



Clinical trial results:

A Randomised Double-Blind, Double-Dummy, Placebo-Controlled, Stratified, Parallel-Group, Multicentre, Dose Ranging Study to Evaluate the Efficacy and Safety of GSK2190915 Tablets Administered Once Daily, Fluticasone Propionate Inhalation Powder 100mcg Twice Daily and Montelukast 10mg Once Daily compared with Placebo for 8 Weeks in Adolescent and Adult Subjects with Persistent Asthma while Treated with Short Acting Beta2-agonist

Summary

EudraCT number	2010-019095-70
Trial protocol	RO BG
Global end of trial date	06 October 2011

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	22 July 2015

Trial information

Trial identification

Sponsor protocol code	LPA112186
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01147744
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

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	18 November 2011
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	06 October 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the efficacy, dose response and safety of four doses of GSK 2190915 (10mg, 30mg, 100mg and 300mg)

Protection of trial subjects:

A protocol amendment was issued restricting the study to females only following a finding from an interim histopathological assessment of the male reproductive tract from ongoing 6 month rat and 9 month dog toxicology studies. These findings related to testicular toxicity at high exposures of GSK2190915, the clinical significance of which was uncertain.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 June 2010
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	Poland: 96
Country: Number of subjects enrolled	Romania: 53
Country: Number of subjects enrolled	Bulgaria: 105
Country: Number of subjects enrolled	Japan: 84
Country: Number of subjects enrolled	Ukraine: 186
Country: Number of subjects enrolled	United States: 176
Worldwide total number of subjects	700
EEA total number of subjects	254

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)	48
Adults (18-64 years)	606
From 65 to 84 years	46
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants (par.) were screened (Visit 1) for eligibility, which included reversibility testing. Following screening and a 14-days Run-in Period, par. who met the eligibility criteria for randomization to study treatment at Visit 3 were randomly assigned to receive one of seven double-blind treatments for 8 weeks.

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, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received two tablets of placebo orally plus one dose of fluticasone propionate (FP) matching placebo twice daily (BID) via dry powder inhaler (DPI) in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally once daily (QD) in evening for the 8-Weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received two tablets of placebo orally plus one dose of fluticasone propionate (FP) matching placebo twice daily (BID) via dry powder inhaler (DPI) in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally once daily (QD) in evening for the 8-Weeks.

Arm title	GSK2190915, 10 mg, QD
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Arm description:

Participants received one tablet of 10 milligrams (mg) GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Arm type	Experimental
Investigational medicinal product name	GSK2190915
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg (1 tablet once daily morning)

Arm title	GSK2190915, 30 mg, QD
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Arm description:

Participants received one tablet of 30 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via

DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Arm type	Experimental
Investigational medicinal product name	GSK2190915
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 30 mg (1 tablet once daily morning)	
Arm title	GSK2190915, 100 mg, QD

Arm description:

Participants received one tablet of 100 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Arm type	Experimental
Investigational medicinal product name	GSK2190915
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 100 mg (1 tablet once daily morning)	
Arm title	GSK2190915, 300 mg, QD

Arm description:

Participants received one tablet of 100 mg GSK2190915 and one tablet of 200 mg GSK 2190915 orally QD plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo BID via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Arm type	Experimental
Investigational medicinal product name	GSK2190915
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 300 mg (2 tablets once daily morning)	
Arm title	FP, 100 µg, BID

Arm description:

Participants received one dose of FP 100 microgram (µg) BID via DPI plus two tablets of placebo in morning and another dose of FP 100 µg via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Arm type	Active comparator
Investigational medicinal product name	Fluticasone propionate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use
Dosage and administration details: 200 µg (100 µg inhaled morning and evening)	
Arm title	Montelukast, 10 mg, QD

Arm description:

Participants received two tablets of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast 10 mg orally

QD in evening for the 8-Weeks.

Arm type	Active comparator
Investigational medicinal product name	Montelukast
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

10 mg (1 capsule once daily evening)

Number of subjects in period 1	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD
Started	100	99	100
Completed	71	76	82
Not completed	29	23	18
Consent withdrawn by subject	8	4	2
Physician decision	-	1	1
Met Protocol-defined Stopping Criteria	1	-	-
Adverse event, non-fatal	1	2	3
Sponsor decision to amend protocol	7	4	2
Lost to follow-up	-	1	-
Lack of efficacy	11	11	9
Protocol deviation	1	-	1

Number of subjects in period 1	GSK2190915, 100 mg, QD	GSK2190915, 300 mg, QD	FP, 100 µg, BID
Started	100	101	103
Completed	82	76	83
Not completed	18	25	20
Consent withdrawn by subject	2	2	5
Physician decision	-	-	-
Met Protocol-defined Stopping Criteria	-	-	1
Adverse event, non-fatal	-	2	1
Sponsor decision to amend protocol	5	7	2
Lost to follow-up	-	-	-
Lack of efficacy	11	13	8
Protocol deviation	-	1	3

Number of subjects in period 1	Montelukast, 10 mg, QD
Started	97
Completed	78
Not completed	19

Consent withdrawn by subject	2
Physician decision	1
Met Protocol-defined Stopping Criteria	-
Adverse event, non-fatal	2
Sponsor decision to amend protocol	6
Lost to follow-up	-
Lack of efficacy	7
Protocol deviation	1

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Participants received two tablets of placebo orally plus one dose of fluticasone propionate (FP) matching placebo twice daily (BID) via dry powder inhaler (DPI) in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally once daily (QD) in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 10 mg, QD
Reporting group description: Participants received one tablet of 10 milligrams (mg) GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 30 mg, QD
Reporting group description: Participants received one tablet of 30 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 100 mg, QD
Reporting group description: Participants received one tablet of 100 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 300 mg, QD
Reporting group description: Participants received one tablet of 100 mg GSK2190915 and one tablet of 200 mg GSK 2190915 orally QD plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo BID via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	FP, 100 µg, BID
Reporting group description: Participants received one dose of FP 100 microgram (µg) BID via DPI plus two tablets of placebo in morning and another dose of FP 100 µg via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	Montelukast, 10 mg, QD
Reporting group description: Participants received two tablets of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast 10 mg orally QD in evening for the 8-Weeks.	

Reporting group values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD
Number of subjects	100	99	100
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	42.3 ± 16.13	40 ± 15.56	43.1 ± 16.17
Gender categorical Units: Subjects			
Female	88	91	94

Male	12	8	6
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Race, Customized Units: Subjects			
African American/African Heritage	6	12	10
American Indian or Alaska Native	0	0	0
Asian - Japanese Heritage	12	12	12
Asian - South East Asian Heritage	0	1	0
White - White/Caucasian/European Heritage	82	74	78

Reporting group values	GSK2190915, 100 mg, QD	GSK2190915, 300 mg, QD	FP, 100 µg, BID
Number of subjects	100	101	103
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	42.2	42.2	41.5
standard deviation	± 14.63	± 14.15	± 15.16
Gender categorical Units: Subjects			
Female	92	93	97
Male	8	8	6
Race, Customized Units: Subjects			
African American/African Heritage	9	9	7
American Indian or Alaska Native	2	1	1
Asian - Japanese Heritage	11	13	12
Asian - South East Asian Heritage	0	0	0
White - White/Caucasian/European Heritage	78	78	83

Reporting group values	Montelukast, 10 mg, QD	Total	
Number of subjects	97	700	
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	44.3		
standard deviation	± 14.97	-	
Gender categorical Units: Subjects			
Female	89	644	
Male	8	56	
Race, Customized Units: Subjects			
African American/African Heritage	9	62	
American Indian or Alaska Native	0	4	

Asian - Japanese Heritage	12	84	
Asian - South East Asian Heritage	0	1	
White - White/Caucasian/European Heritage	76	549	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Participants received two tablets of placebo orally plus one dose of fluticasone propionate (FP) matching placebo twice daily (BID) via dry powder inhaler (DPI) in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally once daily (QD) in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 10 mg, QD
Reporting group description: Participants received one tablet of 10 milligrams (mg) GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 30 mg, QD
Reporting group description: Participants received one tablet of 30 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 100 mg, QD
Reporting group description: Participants received one tablet of 100 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	GSK2190915, 300 mg, QD
Reporting group description: Participants received one tablet of 100 mg GSK2190915 and one tablet of 200 mg GSK 2190915 orally QD plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo BID via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	FP, 100 µg, BID
Reporting group description: Participants received one dose of FP 100 microgram (µg) BID via DPI plus two tablets of placebo in morning and another dose of FP 100 µg via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.	
Reporting group title	Montelukast, 10 mg, QD
Reporting group description: Participants received two tablets of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast 10 mg orally QD in evening for the 8-Weeks.	

Primary: Mean change from Baseline to the end of the 8-Week treatment period in trough FEV1

End point title	Mean change from Baseline to the end of the 8-Week treatment period in trough FEV1
End point description: Pulmonary function was measured by forced expiratory volume in one second (FEV1), defined as the maximal amount of air that can be forcefully exhaled in one second. Trough FEV1 is defined as the morning (AM) pre-dose and pre-rescue bronchodilator FEV1 at the clinic visit. Baseline was the pre-dose value obtained at Visit 3. Change from Baseline was calculated as the end of Week 8 value minus the Baseline value. The analysis was performed using an analysis of covariance (ANCOVA) model with covariates of Baseline trough FEV1, age, gender, country and smoking status. The last observation carried forward (LOCF) method was used to impute missing data. Intent-to-Treat (ITT) Population is comprised of all par. randomized to treatment who received at least one dose of double-blind study medication.	
End point type	Primary

End point timeframe:

Baseline and Week 8

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98 ^[1]	96 ^[2]	99 ^[3]	100 ^[4]
Units: Liters				
least squares mean (standard error)	0.12 (± 0.04)	0.18 (± 0.04)	0.23 (± 0.04)	0.19 (± 0.04)

Notes:

[1] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[2] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[3] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[4] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98 ^[5]	100 ^[6]	95 ^[7]	
Units: Liters				
least squares mean (standard error)	0.19 (± 0.04)	0.31 (± 0.04)	0.19 (± 0.04)	

Notes:

[5] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[6] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[7] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.326
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.056
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.06
upper limit	0.17

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.066
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.104
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.22

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.224
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.069
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.18

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.271
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.062
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.17

Statistical analysis title	Statistical Analysis 5
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Comparison groups	Placebo v FP, 100 µg, BID
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.189
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	0.3

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	193
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.18

Secondary: Mean change from Baseline in daily PM PEF averaged over the 8-Week treatment period

End point title	Mean change from Baseline in daily PM PEF averaged over the 8-Week treatment period
End point description:	
Peak expiratory flow (PEF) is defined as the maximum airflow during a forced expiration beginning with the lungs fully inflated. Change from Baseline was calculated as the value of the averaged PEF daily (pre-dose and pre-rescue bronchodilator) evening (PM) over the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, trough PM PEF, age, gender, country and smoking status.	
End point type	Secondary
End point timeframe:	
From Baseline up to Week 8	

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[8]	99 ^[9]	99 ^[10]	100 ^[11]
Units: Liters per minute				
least squares mean (standard error)	8.01 (± 3.19)	7.62 (± 3.19)	9.37 (± 3.2)	6.21 (± 3.17)

Notes:

[8] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[9] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[10] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[11] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[12]	101 ^[13]	97 ^[14]	
Units: Liters per minute				
least squares mean (standard error)	10.33 (± 3.15)	10.46 (± 3.16)	8.53 (± 3.24)	

Notes:

[12] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[13] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[14] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.932
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.385
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.25
upper limit	8.48

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.762
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.367

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	10.23

Statistical analysis title	Statistical Analysis 3
Comparison groups	GSK2190915, 100 mg, QD v Placebo
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.689
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.798
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.62
upper limit	7.03

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.605
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.321
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.49
upper limit	11.13

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.584
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.36
upper limit	11.28

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.907
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.529
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.4
upper limit	9.45

Secondary: Mean change from Baseline in daily trough AM PEF averaged over the 8-Week treatment period

End point title	Mean change from Baseline in daily trough AM PEF averaged over the 8-Week treatment period
End point description: The PEF is defined as the maximum airflow during a forced expiration beginning with the lungs fully inflated. Trough AM PEF is defined as the AM pre-dose and pre-rescue bronchodilator at the clinic visit. Change from Baseline was calculated as the value of the averaged PEF daily (pre-dose and pre-rescue bronchodilator) AM over the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, trough AM PEF, age, gender, country and smoking status.	
End point type	Secondary
End point timeframe: From Baseline up to Week 8	

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[15]	99 ^[16]	99 ^[17]	100 ^[18]
Units: Liters per minute				
least squares mean (standard error)	11.77 (± 3.28)	13.23 (± 3.28)	15.52 (± 3.29)	8.72 (± 3.26)

Notes:

[15] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[16] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[17] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[18] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[19]	100 ^[20]	97 ^[21]	
Units: Liters per minute				
least squares mean (standard error)	16.35 (± 3.24)	15.25 (± 3.26)	17.38 (± 3.32)	

Notes:

[19] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[20] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[21] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.753
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.463
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.65
upper limit	10.58

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.419
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	3.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.36
upper limit	12.87

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.51
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-3.046
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.12
upper limit	6.03

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.32
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	4.585
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.47
upper limit	13.64

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.452
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	3.484
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.61
upper limit	12.58

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.229
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	5.615
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.55
upper limit	14.78

Secondary: Mean change from Baseline in the percentage of symptom-free days averaged over the 8-Week treatment period

End point title	Mean change from Baseline in the percentage of symptom-free days averaged over the 8-Week treatment period
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End point description:

Asthma symptoms were recorded in a daily electronic diary (eDiary) by the par. every day in the evening at bedtime and before taking any rescue or study medication and before the assessment of the PEF measurement. Participant's responses to evening assessments indicated no symptoms were considered to be symptom free. For participants, the symptom free days were assessed during the 8-Week treatment period. Change from Baseline was calculated as the averaged of symptom-free days during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 8

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[22]	99 ^[23]	99 ^[24]	100 ^[25]
Units: Percentage of symptom-free days				
least squares mean (standard error)	13.98 (± 2.84)	15.15 (± 2.84)	18.54 (± 2.84)	15.31 (± 2.82)

Notes:

[22] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[23] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[24] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[25] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[26]	101 ^[27]	97 ^[28]	
Units: Percentage of symptom-free days				
least squares mean (standard error)	14.06 (± 2.81)	22.18 (± 2.81)	16.87 (± 2.87)	

Notes:

[26] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[27] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[28] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.771
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.169
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.73
upper limit	9.07

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.257
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	4.56

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.33
upper limit	12.45

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.741
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.326
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.54
upper limit	9.19

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.983
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.083
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.76
upper limit	7.93

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.041
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	8.204
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	16.07

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.475
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.891
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.05
upper limit	10.83

Secondary: Mean change from Baseline in the percentage of symptom-free nights averaged over the 8-Week treatment period

End point title	Mean change from Baseline in the percentage of symptom-free nights averaged over the 8-Week treatment period
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End point description:

Asthma symptoms were recorded in a daily eDairy by the par. every day in the morning upon rising and before taking any rescue or study medication and before the assessment of the PEF measurement. Participant's responses to the morning assessments indicated no symptoms were considered to be symptom free. For participants, the symptom free nights were assessed during the 8-Week treatment period. Change from Baseline was calculated as the averaged of symptom-free nights during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 8

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[29]	99 ^[30]	99 ^[31]	100 ^[32]
Units: Percentage of symptom-free nights				
least squares mean (standard error)	13.99 (± 2.9)	14.83 (± 2.9)	16.71 (± 2.9)	16.12 (± 2.88)

Notes:

[29] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[30] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[31] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[32] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[33]	100 ^[34]	97 ^[35]	
Units: Percentage of symptom-free nights				
least squares mean (standard error)	12.21 (± 2.86)	19.94 (± 2.88)	19.39 (± 2.93)	

Notes:

[33] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[34] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[35] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.838
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.837
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.22
upper limit	8.89

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.508
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.715

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.33
upper limit	10.76

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.603
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.124
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	10.14

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.662
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.781
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.78
upper limit	6.22

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.146
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	5.949
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.08
upper limit	13.98

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.191
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	5.394
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.69
upper limit	13.48

Secondary: Mean change from Baseline in the percentage of rescue-free days averaged over the 8-Week treatment period

End point title	Mean change from Baseline in the percentage of rescue-free days averaged over the 8-Week treatment period
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End point description:

The number of inhalations of rescue salbutamol/albuterol inhalation aerosol used during the day and night was recorded by the par. in a eDiary. The time span during which the par. did not have to take any rescue medication (medication intended to relieve symptoms immediately) was considered to be a rescue-free period. For participants, the rescue-free days were assessed during the 8-Week treatment period. Change from Baseline was calculated as the averaged of rescue-free days during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 8

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[36]	99 ^[37]	99 ^[38]	100 ^[39]
Units: Percentage of rescue-free days				
least squares mean (standard error)	16.8 (± 3.1)	22.91 (± 3.1)	20.91 (± 3.09)	18.95 (± 3.08)

Notes:

[36] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[37] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[38] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[39] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[40]	101 ^[41]	97 ^[42]	
Units: Percentage of rescue-free days				
least squares mean (standard error)	18.51 (± 3.06)	26.39 (± 3.06)	23.55 (± 3.13)	

Notes:

[40] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[41] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[42] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.164
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	6.106
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	14.71

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.349
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	4.106

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.49
upper limit	12.7

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.623
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.148
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.42
upper limit	10.72

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.694
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.713
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.84
upper limit	10.26

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.028
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	9.592
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	18.15

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.125
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	6.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.89
upper limit	15.38

Secondary: Mean change from Baseline in the percentage of rescue-free nights averaged over the 8-Week treatment period

End point title	Mean change from Baseline in the percentage of rescue-free nights averaged over the 8-Week treatment period
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End point description:

The number of inhalations of rescue salbutamol/albuterol inhalation aerosol used during the day and night was recorded by the par. in a eDiary. The time span during which the par. did not have to take any rescue medication (medication intended to relieve symptoms immediately) was considered to be a rescue-free period. For participants, the rescue-free nights were assessed during the 8-Week treatment period. Change from Baseline was calculated as the averaged of rescue-free nights during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 8

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[43]	99 ^[44]	99 ^[45]	100 ^[46]
Units: Percentage of rescue-free nights				
least squares mean (standard error)	16.93 (± 3.04)	19.28 (± 3.04)	17.36 (± 3.03)	19.63 (± 3.02)

Notes:

[43] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[44] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[45] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[46] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[47]	100 ^[48]	97 ^[49]	
Units: Percentage of rescue-free nights				
least squares mean (standard error)	15.71 (± 3)	24.42 (± 3.02)	20.54 (± 3.07)	

Notes:

[47] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[48] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[49] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.585
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.346
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.09
upper limit	10.78

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.92
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.431

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	8.86

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.528
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	2.702
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	11.11

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.776
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.218
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.6
upper limit	7.17

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.081
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	7.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.92
upper limit	15.9

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.403
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	3.611
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.87
upper limit	12.09

Secondary: Mean change from Baseline in day-time asthma symptom score over the 8-Week treatment period

End point title	Mean change from Baseline in day-time asthma symptom score over the 8-Week treatment period
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End point description:

Participants recorded their day-time asthma symptom score in the eDiary each PM at bedtime and before taking any rescue or study medication and before assessing the PEF measurement during the 8-Week treatment period. Day-time asthma symptom scores, as: 0=no asthma symptoms, 1=one episode of short-time asthma symptoms, 2=two or more episodes of short-time asthma symptoms, 3=asthma symptoms occurring during most part of daytime without interference with daily life activities, 4=asthma symptoms occurring during most part of daytime with interference with daily life activities, 5=severe asthma symptoms that disable working or perform normal daily activities. Change from Baseline was calculated as the averaged of day-time asthma symptom score during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 8

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[50]	99 ^[51]	99 ^[52]	100 ^[53]
Units: Day-time symptom scores on a scale				
least squares mean (standard error)	-0.34 (± 0.06)	-0.34 (± 0.06)	-0.5 (± 0.06)	-0.36 (± 0.06)

Notes:

[50] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[51] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[52] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[53] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[54]	101 ^[55]	97 ^[56]	
Units: Day-time symptom scores on a scale				
least squares mean (standard error)	-0.34 (± 0.06)	-0.43 (± 0.06)	-0.41 (± 0.06)	

Notes:

[54] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[55] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[56] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.951
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.005
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.16

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD

Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.043
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.166
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	-0.01

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.734
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.028
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.13

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.972
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.003
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.16

Statistical analysis title	Statistical Analysis 5
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Comparison groups	Placebo v FP, 100 µg, BID
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.238
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.097
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.06

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.36
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-0.075
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	0.09

Secondary: Mean change from Baseline in night-time asthma symptom score over the 8-Week treatment period

End point title	Mean change from Baseline in night-time asthma symptom score over the 8-Week treatment period
End point description:	Participants recorded their night-time asthma symptom score in the eDiary each AM upon rising and before taking any rescue or study medication and before assessing the PEF measurement during the 8-Week treatment period. Night-time asthma symptom scores, as: 0=no asthma symptoms, 1= one awakening or waking early due to asthma symptoms, 2= two or more awakenings due to asthma symptoms (including waking early), 3= asthma symptoms almost prevented the participant from sleeping, 4= severe asthma symptoms completely prevented from sleeping. Change from Baseline was calculated as the averaged of night-time asthma symptom score during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.
End point type	Secondary
End point timeframe:	
From Baseline up to Week 8	

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[57]	99 ^[58]	99 ^[59]	100 ^[60]
Units: Night-time symptom scores on a scale				
least squares mean (standard error)	-0.23 (± 0.05)	-0.21 (± 0.05)	-0.33 (± 0.05)	-0.26 (± 0.05)

Notes:

[57] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[58] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[59] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[60] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[61]	100 ^[62]	97 ^[63]	
Units: Night-time symptom scores on a scale				
least squares mean (standard error)	-0.22 (± 0.05)	-0.29 (± 0.05)	-0.32 (± 0.05)	

Notes:

[61] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[62] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[63] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.692
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.028
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.17

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD

Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.176
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.096
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	0.04

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.768
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.021
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.12

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.887
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.15

Statistical analysis title	Statistical Analysis 5
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Comparison groups	Placebo v FP, 100 µg, BID
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.471
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.051
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.09

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.248
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-0.083
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.06

Secondary: Mean change from Baseline in day-time rescue SABA usage over the 8-Week treatment period

End point title	Mean change from Baseline in day-time rescue SABA usage over the 8-Week treatment period
End point description:	
<p>The number of inhalations of rescue short acting beta2-agonist (SABA), salbutamol/albuterol inhalation aerosol used during the day and night was recorded by the par. in a eDiary. Participants who used salbutamol/albuterol inhalation aerosol at day-time were assessed during the 8-Week treatment period. Change from Baseline was calculated as the averaged number of day-time salbutamol/albuterol inhalation aerosol used during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.</p>	
End point type	Secondary
End point timeframe:	
From Baseline up to Week 8	

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[64]	99 ^[65]	99 ^[66]	100 ^[67]
Units: Day-time number of inhalations				
least squares mean (standard error)	-0.42 (± 0.07)	-0.55 (± 0.07)	-0.68 (± 0.07)	-0.5 (± 0.07)

Notes:

[64] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[65] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[66] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[67] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[68]	101 ^[69]	97 ^[70]	
Units: Day-time number of inhalations				
least squares mean (standard error)	-0.47 (± 0.07)	-0.67 (± 0.07)	-0.63 (± 0.07)	

Notes:

[68] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[69] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[70] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.209
Method	ANCOVA
Parameter estimate	Median difference (final values)
Point estimate	-0.131
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	0.07

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.264

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	-0.06

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.464
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.076
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	0.13

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.662
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.045
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.16

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.018
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.245
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	-0.04

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.047
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.207
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	0

Secondary: Mean change from Baseline in night-time rescue SABA usage over the 8-Week treatment period

End point title	Mean change from Baseline in night-time rescue SABA usage over the 8-Week treatment period
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End point description:

The numbers of inhalations of rescue SABA, salbutamol/albuterol inhalation aerosol used during the day and night was recorded by the par. in a eDiary. Participants who used salbutamol/albuterol inhalation aerosol at night-time were assessed during the 8-Week treatment period. Change from Baseline was calculated as the averaged number of night-time salbutamol/albuterol inhalation aerosol used during the 8-Week treatment period minus the Baseline value (defined as the last 7 days prior to randomization of the par.). Analysis was performed using ANCOVA with covariates of Baseline, age, gender, country and smoking status.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 8

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99 ^[71]	99 ^[72]	99 ^[73]	100 ^[74]
Units: Night-time number of inhalations				
least squares mean (standard error)	-0.3 (± 0.07)	-0.4 (± 0.07)	-0.44 (± 0.07)	-0.42 (± 0.07)

Notes:

[71] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[72] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[73] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[74] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[75]	100 ^[76]	97 ^[77]	
Units: Night-time number of inhalations				
least squares mean (standard error)	-0.3 (± 0.07)	-0.47 (± 0.07)	-0.46 (± 0.07)	

Notes:

[75] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[76] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

[77] - ITT Population. Only those par. with analyzable data at the indicated time point were assessed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.098
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	0.09

Statistical analysis title	Statistical Analysis 2
Comparison groups	GSK2190915, 30 mg, QD v Placebo
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.145
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.138

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.32
upper limit	0.05

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.19
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.123
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.31
upper limit	0.06

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.002
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.18

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID

Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.07
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.171
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	0.01

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.095
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.158
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	0.03

Secondary: Number of participants who withdrew due to lack of efficacy during the 8-Week treatment period

End point title	Number of participants who withdrew due to lack of efficacy during the 8-Week treatment period
End point description:	
<p>The participants who met any of the following withdrawal criteria were considered to be withdrawn due to lack of efficacy: 1) Clinic FEV1 below stability limit calculated at Visit 3. 2) More than three days between two consecutive visits, PEF has fallen below stability limit calculated at Visit 3. 3) Use of 12 or more inhalations of SABA per day for more than two days between consecutive visits. 4) Asthma exacerbation defined as worsening requiring any treatment other than study medication or rescue medication. This included requiring the use of systemic or inhaled corticosteroids and /or emergency room visit or hospitalization for the treatment of asthma. The stability limit was calculated as best pre-salbutamol/albuterol FEV1 at Visit 3 x 80 percent (%).</p>	
End point type	Secondary
End point timeframe:	
8 Weeks	

End point values	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD	GSK2190915, 100 mg, QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100 ^[78]	99 ^[79]	100 ^[80]	100 ^[81]
Units: Participants	11	11	9	11

Notes:

[78] - ITT Population

[79] - ITT Population

[80] - ITT Population

[81] - ITT Population

End point values	GSK2190915, 300 mg, QD	FP, 100 µg, BID	Montelukast, 10 mg, QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101 ^[82]	103 ^[83]	97 ^[84]	
Units: Participants	13	8	7	

Notes:

[82] - ITT Population

[83] - ITT Population

[84] - ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v GSK2190915, 10 mg, QD
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v GSK2190915, 30 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.814
Method	Fisher exact

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v GSK2190915, 100 mg, QD
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v GSK2190915, 300 mg, QD
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.828
Method	Fisher exact

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v FP, 100 µg, BID
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.477
Method	Fisher exact

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v Montelukast, 10 mg, QD
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.46
Method	Fisher exact

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from the start of administration of the study drug until the follow-up contact (up to Week 9).

Adverse event reporting additional description:

SAEs and non-serious AEs were reported for members of the ITT population, comprised of all participants who were randomized to treatment, and received at least one dose of double-blind study medication.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received two tablets of placebo orally plus one dose of fluticasone propionate (FP) matching placebo twice daily (BID) via dry powder inhaler (DPI) in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally once daily (QD) in evening for the 8-Weeks.

Reporting group title	GSK2190915, 10 mg, QD
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Reporting group description:

Participants received one tablet of 10 milligrams (mg) GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Reporting group title	GSK2190915, 30 mg, QD
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Reporting group description:

Participants received one tablet of 30 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Reporting group title	GSK2190915, 100 mg, QD
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Reporting group description:

Participants received one tablet of 100 mg GSK2190915 orally QD and one tablet of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Reporting group title	GSK2190915, 300 mg, QD
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Reporting group description:

Participants received one tablet of 100 mg GSK2190915 and one tablet of 200 mg GSK2190915 orally QD plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo BID via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Reporting group title	FP, 100 µg, BID
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Reporting group description:

Participants received one dose of FP 100 microgram (µg) BID via DPI plus two tablets of placebo in morning and another dose of FP 100 µg via DPI plus one capsule of montelukast matching placebo orally QD in evening for the 8-Weeks.

Reporting group title	Montelukast, 10 mg, QD
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Reporting group description:

Participants received two tablets of placebo orally plus one dose of FP matching placebo BID via DPI in morning and another dose of FP matching placebo via DPI plus one capsule of montelukast 10 mg orally QD in evening for the 8-Weeks.

Serious adverse events	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 100 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Cartilage injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK2190915, 100 mg, QD	GSK2190915, 300 mg, QD	FP, 100 µg, BID
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 100 (1.00%)	0 / 101 (0.00%)	1 / 103 (0.97%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Cartilage injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 101 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 101 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Small intestinal obstruction subjects affected / exposed	1 / 100 (1.00%)	0 / 101 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Montelukast, 10 mg, QD		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 97 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Cartilage injury			
subjects affected / exposed	0 / 97 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	0 / 97 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 97 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Placebo	GSK2190915, 10 mg, QD	GSK2190915, 30 mg, QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 100 (10.00%)	13 / 99 (13.13%)	6 / 100 (6.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 100 (3.00%)	7 / 99 (7.07%)	2 / 100 (2.00%)
occurrences (all)	3	7	2
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	5 / 100 (5.00%) 5	6 / 99 (6.06%) 6	3 / 100 (3.00%) 3
Pharyngitis subjects affected / exposed occurrences (all)	2 / 100 (2.00%) 2	0 / 99 (0.00%) 0	1 / 100 (1.00%) 1

Non-serious adverse events	GSK2190915, 100 mg, QD	GSK2190915, 300 mg, QD	FP, 100 µg, BID
Total subjects affected by non-serious adverse events subjects affected / exposed	9 / 100 (9.00%)	9 / 101 (8.91%)	14 / 103 (13.59%)
Nervous system disorders Headache subjects affected / exposed occurrences (all)	4 / 100 (4.00%) 4	4 / 101 (3.96%) 4	9 / 103 (8.74%) 9
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 100 (2.00%) 2	5 / 101 (4.95%) 5	5 / 103 (4.85%) 5
Pharyngitis subjects affected / exposed occurrences (all)	3 / 100 (3.00%) 3	0 / 101 (0.00%) 0	0 / 103 (0.00%) 0

Non-serious adverse events	Montelukast, 10 mg, QD		
Total subjects affected by non-serious adverse events subjects affected / exposed	15 / 97 (15.46%)		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	9 / 97 (9.28%) 9		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	5 / 97 (5.15%) 5		
Pharyngitis subjects affected / exposed occurrences (all)	1 / 97 (1.03%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 October 2010	The amendment restricted the study to females only following a finding from an interim histopathological assessment of the male reproductive tract from ongoing 6 month rat and 9 month dog toxicology studies. These findings related to testicular toxicity at high exposures of GSK2190915, the clinical significance of which was uncertain.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported