOVA |
| Parameter estimate | GMT ratio |
| Point estimate | 1.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.68 |

| **Statistical analysis title** | hSBA GMT ratio for serogroup W |
|---|---|

Statistical analysis description:

To compare the immunogenicity of the investigational MenACWY liquid vaccine with approximately 30% Men A FS (GSK3536820A ACWY_Liq Group) and the currently licensed MenACWY vaccine (ACWY Group), as measured by the adjusted hSBA GMTs directed against N. meningitidis serogroup W at Day 29

| | |
|---|---|
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 926 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | ANCOVA |
| Parameter estimate | GMT ratio |
| Point estimate | 1.23 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.96 |
| upper limit | 1.58 |

| **Statistical analysis title** | hSBA GMT ratio for serogroup Y |
|---|---|

Statistical analysis description:

To compare the immunogenicity of the investigational MenACWY liquid vaccine with approximately 30% Men A FS (GSK3536820A ACWY_Liq Group) and the currently licensed MenACWY vaccine (ACWY Group), as measured by the adjusted hSBA GMTs directed against N. meningitidis serogroup Y at Day 29

| | |
|---|---|
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 926 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | ANCOVA |
| Parameter estimate | GMT ratio |
| Point estimate | 1.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.58 |

## Secondary: Within-group Geometric Mean Ratios (GMRs) against each of the N.meningitidis serogroups A, C, W and Y

| | |
|---|---|
| End point title | Within-group Geometric Mean Ratios (GMRs) against each of the N.meningitidis serogroups A, C, W and Y |

End point description:

Within-group ratios of hSBA GMTs against each of the N.meningitidis serogroups A, C, W and Y at Day 29 compared to Day 1. Analysis was performed on the per protocol set for immunogenicity that includes subjects who received the vaccine, did not have any protocol deviation leading to exclusion, who were not excluded due to other reasons defined prior to unblinding or analysis and had available immuno data for any serogroup and time point considered.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

At Day 29

| **End point values** | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 452 | 455 | | |
| Units: Ratio | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Meningitis A(N=386,404) | 65.24 (51.81 to 82.16) | 73.01 (58.26 to 91.49) | | |
| Meningitis C(N=437,441) | 13.17 (10.30 to 16.84) | 11.07 (8.68 to 14.13) | | |
| Meningitis W(N=445,443) | 6.1 (5.07 to 7.33) | 4.8 (3.99 to 5.77) | | |
| Meningitis Y(N=452,455) | 14.64 (11.88 to 18.04) | 11.48 (9.33 to 14.13) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentages of subjects with a ≥4 fold rise in hSBA antibody titers for each of the N.meningitidis serogroups A, C,W and Y for each vaccine group, and between-group differences

| End point title | Percentages of subjects with a ≥4 fold rise in hSBA antibody titers for each of the N.meningitidis serogroups A, C,W and Y for each vaccine group, and between-group differences |
|---|---|

End point description:

The percentages of subjects with a ≥ 4-fold rise in post-vaccination hSBA (at Day 29 compared to Day 1) and associated 2-sided 95% Clopper-Pearson CIs were computed by group and for each N. meningitidis serogroups A, C, W and Y. A 4-fold rise in the hSBA titers is defined as: for individuals, whose pre-vaccination titers are < the LOD (limit of detection), the post-vaccination titers must be ≥ 4-fold the LOD or ≥ the LLOQ (lower of limit of quantitation) whichever is greater; for individuals, whose pre-vaccination titers are ≥ the LOD and ≤ the LLOQ, the post-vaccination titers must be at least four times the LLOQ; for individuals whose pre-vaccination titers are > the LLOQ, the post-vaccination titers must be at least four times the pre-vaccination

| End point type | Secondary |
|---|---|

End point timeframe:

At Day 29

| End point values | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 452 | 455 | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Meningitis A(N=386,404) | 79.8 (75.4 to 83.7) | 83.7 (79.7 to 87.1) | | |
| Meningitis C(N=437,441) | 56.3 (51.5 to 61.0) | 54.4 (49.6 to 59.1) | | |
| Meningitis W(N=445,443) | 44.7 (40.0 to 49.5) | 40.2 (35.6 to 44.9) | | |
| Meningitis Y(N=452,455) | 63.3 (58.6 to 67.7) | 58 (53.3 to 62.6) | | |

## Statistical analyses

| Statistical analysis title | Between-groups differences- Serogroup A |
|---|---|

Statistical analysis description:

Between-group difference in percentage of subjects with a ≥ 4-fold rise in post-vaccination hSBA for N. meningitidis serogroup A at Day 29.

| | |
|---|---|
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 907 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -3.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.3 |
| upper limit | 1.52 |

| **Statistical analysis title** | Between-group differences- serogroup C |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentage of subjects with a ≥ 4-fold rise in post-vaccination hSBA for N. meningitidis serogroup C at Day 29. | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 907 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | 1.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.7 |
| upper limit | 8.43 |

| **Statistical analysis title** | Between-group differences- serogroup W |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentage of subjects with a ≥ 4-fold rise in post-vaccination hSBA for N. meningitidis serogroup W at Day 29. | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 907 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | 4.54 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.97 |
| upper limit | 11.01 |

| **Statistical analysis title** | Between-group differences- serogroup Y |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentage of subjects with a ≥ 4-fold rise in post-vaccination hSBA for N. meningitidis serogroup Y at Day 29. | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 907 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | 5.25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.11 |
| upper limit | 11.57 |

## Secondary: Percentages of subjects with hSBA titers ≥8 against each of the N. meningitidis serogroups A, C, W and Y for each vaccine group, and between-group differences

| End point title | Percentages of subjects with hSBA titers ≥8 against each of the N. meningitidis serogroups A, C, W and Y for each vaccine group, and between-group differences |
|---|---|
| End point description: | |
| For each vaccine group the percentage of subjects with hSBA titer ≥8, and its associated two-sided 95% Clopper-Pearson CIs were computed for each of the N. meningitidis serogroups A, C, W and Y. Analysis was performed on the per protocol set for immunogenicity that includes subjects who received the vaccine, did not have any protocol deviation leading to exclusion, who were not excluded due to other reasons defined prior to unblinding or analysis and had available immuno data for any serogroup and time point considered. | |
| End point type | Secondary |
| End point timeframe: | |
| At Day 1 and Day 29 | |

| **End point values** | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 460 | 467 | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Meningitis A, Day 1(N=446,446) | 8.7 (6.3 to 11.8) | 11.2 (8.4 to 14.5) | | |
| Meningitis A, Day 29(N=406, 428) | 82.8 (78.7 to 86.3) | 86.4 (82.8 to 89.5) | | |
| Meningitis C, Day 1(N=459,467) | 53.8 (49.1 to 58.4) | 54.4 (49.7 to 59.0) | | |

| | | | | |
|---|---|---|---|---|
| Meningitis C, Day 29(N=443,446) | 74.5 (70.2 to 78.5) | 74.9 (70.6 to 78.8) | | |
| Meningitis W, Day 1(N=455,457) | 39.8 (35.3 to 44.4) | 45.7 (41.1 to 50.4) | | |
| Meningitis W, Day 29(N=454,457) | 73.3 (69.0 to 77.4) | 73.1 (68.8 to 77.1) | | |
| Meningitis Y, Day 1(N=458,463) | 22.7 (18.9 to 26.8) | 25.5 (21.6 to 29.7) | | |
| Meningitis Y, Day 29(N=460,463) | 77.2 (73.1 to 80.9) | 76 (71.9 to 79.8) | | |

## Statistical analyses

| **Statistical analysis title** | Between-group differences- Serogroup A, Day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup A at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -2.47 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.47 |
| upper limit | 1.49 |

| **Statistical analysis title** | Between-group differences-Serogroup C, day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup C at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -0.58 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.99 |
| upper limit | 5.83 |

| **Statistical analysis title** | Between-group differences-Serogroup W, day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup W at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -5.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.33 |
| upper limit | 0.47 |

| **Statistical analysis title** | Between-group differences-Serogroup Y, day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup Y at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -2.78 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.3 |
| upper limit | 2.76 |

| **Statistical analysis title** | Between-group differences-Serogroup A, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup A at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -3.69 |

| | |
|---|---|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.65 |
| upper limit | 1.21 |

| **Statistical analysis title** | Between-group differences-Serogroup C, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup C at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -0.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.12 |
| upper limit | 5.33 |

| **Statistical analysis title** | Between-group differences-Serogroup W, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup W at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | 0.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.49 |
| upper limit | 6.02 |

| **Statistical analysis title** | Between-group differences-Serogroup Y, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥8 for the N. meningitidis serogroup Y at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |

| | |
|---|---|
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | 1.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.33 |
| upper limit | 6.62 |

## Secondary: Percentages of subjects with hSBA titers ≥LLOQ against each of the N. meningitidis serogroups A, C, W and Y for each vaccine group, and between-group differences

| | |
|---|---|
| End point title | Percentages of subjects with hSBA titers ≥LLOQ against each of the N. meningitidis serogroups A, C, W and Y for each vaccine group, and between-group differences |

End point description:

For each vaccine group the percentage of subjects with hSBA titer ≥LLOQ, and its associated two-sided 95% Clopper-Pearson CIs were computed for each of the N. meningitidis serogroups A, C, W and Y. Analysis was performed on the per protocol set for immunogenicity that includes subjects who received the vaccine, did not have any protocol deviation leading to exclusion, who were not excluded due to other reasons defined prior to unblinding or analysis and had available immuno data for any serogroup and time point considered.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

At Day 1 and Day 29

| **End point values** | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 460 | 467 | | |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Meningitis A, Day 1(N=446,446) | 10.5 (7.8 to 13.8) | 13.5 (10.4 to 17.0) | | |
| Meningitis A, Day 29(N=406,428) | 82.8 (78.7 to 86.3) | 86.7 (83.1 to 89.8) | | |
| Meningitis C, Day 1(N=459,467) | 61.2 (56.6 to 65.7) | 62.3 (57.7 to 66.7) | | |
| Meningitis C, Day 29(N=443,446) | 76.5 (72.3 to 80.4) | 76.5 (72.2 to 80.3) | | |
| Meningitis W, Day 1(N=455,457) | 41.3 (36.8 to 46.0) | 47.3 (42.6 to 52.0) | | |
| Meningitis W, Day 29(N=454,457) | 73.3 (69.0 to 77.4) | 73.5 (69.2 to 77.5) | | |
| Meningitis Y, Day 1(N=458,463) | 23.8 (20.0 to 28.0) | 26.3 (22.4 to 30.6) | | |
| Meningitis Y, Day 29(N=460, 463) | 77.8 (73.7 to 81.5) | 77.3 (73.2 to 81.1) | | |

## Statistical analyses

| **Statistical analysis title** | Between-group differences-Serogroup A, day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup A at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -2.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.24 |
| upper limit | 1.37 |

| **Statistical analysis title** | Between-group differences-Serogroup C, day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup C at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -1.09 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.34 |
| upper limit | 5.16 |

| **Statistical analysis title** | Between-group differences-Serogroup W, day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup W at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |

| | |
|---|---|
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -5.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.35 |
| upper limit | 0.5 |

| **Statistical analysis title** | Between-group differences-Serogroup Y, day 1 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup Y at Day 1 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -2.55 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.15 |
| upper limit | 3.06 |

| **Statistical analysis title** | Between-group differences-Serogroup A, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup A at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -3.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.87 |
| upper limit | 0.96 |

| **Statistical analysis title** | Between-group differences-Serogroup C, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup C at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | 0.07 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.52 |
| upper limit | 5.65 |

| **Statistical analysis title** | Between-group differences-Serogroup W, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup W at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | -0.17 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.92 |
| upper limit | 5.57 |

| **Statistical analysis title** | Between-group differences-Serogroup Y, day 29 |
|---|---|
| Statistical analysis description: | |
| Between-group difference in percentages of subjects with hSBA titer ≥LLOQ for the N. meningitidis serogroup Y at Day 29 | |
| Comparison groups | GSK3536820A ACWY_Liq Group v ACWY Group |

| | |
|---|---|
| Number of subjects included in analysis | 927 |
| Analysis specification | Pre-specified |
| Analysis type | |
| Method | Miettinen and Nurminen score method |
| Parameter estimate | Difference in percentage of subjects |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.89 |
| upper limit | 5.9 |

## Secondary: Number of subjects reported with solicited local and systemic AEs

| | |
|---|---|
| End point title | Number of subjects reported with solicited local and systemic AEs |

End point description:

Number of subjects with solicited local and systemic AEs during the 7-days period (including the day of vaccination) after the vaccination. Analysis was performed on the solicited safety set that includes all enrolled subjects who received a study vaccination and reported any solicited adverse events data for the defined period.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

From Day 1 (6 hours) to Day 7 after vaccination

| End point values | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 489 | 487 | | |
| Units: Participants | | | | |
| Erythema | 28 | 28 | | |
| Induration | 25 | 24 | | |
| Pain | 200 | 182 | | |
| Arthralgia | 43 | 46 | | |
| Chills | 42 | 40 | | |
| Fatigue | 159 | 159 | | |
| Fever (Temperature >= 38 C) | 7 | 10 | | |
| Headache | 158 | 165 | | |
| Loss of Appetite | 31 | 40 | | |
| Myalgia | 58 | 58 | | |
| Nausea | 49 | 50 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects reported with other indicators of reactogenicity

| End point title | Number of subjects reported with other indicators of reactogenicity |
|---|---|

End point description:

Number of subjects reporting other indicators of reactogenicity such as use of analgesics/antipyretics within 7 days after vaccination. Analysis was performed on the solicited safety set that includes all enrolled subjects who received a study vaccination and reported any indicators of reactogenicity data for the defined period.

| End point type | Secondary |
|---|---|

End point timeframe:

From Day 1 to Day 7 after vaccination

| **End point values** | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 489 | 487 | | |
| Units: Participants | | | | |
| Analgesic/Antipyretic Prevention, Yes | 36 | 40 | | |
| Analgesic/Antipyretic Prevention, No | 453 | 447 | | |
| Analgesic/Antipyretic Treatment, Yes | 80 | 79 | | |
| Analgesic/Antipyretic Treatment, No | 409 | 408 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects reported with any unsolicited AEs within 29 days after vaccination

| End point title | Number of subjects reported with any unsolicited AEs within 29 days after vaccination |
|---|---|

End point description:

An AE is defined as any untoward medical occurrence in a subject or clinical investigation subject administered with a pharmaceutical product at any dose that does not necessarily have to have a causal relationship with this treatment. Analysis was performed on the unsolicited safety set that includes all enrolled subjects who received a study vaccination and reported unsolicited adverse events data for the defined period.

| End point type | Secondary |
|---|---|

End point timeframe:

From Day 1 to Day 29 after vaccination

| End point values | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 489 | 489 | | |
| Units: Participants | 117 | 111 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects reported with AEs leading to withdrawal, medically attended AEs and serious adverse events (SAEs)

| End point title | Number of subjects reported with AEs leading to withdrawal, medically attended AEs and serious adverse events (SAEs) |
|---|---|

End point description:

Medically attended AEs are defined as events for which the subject received medical attention defined as hospitalization, an emergency room visit, or a visit to or from medical personnel (medical doctor) for any reason. Any medically attended AE(s) is occurrence of any medically attended AE(s) regardless of intensity grade or relation to vaccination. Serious adverse event is any congenital anomaly/birth defect in the offspring of a study subject or any untoward medical occurrence that results in death or life threatening or requires hospitalization or results in disability or incapacity. Analysis was performed on the unsolicited safety set that includes all enrolled subjects who received a study vaccination and reported any adverse events data in the defined period.

| End point type | Secondary |
|---|---|

End point timeframe:

From Day 1 to Day 181 (during the entire study period)

| End point values | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 489 | 489 | | |
| Units: Participants | | | | |
| Aes leading to withdrawal | 0 | 0 | | |
| MAEs | 79 | 84 | | |
| SAEs | 6 | 9 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects reported with any unsolicited adverse events (AEs) within 30 minutes after vaccination

| End point title | Number of subjects reported with any unsolicited adverse events (AEs) within 30 minutes after vaccination |
|---|---|

End point description:

An AE is defined as any untoward medical occurrence in a subject or clinical investigation subject

administered with a pharmaceutical product at any dose that does not necessarily have to have a causal relationship with this treatment. Analysis was performed on the unsolicited safety set that includes all enrolled subjects who received a study vaccination and reported unsolicited adverse events data for the defined period.

| End point type | Secondary |
|---|---|

End point timeframe:

Within 30 minutes after vaccination at Day 1

| **End point values** | GSK3536820A ACWY_Liq Group | ACWY Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 489 | 489 | | |
| Units: Participants | 5 | 5 | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected from Day 1 to Day 7 after vaccination and Unsolicited AEs from Day 1 to Day 29 after vaccination. SAEs were collected from Day 1 to Day 181 (during the entire study period)

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 23.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | GSK3536820A ACWY_Liq Group |

Reporting group description:

Healthy adults, 18 to 44 years of age, receiving at Day 1 a single dose of investigational MenACWY liquid vaccine (GSK3536820A) formulation with approximately 30% Men A FS.

| | |
|---|---|
| Reporting group title | ACWY Group |

Reporting group description:

Healthy adults, 18 to 40 years of age, receiving at Day 1 a single dose of licensed GSK's MenACWY vaccine formulation (Menveo).

| Serious adverse events | GSK3536820A ACWY_Liq Group | ACWY Group | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 490 (1.22%) | 9 / 489 (1.84%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Uterine cancer | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| 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 | | | |
| Jaw fracture | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Cardiac disorders | | | |
| Atrial flutter | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Hemiplegic migraine | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion spontaneous incomplete | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ectopic pregnancy | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Hernia | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Ovarian cyst ruptured | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |

| | | | |
|---|---|---|---|
| Biliary colic | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Suicide attempt | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Dengue fever | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| **Non-serious adverse events** | GSK3536820A ACWY_Liq Group | ACWY Group | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 336 / 490 (68.57%) | 335 / 489 (68.51%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign breast neoplasm | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Vascular disorders | | | |

| | | | |
|---|---|---|---|
| Hypertension | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| General disorders and administration site conditions | | | |
| Administration site joint pain | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Chills | | | |
| subjects affected / exposed | 43 / 490 (8.78%) | 40 / 489 (8.18%) | |
| occurrences (all) | 44 | 40 | |
| Fatigue | | | |
| subjects affected / exposed | 160 / 490 (32.65%) | 162 / 489 (33.13%) | |
| occurrences (all) | 163 | 163 | |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Feeling hot | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Influenza like illness | | | |
| subjects affected / exposed | 5 / 490 (1.02%) | 2 / 489 (0.41%) | |
| occurrences (all) | 5 | 2 | |
| Injection site bruising | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Injection site erythema | | | |
| subjects affected / exposed | 30 / 490 (6.12%) | 31 / 489 (6.34%) | |
| occurrences (all) | 31 | 32 | |
| Injection site haemorrhage | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Injection site induration | | | |
| subjects affected / exposed | 26 / 490 (5.31%) | 25 / 489 (5.11%) | |
| occurrences (all) | 27 | 25 | |
| Injection site joint pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Injection site oedema | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Injection site pain | | | |
| subjects affected / exposed | 200 / 490 (40.82%) | 184 / 489 (37.63%) | |
| occurrences (all) | 204 | 184 | |
| Injection site pruritus | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injection site rash | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Injection site swelling | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Injection site warmth | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Malaise | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Mass | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Pyrexia | | | |
| subjects affected / exposed | 10 / 490 (2.04%) | 10 / 489 (2.04%) | |
| occurrences (all) | 11 | 10 | |
| Vaccination site induration | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vaccination site paraesthesia | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Seasonal allergy | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 1 / 489 (0.20%) | |
| occurrences (all) | 2 | 1 | |
| Menorrhagia | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Allergic sinusitis | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cough | | | |
| subjects affected / exposed | 3 / 490 (0.61%) | 1 / 489 (0.20%) | |
| occurrences (all) | 3 | 1 | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 7 / 490 (1.43%) | 2 / 489 (0.41%) | |
| occurrences (all) | 7 | 2 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Throat irritation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Psychiatric disorders | | | |
| Agitation | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Disorientation | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Insomnia | | | |
| subjects affected / exposed | 3 / 490 (0.61%) | 0 / 489 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Panic attack | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Cartilage injury | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Contusion | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Fall | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Muscle strain | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 1 / 489 (0.20%) | |
| occurrences (all) | 2 | 1 | |
| Post-traumatic pain | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Procedural pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 490 (0.20%) | 2 / 489 (0.41%) | |
| occurrences (all) | 1 | 2 | |
| Skin laceration | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Cardiac disorders | | | |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 2 / 489 (0.41%) | |
| occurrences (all) | 0 | 2 | |
| Dizziness | | | |
| subjects affected / exposed | 4 / 490 (0.82%) | 1 / 489 (0.20%) | |
| occurrences (all) | 4 | 1 | |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Headache | | | |
| subjects affected / exposed | 162 / 490 (33.06%) | 171 / 489 (34.97%) | |
| occurrences (all) | 167 | 183 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Migraine with aura | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Presyncope | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 3 / 489 (0.61%) | |
| occurrences (all) | 1 | 4 | |
| Ear and labyrinth disorders | | | |
| Meniere's disease | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vertigo | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eye disorders | | | |
| Eye pain | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 1 / 489 (0.20%) | |
| occurrences (all) | 2 | 1 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 2 / 489 (0.41%) | |
| occurrences (all) | 0 | 2 | |
| Constipation | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Dental caries | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 2 / 489 (0.41%) | |
| occurrences (all) | 2 | 2 | |
| Dyspepsia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 490 (0.41%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 51 / 490 (10.41%) | 51 / 489 (10.43%) | |
| occurrences (all) | 52 | 52 | |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Toothache | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 2 / 489 (0.41%) | |
| occurrences (all) | 1 | 2 | |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Pruritus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Sensitive skin | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Renal and urinary disorders | | | |
| Renal colic | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 43 / 490 (8.78%) | 49 / 489 (10.02%) | |
| occurrences (all) | 44 | 49 | |
| Back pain | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Bursitis | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Flank pain | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Joint stiffness | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Musculoskeletal chest pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Myalgia | | | |
| subjects affected / exposed | 59 / 490 (12.04%) | 58 / 489 (11.86%) | |
| occurrences (all) | 59 | 58 | |
| Myosclerosis | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Neck pain | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Synovitis | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 2 / 489 (0.41%) | |
| occurrences (all) | 1 | 2 | |
| Candida infection | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Cellulitis orbital | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cystitis | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |

| | | | |
|---|---|---|---|
| Diarrhoea infectious | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 3 / 490 (0.61%) | 0 / 489 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 2 / 489 (0.41%) | |
| occurrences (all) | 0 | 2 | |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Infected cyst | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 0 / 489 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Influenza | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Laryngitis | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 1 / 489 (0.20%) | |
| occurrences (all) | 2 | 1 | |
| Localised infection | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 11 / 490 (2.24%) | 10 / 489 (2.04%) | |
| occurrences (all) | 11 | 10 | |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Otitis media | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 2 / 489 (0.41%) | |
| occurrences (all) | 2 | 2 | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Post procedural infection | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 0 / 489 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 6 / 489 (1.23%) | |
| occurrences (all) | 1 | 6 | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 4 / 489 (0.82%) | |
| occurrences (all) | 0 | 4 | |
| Streptococcal infection | | | |
| subjects affected / exposed | 1 / 490 (0.20%) | 1 / 489 (0.20%) | |
| occurrences (all) | 1 | 1 | |
| Tonsillitis | | | |
| subjects affected / exposed | 2 / 490 (0.41%) | 1 / 489 (0.20%) | |
| occurrences (all) | 2 | 1 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 10 / 490 (2.04%) | 6 / 489 (1.23%) | |
| occurrences (all) | 10 | 6 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 1 / 489 (0.20%) | |
| occurrences (all) | 0 | 1 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 490 (0.00%) | 2 / 489 (0.41%) | |
| occurrences (all) | 0 | 2 | |

| | | | |
|---|---|---|---|
| Viral upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 2 / 490 (0.41%)<br>2 | 2 / 489 (0.41%)<br>2 | |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all) | 31 / 490 (6.33%)<br>31 | 41 / 489 (8.38%)<br>42 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 17 January 2018 | -Two similar exclusion criteria combined into a single criterion -Clarification of immunogenicity endpoints that will be included in a sub group analysis -Editorial changes to the protocol |
| 15 March 2018 | Intensity scales for solicited AEs were updated to correct the intensity scores of some of the AEs solicited.<br>Redness/ swelling changed to erythema/induration, in line with local AEs solicited. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported