



## Clinical trial results:

### A 52-week, Randomised, Double-blind, Placebo-controlled, Parallel group, Multi-centre Study of the Efficacy and Safety of GSK3511294 Adjunctive Therapy in Adult and Adolescent Participants with Severe Uncontrolled Asthma with an Eosinophilic Phenotype

#### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2020-003611-10    |
| Trial protocol           | FR CZ PL IT ES HU |
| Global end of trial date | 11 April 2024     |

#### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1              |
| This version publication date  | 24 October 2024 |
| First version publication date | 24 October 2024 |

#### Trial information

##### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 213744 |
|-----------------------|--------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04718103 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |                                                                                  |
|------------------------------|----------------------------------------------------------------------------------|
| Sponsor organisation name    | GlaxoSmithKline                                                                  |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS               |
| Public contact               | GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact           | GSK Response Center, GlaxoSmithKline, 1 8664357343, 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                       | 20 May 2024   |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 11 April 2024 |
| Global end of trial reached?                         | Yes           |
| Global end of trial date                             | 11 April 2024 |
| Was the trial ended prematurely?                     | No            |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the efficacy of GSK3511294 100 mg (SC) every 26 weeks versus placebo in participants with severe uncontrolled asthma with an eosinophilic phenotype on top of existing asthma therapy.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 04 February 2021 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Taiwan: 13         |
| Country: Number of subjects enrolled | Japan: 71          |
| Country: Number of subjects enrolled | Canada: 2          |
| Country: Number of subjects enrolled | Australia: 5       |
| Country: Number of subjects enrolled | United States: 139 |
| Country: Number of subjects enrolled | Poland: 60         |
| Country: Number of subjects enrolled | Spain: 45          |
| Country: Number of subjects enrolled | Italy: 14          |
| Country: Number of subjects enrolled | Hungary: 14        |
| Country: Number of subjects enrolled | Czechia: 25        |
| Country: Number of subjects enrolled | France: 9          |
| Worldwide total number of subjects   | 397                |
| EEA total number of subjects         | 167                |

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)                | 22  |
| Adults (18-64 years)                     | 277 |
| From 65 to 84 years                      | 98  |
| 85 years and over                        | 0   |

## Subject disposition

### Recruitment

Recruitment details:

Of 397 participants who were randomized, 380 participants were included in Full analysis set (FAS) population. FAS included all randomized participants who received at least 1 dose of study drug excluding 12 participants from 2 Good Clinical Practice (GCP) violation sites and 5 participants were randomized in error & did not receive any study drug.

### Pre-assignment

Screening details:

In this study, out of 663 participants screened, 397 participants were enrolled/randomized to the study. In total 380 participants received at least one dose of study drug & included in the FAS.

### 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, Assessor |

### Arms

|                              |            |
|------------------------------|------------|
| Are arms mutually exclusive? | Yes        |
| <b>Arm title</b>             | GSK3511294 |

Arm description:

Participants received a 100 milligram (mg) dose of GSK3511294 subcutaneous (SC) injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.

|                                        |                        |
|----------------------------------------|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | GSK3511294             |
| Investigational medicinal product code |                        |
| Other name                             | Depemokimab            |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

100 milligram (mg) per milligram once every 26 weeks

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

Arm description:

Participants received placebo SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.

|                                        |                        |
|----------------------------------------|------------------------|
| Arm type                               | Placebo                |
| Investigational medicinal product name | Placebo                |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

Matching Placebo once every 26 weeks

| <b>Number of subjects in period 1<sup>[1]</sup></b> | <b>GSK3511294</b> | <b>Placebo</b> |
|-----------------------------------------------------|-------------------|----------------|
| Started                                             | 252               | 128            |
| Completed                                           | 233               | 117            |
| Not completed                                       | 19                | 11             |
| Consent withdrawn by subject                        | 10                | 6              |
| Physician decision                                  | 2                 | -              |
| Adverse event, non-fatal                            | 1                 | 1              |
| Pregnancy                                           | -                 | 1              |
| Lost to follow-up                                   | 2                 | 2              |
| Lack of efficacy                                    | 4                 | 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: Of 17 participants who were randomized, 12 participants from 2 sites were excluded from the full analysis population due to data integrity concerns & GCP violations, and 5 randomized participants did not receive any study intervention, hence not included in the FAS population.

## Baseline characteristics

### Reporting groups

|                       |            |
|-----------------------|------------|
| Reporting group title | GSK3511294 |
|-----------------------|------------|

Reporting group description:

Participants received a 100 milligram (mg) dose of GSK3511294 subcutaneous (SC) injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Participants received placebo SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.

| Reporting group values                                | GSK3511294 | Placebo | Total |
|-------------------------------------------------------|------------|---------|-------|
| Number of subjects                                    | 252        | 128     | 380   |
| Age categorical<br>Units: Subjects                    |            |         |       |
| In utero                                              | 0          | 0       | 0     |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0          | 0       | 0     |
| Newborns (0-27 days)                                  | 0          | 0       | 0     |
| Infants and toddlers (28 days-23<br>months)           | 0          | 0       | 0     |
| Children (2-11 years)                                 | 0          | 0       | 0     |
| Adolescents (12-17 years)                             | 12         | 10      | 22    |
| Adults (18-64 years)                                  | 169        | 93      | 262   |
| From 65-84 years                                      | 71         | 25      | 96    |
| 85 years and over                                     | 0          | 0       | 0     |
| Age continuous<br>Units: years                        |            |         |       |
| arithmetic mean                                       | 53.6       | 51.2    |       |
| standard deviation                                    | ± 16.00    | ± 16.58 | -     |
| Sex: Female, Male<br>Units: Participants              |            |         |       |
| Female                                                | 160        | 81      | 241   |
| Male                                                  | 92         | 47      | 139   |
| Race/Ethnicity, Customized<br>Units: Subjects         |            |         |       |
| Asian                                                 | 52         | 23      | 75    |
| White                                                 | 181        | 91      | 272   |
| De-identified                                         | 19         | 14      | 33    |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                             |            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Reporting group title                                                                                                                                                                                                                                                                                       | GSK3511294 |
| Reporting group description:<br>Participants received a 100 milligram (mg) dose of GSK3511294 subcutaneous (SC) injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study. |            |
| Reporting group title                                                                                                                                                                                                                                                                                       | Placebo    |
| Reporting group description:<br>Participants received placebo SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.                                                |            |

### Primary: Annualized Rate of Clinically Significant Exacerbations up to 52 Weeks

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Annualized Rate of Clinically Significant Exacerbations up to 52 Weeks |
| End point description:<br>Clinically significant exacerbations recorded were defined as worsening of asthma requiring the use of systemic corticosteroids (CS) [such as intramuscular (IM), intravenous (IV) or oral] and/or hospitalization and/or Emergency Department (ED) visit. For all participants, IV or oral steroids (e.g., prednisone) for at least 3 days or a single IM corticosteroid dose is required. For participants on maintenance systemic corticosteroids, at least double the existing maintenance dose for at least 3 days is required. Exacerbations recorded in the eCRF were considered as verified clinically significant exacerbations and included in the primary analysis. Exacerbations separated by less than 7 days was treated as a continuation of the same exacerbation. The analysis was performed on the Full Analysis Set population. |                                                                        |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Primary                                                                |
| End point timeframe:<br>Up to Week 52                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                        |

| End point values                             | GSK3511294          | Placebo             |  |  |
|----------------------------------------------|---------------------|---------------------|--|--|
| Subject group type                           | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed                  | 252                 | 128                 |  |  |
| Units: Exacerbation per participant per year |                     |                     |  |  |
| number (confidence interval 95%)             | 0.56 (0.44 to 0.70) | 1.08 (0.83 to 1.41) |  |  |

### Statistical analyses

|                                                                                                                                                                                                                                                                                                                |                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Statistical analysis title                                                                                                                                                                                                                                                                                     | Statistical Analysis 1 |
| Statistical analysis description:<br>To demonstrate the superiority of GSK3511294 100 mg SC + SoC following two doses (at Week 0 and at Week 26) compared with placebo + SoC, assessed by the annualized rate of clinically significant exacerbations measured over the study intervention period of 52 weeks. |                        |
| Comparison groups                                                                                                                                                                                                                                                                                              | GSK3511294 v Placebo   |

|                                         |                                |
|-----------------------------------------|--------------------------------|
| Number of subjects included in analysis | 380                            |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | superiority <sup>[1]</sup>     |
| P-value                                 | < 0.001                        |
| Method                                  | Negative binomial distribution |
| Parameter estimate                      | Rate Ratio                     |
| Point estimate                          | 0.52                           |
| Confidence interval                     |                                |
| level                                   | 95 %                           |
| sides                                   | 2-sided                        |
| lower limit                             | 0.36                           |
| upper limit                             | 0.73                           |

Notes:

[1] - Analysis performed using a generalized linear model assuming a negative binomial distribution and covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region and baseline pre-bronchodilator percent predicted Forced Expiratory Volume in one second (FEV1) and offset of log (total time in the study in years).

## Secondary: Change From Baseline in St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 52

|                 |                                                                                              |
|-----------------|----------------------------------------------------------------------------------------------|
| End point title | Change From Baseline in St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 52 |
|-----------------|----------------------------------------------------------------------------------------------|

End point description:

The SGRQ is a 50-item patient-reported outcome tool used to measure Quality of Life in participants with airway obstruction diseases. The questions are designed to be self-completed by the participant. The total score was calculated by the symptom score, activity and impact score; and summarizing the impact of the disease on overall health status. Scores are expressed as a percentage of overall impairment where 100 representing worst possible health status and 0 indicating best possible health status. Higher scores also indicating greater impairment of quality of life. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed on the FAS population that included all randomized participants who received at least 1 dose of study intervention excluding participants from 2 GCP violation sites.

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

End point timeframe:

Baseline (Day 1) and Week 52

|                                     |                  |                  |  |  |
|-------------------------------------|------------------|------------------|--|--|
| <b>End point values</b>             | GSK3511294       | Placebo          |  |  |
| Subject group type                  | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed         | 246              | 124              |  |  |
| Units: Scores on a scale            |                  |                  |  |  |
| least squares mean (standard error) | -14.80 (± 1.041) | -12.49 (± 1.455) |  |  |

## Statistical analyses

|                                   |                        |
|-----------------------------------|------------------------|
| <b>Statistical analysis title</b> | Statistical Analysis 2 |
|-----------------------------------|------------------------|

Statistical analysis description:

To demonstrate the superiority of GSK3511294 100 mg SC + SoC following two doses (at Week 0 and at Week 26) compared with placebo + SoC, assessed by SGRQ Total Score measured over the study intervention period of 52 weeks.

|                   |                      |
|-------------------|----------------------|
| Comparison groups | Placebo v GSK3511294 |
|-------------------|----------------------|



|                                         |                                       |
|-----------------------------------------|---------------------------------------|
| Number of subjects included in analysis | 370                                   |
| Analysis specification                  | Pre-specified                         |
| Analysis type                           | superiority <sup>[2]</sup>            |
| P-value                                 | = 0.2                                 |
| Method                                  | Mixed Models Repeated Measures (MMRM) |
| Parameter estimate                      | Difference in Least-Square Means      |
| Point estimate                          | -2.31                                 |
| Confidence interval                     |                                       |
| level                                   | 95 %                                  |
| sides                                   | 2-sided                               |
| lower limit                             | -5.84                                 |
| upper limit                             | 1.23                                  |

Notes:

[2] - Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline SGRQ total score, baseline pre- bronchodilator percent predicted FEV1, visit, visit by baseline SGRQ total score and visit by treatment group.

## Secondary: Change From Baseline in Asthma Control Questionnaire-5 (ACQ-5) Score at Week 52

|                 |                                                                                 |
|-----------------|---------------------------------------------------------------------------------|
| End point title | Change From Baseline in Asthma Control Questionnaire-5 (ACQ-5) Score at Week 52 |
|-----------------|---------------------------------------------------------------------------------|

End point description:

The ACQ-5 is a five-item questionnaire developed as a measure of participants asthma symptom control. The questions are designed to be self-completed by the participant. The 5 questions enquired to recall their how their asthma had been during the previous week and to respond about the frequency and/or severity of symptoms (nocturnal awakening, waking in the morning, activity limitation, shortness of breath and wheezing). The overall ACQ-5 response option is the mean score of all 5 questions representing 0 with no impairment/limitation and 6 as total impairment/ limitation. Higher scores indicated more limitations and lower score with better asthma control. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed on the FAS population that included all randomized participants who received at least 1 dose of study intervention excluding participants from 2 GCP violation sites.

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

End point timeframe:

Baseline (Day 1) and Week 52

| End point values                    | GSK3511294      | Placebo         |  |  |
|-------------------------------------|-----------------|-----------------|--|--|
| Subject group type                  | Reporting group | Reporting group |  |  |
| Number of subjects analysed         | 246             | 124             |  |  |
| Units: Scores on a scale            |                 |                 |  |  |
| least squares mean (standard error) | -0.81 (± 0.065) | -0.70 (± 0.091) |  |  |

## Statistical analyses

|                            |                        |
|----------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 3 |
|----------------------------|------------------------|

Statistical analysis description:

Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline ACQ-5 score, baseline pre-bronchodilator percent predicted FEV1, visit, visit by baseline ACQ-5 score and visit by

treatment group.

|                                         |                                       |
|-----------------------------------------|---------------------------------------|
| Comparison groups                       | GSK3511294 v Placebo                  |
| Number of subjects included in analysis | 370                                   |
| Analysis specification                  | Pre-specified                         |
| Analysis type                           | superiority                           |
| P-value                                 | = 0.333                               |
| Method                                  | Mixed Models Repeated Measures (MMRM) |
| Parameter estimate                      | Difference in Least-Square Means      |
| Point estimate                          | -0.11                                 |
| Confidence interval                     |                                       |
| level                                   | 95 %                                  |
| sides                                   | 2-sided                               |
| lower limit                             | -0.33                                 |
| upper limit                             | 0.11                                  |

### Secondary: Change From Baseline in Pre-Bronchodilator Forced Expiratory Volume in One Second (FEV1) At Week 52

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Change From Baseline in Pre-Bronchodilator Forced Expiratory Volume in One Second (FEV1) At Week 52 |
| End point description:<br>Forced Expiratory Volume in One Second (FEV1) is defined as the maximum volume of air that can be forced out in one second after taking a deep breath by a person and will be measured by spirometry. Change from Baseline in clinic pre-bronchodilator FEV1 was determined. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed on the FAS population that included all randomized participants who received at least 1 dose of study intervention excluding participants from 2 GCP violation sites. |                                                                                                     |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Secondary                                                                                           |
| End point timeframe:<br>Baseline (Day 1) and Week 52                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                     |

|                                     |                  |                  |  |  |
|-------------------------------------|------------------|------------------|--|--|
| <b>End point values</b>             | GSK3511294       | Placebo          |  |  |
| Subject group type                  | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed         | 239              | 119              |  |  |
| Units: Liters (L)                   |                  |                  |  |  |
| least squares mean (standard error) | 0.240 (± 0.0286) | 0.184 (± 0.0407) |  |  |

### Statistical analyses

|                                                                                                                                                                                                                                                                                                                                        |                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                                                                                      | Statistical Analysis 4 |
| Statistical analysis description:<br>Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline pre-bronchodilator FEV1, visit, visit by baseline pre-bronchodilator FEV1 and visit by treatment group. |                        |
| Comparison groups                                                                                                                                                                                                                                                                                                                      | GSK3511294 v Placebo   |

|                                         |                                       |
|-----------------------------------------|---------------------------------------|
| Number of subjects included in analysis | 358                                   |
| Analysis specification                  | Pre-specified                         |
| Analysis type                           | superiority                           |
| P-value                                 | = 0.267                               |
| Method                                  | Mixed Models Repeated Measures (MMRM) |
| Parameter estimate                      | Difference in Least-Square Means      |
| Point estimate                          | 0.056                                 |
| Confidence interval                     |                                       |
| level                                   | 95 %                                  |
| sides                                   | 2-sided                               |
| lower limit                             | -0.043                                |
| upper limit                             | 0.154                                 |

## Secondary: Change From Baseline in Asthma Nighttime Symptom Diary (ANSD) Weekly Mean Score at Week 52

|                 |                                                                                            |
|-----------------|--------------------------------------------------------------------------------------------|
| End point title | Change From Baseline in Asthma Nighttime Symptom Diary (ANSD) Weekly Mean Score at Week 52 |
|-----------------|--------------------------------------------------------------------------------------------|

### End point description:

The ANSD is a 6-item self-administered patient reported diary developed by Patient Related Outcomes (PRO) Consortium's Asthma Working Group to facilitate comprehensive and reliable assessment of asthma symptoms from a participant's perspective. Participants were required to rate the severity of symptoms in 3 categories: breathing symptoms (wheezing, shortness of breath), chest symptoms (chest tightness, chest pain) & cough. The ANSD was to be completed before going to bed & refers to asthma symptoms during the day. Symptoms are rated at their worst using an 11-point numeric rating scale ranging from 0 (None) to 10 (As bad as you can imagine). Higher scores indicate more severe symptoms. Mean daily scores of ANSD was calculated by weekly intervals. The baseline was defined as average score from Days -7 to -1 inclusive (at least 4 days must be non-missing). Change from Baseline as value at each time point minus Baseline value. The FAS included with 1 ANSD questionnaire was administered.

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

### End point timeframe:

Baseline to Week 52

| End point values                    | GSK3511294      | Placebo         |  |  |
|-------------------------------------|-----------------|-----------------|--|--|
| Subject group type                  | Reporting group | Reporting group |  |  |
| Number of subjects analysed         | 232             | 117             |  |  |
| Units: Scores on a scale            |                 |                 |  |  |
| least squares mean (standard error) |                 |                 |  |  |
| ANSD Mean Score                     | -1.18 (± 0.091) | -0.97 (± 0.127) |  |  |

## Statistical analyses

|                            |                               |
|----------------------------|-------------------------------|
| Statistical analysis title | Statistical Analysis for ANSD |
|----------------------------|-------------------------------|

### Statistical analysis description:

Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline ANSD weekly mean score, baseline pre-bronchodilator percent predicted FEV1, visit, visit by baseline ANSD weekly

mean score and visit by treatment group.

|                                         |                                       |
|-----------------------------------------|---------------------------------------|
| Comparison groups                       | GSK3511294 v Placebo                  |
| Number of subjects included in analysis | 349                                   |
| Analysis specification                  | Pre-specified                         |
| Analysis type                           | superiority <sup>[3]</sup>            |
| P-value                                 | = 0.173                               |
| Method                                  | Mixed Models Repeated Measures (MMRM) |
| Parameter estimate                      | Difference in Least square means      |
| Point estimate                          | -0.21                                 |
| Confidence interval                     |                                       |
| level                                   | 95 %                                  |
| sides                                   | 2-sided                               |
| lower limit                             | -0.52                                 |
| upper limit                             | 0.09                                  |

Notes:

[3] - ANSD at Week 52

### Secondary: Change From Baseline in Asthma Daily Symptom Diary (ADSD) Weekly Mean Score at Week 52

|                 |                                                                                        |
|-----------------|----------------------------------------------------------------------------------------|
| End point title | Change From Baseline in Asthma Daily Symptom Diary (ADSD) Weekly Mean Score at Week 52 |
|-----------------|----------------------------------------------------------------------------------------|

End point description:

The ADSD is a 6-item self-administered patient reported diary developed by Patient Related Outcomes (PRO) Consortium's Asthma Working Group to facilitate comprehensive and reliable assessment of asthma symptoms from a participant's perspective. Participants were required to rate the severity of symptoms in 3 categories: breathing symptoms (wheezing, shortness of breath), chest symptoms (chest tightness, chest pain) & cough. The ADSD was to be completed before going to bed & refers to asthma symptoms during the day. Symptoms are rated at their worst using an 11-point numeric rating scale ranging from 0 (None) to 10 (As bad as you can imagine). Higher scores indicate more severe symptoms. Mean daily scores of ADSD was calculated by weekly intervals. The baseline was defined as average score from Days -7 to -1 inclusive (at least 4 days must be non-missing). Change from Baseline as value at each time point minus Baseline value. The FAS included with 1 ADSD questionnaire was administered.

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

End point timeframe:

Baseline to Week 52

| End point values                    | GSK3511294      | Placebo         |  |  |
|-------------------------------------|-----------------|-----------------|--|--|
| Subject group type                  | Reporting group | Reporting group |  |  |
| Number of subjects analysed         | 249             | 126             |  |  |
| Units: Scores on a Scale            |                 |                 |  |  |
| least squares mean (standard error) |                 |                 |  |  |
| ADSD Mean Score                     | -1.13 (± 0.080) | -0.93 (± 0.112) |  |  |

### Statistical analyses

|                            |                               |
|----------------------------|-------------------------------|
| Statistical analysis title | Statistical Analysis for ADSD |
|----------------------------|-------------------------------|

#### Statistical analysis description:

Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline ADSD weekly mean score, baseline pre-bronchodilator percent predicted FEV1, visit, visit by baseline ADSD weekly mean score and visit by treatment group.

|                                         |                                       |
|-----------------------------------------|---------------------------------------|
| Comparison groups                       | GSK3511294 v Placebo                  |
| Number of subjects included in analysis | 375                                   |
| Analysis specification                  | Pre-specified                         |
| Analysis type                           | superiority <sup>[4]</sup>            |
| P-value                                 | = 0.138                               |
| Method                                  | Mixed Models Repeated Measures (MMRM) |
| Parameter estimate                      | Difference in Least Square Means      |
| Point estimate                          | -0.21                                 |
| Confidence interval                     |                                       |
| level                                   | 95 %                                  |
| sides                                   | 2-sided                               |
| lower limit                             | -0.48                                 |
| upper limit                             | 0.07                                  |

Notes:

[4] - ADSD at Week 52

#### **Secondary: Annualized Rate of Exacerbations Requiring Hospitalization and/or Emergency Department (ED) Visit up to 52 Weeks**

|                 |                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------|
| End point title | Annualized Rate of Exacerbations Requiring Hospitalization and/or Emergency Department (ED) Visit up to 52 Weeks |
|-----------------|------------------------------------------------------------------------------------------------------------------|

End point description:

Annualized Rate of exacerbations of asthma were defined as worsening of asthma which required use of systemic corticosteroids (CSs) and/or hospitalization and/or ED visit. For all participants, IV or oral steroids (e.g., prednisone) for at least 3 days or a single IM CS dose is required. For participants on maintenance systemic CSs, at least double the existing maintenance dose for at least 3 days is required. Exacerbations separated by less than 7 days will be treated as a continuation of the same exacerbation. Exacerbations Requiring Hospitalization and/or ED Visit are reported here. The analysis was performed on the FAS population that included all randomized participants who received at least 1 dose of study intervention excluding participants from 2 GCP violation sites.

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

End point timeframe:

Up to Week 52

|                                              |                     |                     |  |  |
|----------------------------------------------|---------------------|---------------------|--|--|
| <b>End point values</b>                      | GSK3511294          | Placebo             |  |  |
| Subject group type                           | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed                  | 252                 | 128                 |  |  |
| Units: Exacerbation per participant per year |                     |                     |  |  |
| number (confidence interval 95%)             | 0.05 (0.02 to 0.09) | 0.11 (0.05 to 0.22) |  |  |

#### **Statistical analyses**

|                                                                                                                                                                                                                                                                                   |                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                                 | Statistical Analysis           |
| Statistical analysis description:                                                                                                                                                                                                                                                 |                                |
| Analysis performed using a generalized linear model assuming a negative binomial distribution and covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region and baseline pre-bronchodilator percent predicted FEV1. |                                |
| Comparison groups                                                                                                                                                                                                                                                                 | GSK3511294 v Placebo           |
| Number of subjects included in analysis                                                                                                                                                                                                                                           | 380                            |
| Analysis specification                                                                                                                                                                                                                                                            | Pre-specified                  |
| Analysis type                                                                                                                                                                                                                                                                     | superiority                    |
| P-value                                                                                                                                                                                                                                                                           | = 0.087                        |
| Method                                                                                                                                                                                                                                                                            | Negative binomial distribution |
| Parameter estimate                                                                                                                                                                                                                                                                | Rate Ratio                     |
| Point estimate                                                                                                                                                                                                                                                                    | 0.42                           |
| Confidence interval                                                                                                                                                                                                                                                               |                                |
| level                                                                                                                                                                                                                                                                             | 95 %                           |
| sides                                                                                                                                                                                                                                                                             | 2-sided                        |
| lower limit                                                                                                                                                                                                                                                                       | 0.16                           |
| upper limit                                                                                                                                                                                                                                                                       | 1.13                           |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs), deaths and non-serious adverse events (non-SAEs) were collected from the start of the study intervention (Day 1) till follow up week 56.

Adverse event reporting additional description:

Safety analysis set included all participants who received at least 1 dose of study drug excluding participants from 2 GCP violation sites. One participant was randomized to receive GSK3511294 but received 1 dose of placebo in error & did not receive 2nd planned dose. This participant was included in actual placebo group for analysis.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 26.1 |
|--------------------|------|

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Participants received placebo SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma SOC treatment throughout the study.

|                       |            |
|-----------------------|------------|
| Reporting group title | GSK3511294 |
|-----------------------|------------|

Reporting group description:

Participants received a 100 mg dose of GSK3511294 SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma SOC treatment throughout the study.

| Serious adverse events                                              | Placebo           | GSK3511294       |  |
|---------------------------------------------------------------------|-------------------|------------------|--|
| Total subjects affected by serious adverse events                   |                   |                  |  |
| subjects affected / exposed                                         | 13 / 129 (10.08%) | 19 / 251 (7.57%) |  |
| number of deaths (all causes)                                       | 0                 | 0                |  |
| number of deaths resulting from adverse events                      |                   |                  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                   |                  |  |
| Small intestine adenocarcinoma                                      |                   |                  |  |
| subjects affected / exposed                                         | 0 / 129 (0.00%)   | 1 / 251 (0.40%)  |  |
| occurrences causally related to treatment / all                     | 0 / 0             | 0 / 1            |  |
| deaths causally related to treatment / all                          | 0 / 0             | 0 / 0            |  |
| Ovarian cancer                                                      |                   |                  |  |
| subjects affected / exposed                                         | 0 / 129 (0.00%)   | 1 / 251 (0.40%)  |  |
| occurrences causally related to treatment / all                     | 0 / 0             | 0 / 1            |  |
| deaths causally related to treatment / all                          | 0 / 0             | 0 / 0            |  |
| Metastases to peritoneum                                            |                   |                  |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Basal cell carcinoma                            |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Immune system disorders                         |                 |                 |  |
| Anaphylactic reaction                           |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Reproductive system and breast disorders        |                 |                 |  |
| Benign prostatic hyperplasia                    |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Respiratory, thoracic and mediastinal disorders |                 |                 |  |
| Asthma                                          |                 |                 |  |
| subjects affected / exposed                     | 6 / 129 (4.65%) | 7 / 251 (2.79%) |  |
| occurrences causally related to treatment / all | 0 / 8           | 0 / 12          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Investigations                                  |                 |                 |  |
| Alanine aminotransferase abnormal               |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Blood bilirubin abnormal                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| 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  |                 |                 |  |
| Accidental exposure to product                  |                 |                 |  |



|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Congenital, familial and genetic disorders      |                 |                 |  |
| Phimosi                                         |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cardiac disorders                               |                 |                 |  |
| Coronary artery disease                         |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Nervous system disorders                        |                 |                 |  |
| Epilepsy                                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Headache                                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Seizure                                         |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cerebral infarction                             |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastrointestinal disorders                      |                 |                 |  |
| Abdominal pain                                  |                 |                 |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Large intestine polyp                           |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal and urinary disorders                     |                 |                 |  |
| Nephrolithiasis                                 |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Ureterolithiasis                                |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Musculoskeletal and connective tissue disorders |                 |                 |  |
| Tenosynovitis stenosans                         |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Osteochondritis                                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Foot deformity                                  |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Spondylolisthesis                               |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| Infections and infestations                     |                 |                 |  |
| COVID-19                                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 129 (0.00%) | 1 / 251 (0.40%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia                                       |                 |                 |  |
| subjects affected / exposed                     | 2 / 129 (1.55%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Sepsis                                          |                 |                 |  |
| subjects affected / exposed                     | 1 / 129 (0.78%) | 0 / 251 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

Frequency threshold for reporting non-serious adverse events: 3 %

| <b>Non-serious adverse events</b>                     | Placebo           | GSK3511294         |  |
|-------------------------------------------------------|-------------------|--------------------|--|
| Total subjects affected by non-serious adverse events |                   |                    |  |
| subjects affected / exposed                           | 80 / 129 (62.02%) | 138 / 251 (54.98%) |  |
| Vascular disorders                                    |                   |                    |  |
| Hypertension                                          |                   |                    |  |
| subjects affected / exposed                           | 7 / 129 (5.43%)   | 7 / 251 (2.79%)    |  |
| occurrences (all)                                     | 8                 | 7                  |  |
| Nervous system disorders                              |                   |                    |  |
| Headache                                              |                   |                    |  |
| subjects affected / exposed                           | 10 / 129 (7.75%)  | 20 / 251 (7.97%)   |  |
| occurrences (all)                                     | 12                | 30                 |  |
| Dizziness                                             |                   |                    |  |
| subjects affected / exposed                           | 1 / 129 (0.78%)   | 8 / 251 (3.19%)    |  |
| occurrences (all)                                     | 1                 | 10                 |  |
| Gastrointestinal disorders                            |                   |                    |  |
| Diarrhoea                                             |                   |                    |  |
| subjects affected / exposed                           | 3 / 129 (2.33%)   | 8 / 251 (3.19%)    |  |
| occurrences (all)                                     | 3                 | 10                 |  |
| Nausea                                                |                   |                    |  |

|                                                                                       |                      |                        |  |
|---------------------------------------------------------------------------------------|----------------------|------------------------|--|
| subjects affected / exposed<br>occurrences (all)                                      | 4 / 129 (3.10%)<br>4 | 1 / 251 (0.40%)<br>1   |  |
| Respiratory, thoracic and mediastinal disorders                                       |                      |                        |  |
| Rhinitis allergic<br>subjects affected / exposed<br>occurrences (all)                 | 3 / 129 (2.33%)<br>3 | 18 / 251 (7.17%)<br>23 |  |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)                | 5 / 129 (3.88%)<br>5 | 3 / 251 (1.20%)<br>3   |  |
| Musculoskeletal and connective tissue disorders                                       |                      |                        |  |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)                        | 5 / 129 (3.88%)<br>5 | 14 / 251 (5.58%)<br>16 |  |
| Back pain<br>subjects affected / exposed<br>occurrences (all)                         | 6 / 129 (4.65%)<br>7 | 7 / 251 (2.79%)<br>7   |  |
| Infections and infestations                                                           |                      |                        |  |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)           | 4 / 129 (3.10%)<br>5 | 6 / 251 (2.39%)<br>8   |  |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 6 / 129 (4.65%)<br>6 | 21 / 251 (8.37%)<br>29 |  |
| Sinusitis<br>subjects affected / exposed<br>occurrences (all)                         | 6 / 129 (4.65%)<br>7 | 11 / 251 (4.38%)<br>11 |  |
| Rhinitis<br>subjects affected / exposed<br>occurrences (all)                          | 5 / 129 (3.88%)<br>6 | 7 / 251 (2.79%)<br>7   |  |
| Respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)       | 8 / 129 (6.20%)<br>4 | 5 / 251 (1.99%)<br>5   |  |
| Pharyngitis<br>subjects affected / exposed<br>occurrences (all)                       | 1 / 129 (0.78%)<br>1 | 10 / 251 (3.98%)<br>10 |  |
| Bronchitis                                                                            |                      |                        |  |

|                                   |                   |                   |  |
|-----------------------------------|-------------------|-------------------|--|
| subjects affected / exposed       | 12 / 129 (9.30%)  | 10 / 251 (3.98%)  |  |
| occurrences (all)                 | 12                | 11                |  |
| COVID-19                          |                   |                   |  |
| subjects affected / exposed       | 19 / 129 (14.73%) | 36 / 251 (14.34%) |  |
| occurrences (all)                 | 20                | 38                |  |
| Influenza                         |                   |                   |  |
| subjects affected / exposed       | 9 / 129 (6.98%)   | 5 / 251 (1.99%)   |  |
| occurrences (all)                 | 9                 | 5                 |  |
| Lower respiratory tract infection |                   |                   |  |
| subjects affected / exposed       | 5 / 129 (3.88%)   | 4 / 251 (1.59%)   |  |
| occurrences (all)                 | 8                 | 5                 |  |
| Nasopharyngitis                   |                   |                   |  |
| subjects affected / exposed       | 27 / 129 (20.93%) | 33 / 251 (13.15%) |  |
| occurrences (all)                 | 44                | 45                |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date           | Amendment    |
|----------------|--------------|
| 17 August 2021 | Amendment 01 |
| 05 April 2022  | Amendment 02 |

Notes:

---

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

---

### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/39248309>