



Clinical trial results:

A Phase IIb, Double-Blind, Placebo-Controlled, Dose-Adaptive, Study of the Efficacy and Safety of GSK3196165 in Combination with Methotrexate Therapy, in Subjects with Active Moderate-Severe Rheumatoid Arthritis Despite Treatment with Methotrexate

Summary

EudraCT number	2014-003453-34
Trial protocol	EE DE HU CZ ES GB PL IT
Global end of trial date	29 December 2017

Results information

Result version number	v1
This version publication date	02 January 2019
First version publication date	02 January 2019

Trial information

Trial identification

Sponsor protocol code	201755
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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 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	29 March 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of GSK3196165

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 July 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Ukraine: 53
Country: Number of subjects enrolled	Poland: 42
Country: Number of subjects enrolled	Russian Federation: 34
Country: Number of subjects enrolled	Czech Republic: 30
Country: Number of subjects enrolled	Mexico: 17
Country: Number of subjects enrolled	Bulgaria: 14
Country: Number of subjects enrolled	South Africa: 11
Country: Number of subjects enrolled	Estonia: 9
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	Germany: 1
Worldwide total number of subjects	222
EEA total number of subjects	102

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	198
From 65 to 84 years	24
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at a total of 60 sites in 12 countries: Ukraine (11), Poland (10), Russian Federation (10), Mexico (6), Czech Republic (5), Bulgaria (4), South Africa (3), Hungary (3), Estonia (2), Canada (2), United Kingdom (2), and Germany (2) from 23-July-2015 until 29-December-2017.

Pre-assignment

Screening details:

A total of 526 participants were screened of which 304 were screen failures and 222 participants were enrolled in the study.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo liquid (sterile 0.9% weight/volume) sodium chloride solution) 0.6 milliliter (mL) drawn into a small (1 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with methotrexate (MTX) tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 milligram (mg)/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

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:

A 0.9% weight by volume (w/v) sodium chloride solution will be used as placebo. Placebo will be administered subcutaneously into thigh or abdomen.

Investigational medicinal product name	Methotrexate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Methotrexate will be available in tablet or liquid dosage forms to be given orally or administered as subcutaneous injection.

Investigational medicinal product name	GSK3196165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3196165 will be available as liquid dosage form to be administered subcutaneously into thigh or

abdomen.

Investigational medicinal product name	Folic (or folinic) acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Folic acid will be available as capsule, tablet or liquid form to be taken orally.

Arm title	GSK3196165 22.5 mg
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Arm description:

Participants received GSK3196165 22.5 mg (0.15 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Arm type	Experimental
Investigational medicinal product name	GSK3196165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3196165 will be available as liquid dosage form to be administered subcutaneously into thigh or abdomen.

Investigational medicinal product name	Methotrexate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Methotrexate will be available in tablet or liquid dosage forms to be given orally or administered as subcutaneous injection.

Investigational medicinal product name	Folic (or folinic) acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Folic acid will be available as capsule, tablet or liquid form to be taken orally.

Arm title	GSK3196165 45 mg
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Arm description:

Participants received GSK3196165 45 mg (0.3 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Arm type	Experimental
Investigational medicinal product name	GSK3196165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3196165 will be available as liquid dosage form to be administered subcutaneously into thigh or abdomen.

Investigational medicinal product name	Folic (or folinic) acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Folic acid will be available as capsule, tablet or liquid form to be taken orally.

Investigational medicinal product name	Methotrexate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Methotrexate will be available in tablet or liquid dosage forms to be given orally or administered as subcutaneous injection.

Arm title	GSK3196165 90 mg
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Arm description:

Participants received GSK3196165 90 mg (0.6 mL) liquid drawn into a small (1 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Arm type	Experimental
Investigational medicinal product name	GSK3196165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3196165 will be available as liquid dosage form to be administered subcutaneously into thigh or abdomen.

Investigational medicinal product name	Folic (or folinic) acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Folic acid will be available as capsule, tablet or liquid form to be taken orally.

Investigational medicinal product name	Methotrexate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Methotrexate will be available in tablet or liquid dosage forms to be given orally or administered as subcutaneous injection.

Arm title	GSK3196165 135 mg
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Arm description:

Participants received GSK3196165 135 mg (0.9 mL) liquid drawn into a small (1 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets

(orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Arm type	Experimental
Investigational medicinal product name	GSK3196165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3196165 will be available as liquid dosage form to be administered subcutaneously into thigh or abdomen.

Investigational medicinal product name	Methotrexate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Methotrexate will be available in tablet or liquid dosage forms to be given orally or administered as subcutaneous injection.

Investigational medicinal product name	Folic (or folinic) acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Folic acid will be available as capsule, tablet or liquid form to be taken orally.

Arm title	GSK3196165 180 mg
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Arm description:

Participants received GSK3196165 180 mg (1.2 mL) liquid drawn into a small (2 mL/3 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Arm type	Experimental
Investigational medicinal product name	GSK3196165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3196165 will be available as liquid dosage form to be administered subcutaneously into thigh or abdomen.

Investigational medicinal product name	Methotrexate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Methotrexate will be available in tablet or liquid dosage forms to be given orally or administered as subcutaneous injection.

Investigational medicinal product name	Folic (or folinic) acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Folic acid will be available as capsule, tablet or liquid form to be taken orally.

Number of subjects in period 1	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg
Started	37	37	37
Completed	25	23	27
Not completed	12	14	10
Consent withdrawn by subject	1	5	4
Adverse event, non-fatal	1	1	-
Protocol defined stopping criteria	7	4	3
Lost to follow-up	-	-	2
Lack of efficacy	1	3	1
Protocol deviation	2	1	-

Number of subjects in period 1	GSK3196165 90 mg	GSK3196165 135 mg	GSK3196165 180 mg
Started	37	37	37
Completed	27	25	23
Not completed	10	12	14
Consent withdrawn by subject	4	5	3
Adverse event, non-fatal	1	-	2
Protocol defined stopping criteria	5	3	3
Lost to follow-up	-	-	1
Lack of efficacy	-	4	4
Protocol deviation	-	-	1

Baseline characteristics

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received placebo liquid (sterile 0.9% weight/volume) sodium chloride solution) 0.6 milliliter (mL) drawn into a small (1 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with methotrexate (MTX) tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 milligram (mg)/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 22.5 mg
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Reporting group description:

Participants received GSK3196165 22.5 mg (0.15 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 45 mg
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Reporting group description:

Participants received GSK3196165 45 mg (0.3 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 90 mg
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Reporting group description:

Participants received GSK3196165 90 mg (0.6 mL) liquid drawn into a small (1 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 135 mg
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Reporting group description:

Participants received GSK3196165 135 mg (0.9 mL) liquid drawn into a small (1 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 180 mg
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Reporting group description:

Participants received GSK3196165 180 mg (1.2 mL) liquid drawn into a small (2 mL/3 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg
Number of subjects	37	37	37

Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	32	34	31
From 65-84 years	5	3	6
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	50.0	48.4	52.8
standard deviation	± 11.33	± 11.31	± 12.22
Sex: Female, Male Units: Subjects			
Female	28	30	33
Male	9	7	4
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	2	3	1
Black or African American	0	3	0
White	34	30	35
American Indian/ Alaskan Native+White	1	0	1
Black or African American+White	0	1	0

Reporting group values	GSK3196165 90 mg	GSK3196165 135 mg	GSK3196165 180 mg
Number of subjects	37	37	37
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	31	36	34
From 65-84 years	6	1	3
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	52.7	47.1	52.3
standard deviation	± 11.28	± 10.04	± 10.76
Sex: Female, Male Units: Subjects			
Female	27	33	29
Male	10	4	8

Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaskan Native	2	2	1
Black or African American	0	0	0
White	35	34	35
American Indian/ Alaskan Native+White	0	0	0
Black or African American+White	0	1	1

Reporting group values	Total		
Number of subjects	222		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	198		
From 65-84 years	24		
85 years and over	0		
Age Continuous			
Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: Subjects			
Female	180		
Male	42		
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaskan Native	11		
Black or African American	3		
White	203		
American Indian/ Alaskan Native+White	2		
Black or African American+White	3		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received placebo liquid (sterile 0.9% weight/volume) sodium chloride solution) 0.6 milliliter (mL) drawn into a small (1 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with methotrexate (MTX) tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 milligram (mg)/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.	
Reporting group title	GSK3196165 22.5 mg
Reporting group description:	
Participants received GSK3196165 22.5 mg (0.15 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.	
Reporting group title	GSK3196165 45 mg
Reporting group description:	
Participants received GSK3196165 45 mg (0.3 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.	
Reporting group title	GSK3196165 90 mg
Reporting group description:	
Participants received GSK3196165 90 mg (0.6 mL) liquid drawn into a small (1 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.	
Reporting group title	GSK3196165 135 mg
Reporting group description:	
Participants received GSK3196165 135 mg (0.9 mL) liquid drawn into a small (1 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/ divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.	
Reporting group title	GSK3196165 180 mg
Reporting group description:	
Participants received GSK3196165 180 mg (1.2 mL) liquid drawn into a small (2 mL/3 mL syringe) administered subcutaneously in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.	

Primary: Percentage of participants who achieved disease activity score for 28 different joints with C-reactive protein value (DAS28{CRP}) remission (DAS28 <2.6) at Week 24

End point title	Percentage of participants who achieved disease activity score for 28 different joints with C-reactive protein value (DAS28{CRP}) remission (DAS28 <2.6) at Week 24
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End point description:

DAS28 is a modification of the original DAS and is based on a count of 28 swollen and tender joints and is used to evaluate a participant's response to treatment. DAS 28 CRP utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal- phalangeal I-V, proximal interphalangeal I-V and knees and is calculated using the following formula: $DAS28 (CRP) = 0.56 \cdot \sqrt{(TJC28)} + 0.28 \cdot \sqrt{(SJC28)} + 0.014 \cdot GH + 0.36 \cdot \ln(CRP + 1) + 0.96$. Where TJC – Tender joint Count, SJC= Swollen Joint Count, (GH=participant assessment of disease activity using a 100 millimeter [mm] visual analogue scale with 0 = best, 100 = worst) and CRP= C reactive Protein (in [milligrams/liter] mg/L). It ranges between 0.96 and 8.61. High score (worse outcome) and low scores (better outcome). ITT population comprised of all participants who were randomized to treatment and who received at least one dose of study treatment (GSK3196165 or placebo).

End point type	Primary
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End point timeframe:

Week 24

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[1]	37 ^[2]	37 ^[3]	37 ^[4]
Units: Percentage of participants				
number (not applicable)	3	5	16	19

Notes:

[1] - ITT Population

[2] - ITT Population

[3] - ITT Population

[4] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[5]	37 ^[6]		
Units: Percentage of participants				
number (not applicable)	14	14		

Notes:

[5] - ITT Population

[6] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
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Statistical analysis description:

95% Confidence Intervals (CI) were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	GSK3196165 22.5 mg v Placebo
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.547
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	24.52

Statistical analysis title	Stat 2
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Statistical analysis description:

95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.077
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	62.44

Statistical analysis title	Stat 3
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Statistical analysis description:

95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.053
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	8.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	72.14

Statistical analysis title	Stat 4
Statistical analysis description: 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.122
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	51.4

Statistical analysis title	Stat 5
Statistical analysis description: 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.134
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	48.83

Secondary: Change from Baseline in DAS28(CRP) at Week 12

End point title	Change from Baseline in DAS28(CRP) at Week 12
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End point description:

DAS28 is a modification of the original DAS and is based on a count of 28 swollen and tender joints and is used to evaluate a participant's response to treatment. DAS 28 CRP utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal- phalangeal I-V, proximal interphalangeal I-V and knees and is calculated using the following formula: $DAS28(CRP) = 0.56 * \sqrt{(TJC28)} + 0.28 * \sqrt{(SJC28)} + 0.014 * GH + 0.36 * \ln(CRP + 1) + 0.96$. Where TJC = Tender joint Count, SJC= Swollen Joint Count, (GH=participant assessment of disease activity [PtGA]) and CRP= C reactive Protein (in mg/L). It ranges between 0.96 and 8.61. High score (worse outcome) and low scores (better outcome). Baseline was defined as the last available assessment prior to the start of study treatment.

Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants with data available at the indicated time point were analyzed.

End point type	Secondary
End point timeframe:	
Baseline and Week 12	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34 ^[7]	35 ^[8]	33 ^[9]	37 ^[10]
Units: Scores on a scale				
least squares mean (standard error)				
CRP	-5.21 (± 2.730)	-4.75 (± 2.701)	-8.57 (± 2.749)	-7.79 (± 2.624)
PtGA	-6.72 (± 3.660)	-14.40 (± 3.653)	-20.40 (± 3.611)	-24.11 (± 3.544)
SJC28	-2.35 (± 1.093)	-4.77 (± 1.085)	-5.52 (± 1.080)	-6.91 (± 1.056)
TJC28	-2.81 (± 1.191)	-5.11 (± 1.181)	-6.73 (± 1.173)	-8.53 (± 1.151)

Notes:

[7] - ITT Population

[8] - ITT Population

[9] - ITT Population

[10] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34 ^[11]	36 ^[12]		
Units: Scores on a scale				
least squares mean (standard error)				
CRP	-7.71 (± 2.722)	-7.21 (± 2.659)		
PtGA	-19.35 (± 3.614)	-23.90 (± 3.606)		
SJC28	-5.33 (± 1.080)	-8.39 (± 1.070)		
TJC28	-6.43 (± 1.175)	-9.13 (± 1.167)		

Notes:

[11] - ITT Population

[12] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
CRP, Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.905 ^[13]
Method	Mixed Model Repeated Measures (MMRM)
Parameter estimate	Mean difference (net)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.13
upper limit	8.05

Notes:

[13] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
Statistical analysis description:	
CRP, Week 12	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.387 ^[14]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	4.28

Notes:

[14] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
Statistical analysis description:	
CRP, Week 12	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.495 ^[15]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.04
upper limit	4.87

Notes:

[15] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
Statistical analysis description: PtGA, Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.14 ^[16]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.92
upper limit	2.55

Notes:

[16] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
Statistical analysis description: PtGA, Week 12	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.009 ^[17]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.85
upper limit	-3.52

Notes:

[17] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
Statistical analysis description: PtGA, Week 12	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[18]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-17.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.44
upper limit	-7.35

Notes:

[18] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
Statistical analysis description:	
SJC28, Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.118 ^[19]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.45
upper limit	0.62

Notes:

[19] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
Statistical analysis description:	
SJC28, Week 12	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.041 ^[20]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.2
upper limit	-0.14

Notes:

[20] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
Statistical analysis description: SJC28, Week 12	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003 ^[21]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	0.05

Notes:

[21] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
Statistical analysis description: TJC28, Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.172 ^[22]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.61
upper limit	1.01

Notes:

[22] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
Statistical analysis description: TJC28, Week 12	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.02 ^[23]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.22
upper limit	-0.62

Notes:

[23] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
Statistical analysis description:	
TJC28, Week 12	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[24]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.98
upper limit	-2.45

Notes:

[24] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
CRP, Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.518 ^[25]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.13
upper limit	5.12

Notes:

[25] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
Statistical analysis description:	
CRP, Week 12	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.599 ^[26]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	5.49

Notes:

[26] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
Statistical analysis description:	
PtGA, Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.015 ^[27]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-12.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.78
upper limit	-2.48

Notes:

[27] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 16
Statistical analysis description:	
PtGA, Week 12	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[28]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-17.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.27
upper limit	-7.1

Notes:

[28] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 17
Statistical analysis description:	
SJC28, Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.054 ^[29]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	0.05

Notes:

[29] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 18
Statistical analysis description:	
SJC28, Week 12	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[30]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.05
upper limit	-3.02

Notes:

[30] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 19
Statistical analysis description: TJC28, Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.031 ^[31]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.92
upper limit	-0.33

Notes:

[31] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 20
Statistical analysis description: TJC28, Week 12	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[32]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.61
upper limit	-3.02

Notes:

[32] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Percentage of participants who achieved DAS28(CRP) remission (DAS28 <2.6) at all time points

End point title	Percentage of participants who achieved DAS28(CRP) remission (DAS28 <2.6) at all time points
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End point description:

DAS28(CRP) remission is defined as a DAS28 score of <2.6 points. The DAS index combines information relating to the number of swollen and tender joints. The DAS28 is a modification of the original DAS and is based on a count of 28 swollen and tender joints and is used to evaluate a participant's response to treatment. DAS 28 CRP utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal- phalangeal I-V, proximal interphalangeal I-V and knees and is calculated using the following formula: $\text{DAS28 (CRP)} = 0.56 \cdot \sqrt{\text{TJC28}} + 0.28 \cdot \sqrt{\text{SJC28}} + 0.014 \cdot \text{GH} + 0.36 \cdot \ln(\text{CRP} + 1) + 0.96$.

Where TJC – Tender joint Count, SJC= Swollen Joint Count, (GH=participant assessment of disease activity using a 100 mm visual analogue scale with 0 = best, 100 = worst) and CRP= C reactive Protein (in mg/L). It ranges between 0.96 and 8.61. High score (worse outcome) and low scores (better outcome).

End point type	Secondary
End point timeframe:	
Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and Week 62 (follow-up)	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[33]	37 ^[34]	37 ^[35]	37 ^[36]
Units: Percentage of participants				
Week 1	0	0	0	0
Week 2	0	0	0	0
Week 4	0	0	0	5
Week 6	5	5	0	5
Week 8	3	0	5	14
Week 12	3	8	5	24
Week 16	0	3	14	27
Week 20	3	0	16	19
Week 24	3	5	16	19
Week 28	3	3	16	16
Week 32	3	5	22	14
Week 36	3	5	19	8
Week 40	0	5	14	14
Week 44	3	5	14	16
Week 48	0	5	14	14
Week 52	3	5	14	11
Week 62 (follow-up)	3	0	8	3

Notes:

[33] - ITT Population

[34] - ITT Population

[35] - ITT Population

[36] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[37]	37 ^[38]		
Units: Percentage of participants				
Week 1	0	0		
Week 2	0	1		
Week 4	3	4		
Week 6	3	8		
Week 8	5	8		
Week 12	3	16		
Week 16	5	19		
Week 20	14	16		
Week 24	14	14		

Week 28	14	22		
Week 32	11	19		
Week 36	16	19		
Week 40	11	24		
Week 44	14	16		
Week 48	14	19		
Week 52	14	14		
Week 62 (follow-up)	11	19		

Notes:

[37] - ITT Population

[38] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 2
Statistical analysis description:	
Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	10.3

Statistical analysis title	Stat 3
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Statistical analysis description:

Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.7
upper limit	1.9

Statistical analysis title	Stat 4
Statistical analysis description: Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	10.3

Statistical analysis title	Stat 5
Statistical analysis description: Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 6
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Statistical analysis description:

Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title

Stat 7

Statistical analysis description:

Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title

Stat 8

Statistical analysis description:

Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 9
Statistical analysis description:	
Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 10
Statistical analysis description:	
Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.8
upper limit	36.4

Statistical analysis title	Stat 11
Statistical analysis description:	
Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 12
Statistical analysis description: Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 13
Statistical analysis description: Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.7
upper limit	41.3

Statistical analysis title	Stat 14
Statistical analysis description: Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 15
Statistical analysis description:	
Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 16
Statistical analysis description:	
Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 17
Statistical analysis description:	
Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 18
Statistical analysis description: Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 19
Statistical analysis description: Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 20
Statistical analysis description: Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.	

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 21
Statistical analysis description: Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 22
Statistical analysis description: Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 23
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Statistical analysis description:	
Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 24
Statistical analysis description:	
Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 25
Statistical analysis description:	
Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 26
Statistical analysis description:	
Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 27
Statistical analysis description:	
Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 28
Statistical analysis description:	
Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 29
Statistical analysis description: Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 30
Statistical analysis description: Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 31
Statistical analysis description: Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 32
Statistical analysis description:	
Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 33
Statistical analysis description:	
Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 34
Statistical analysis description:	
Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 35
Statistical analysis description: Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 36
Statistical analysis description: Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 37
Statistical analysis description: Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.	

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 38
Statistical analysis description: Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 39
Statistical analysis description: Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 40
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Statistical analysis description:

Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title

Stat 41

Statistical analysis description:

Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title

Stat 42

Statistical analysis description:

Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 43
Statistical analysis description: Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 44
Statistical analysis description: Week 2. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 45
Statistical analysis description: Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 46
Statistical analysis description:	
Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 47
Statistical analysis description:	
Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	6.3

Statistical analysis title	Stat 48
Statistical analysis description:	
Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	14.1

Statistical analysis title	Stat 49
Statistical analysis description:	
Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 50
Statistical analysis description:	
Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 51
Statistical analysis description:	
Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.	

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 52
Statistical analysis description: Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 53
Statistical analysis description: Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 54
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Statistical analysis description:

Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.3
upper limit	31.5

Statistical analysis title

Stat 55

Statistical analysis description:

Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title

Stat 56

Statistical analysis description:

Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 57
Statistical analysis description:	
Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 58
Statistical analysis description:	
Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 59
Statistical analysis description:	
Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 60
Statistical analysis description: Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 61
Statistical analysis description: Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title	Stat 62
Statistical analysis description: Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 63
Statistical analysis description:	
Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 64
Statistical analysis description:	
Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 65
Statistical analysis description:	
Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 66
Statistical analysis description: Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.5
upper limit	38.1

Statistical analysis title	Stat 67
Statistical analysis description: Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 68
Statistical analysis description: Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.	

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 69
Statistical analysis description: Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 70
Statistical analysis description: Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.3
upper limit	31.5

Statistical analysis title	Stat 71
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Statistical analysis description:

Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title

Stat 72

Statistical analysis description:

Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title

Stat 73

Statistical analysis description:

Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title	Stat 74
Statistical analysis description: Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Secondary: Change from Baseline in DAS28(CRP) at all assessment time points

End point title	Change from Baseline in DAS28(CRP) at all assessment time points
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End point description:

DAS28 modification of the original DAS is based on a count of 28 swollen and tender joints used to evaluate a participant's response to treatment. DAS28 CRP utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal- phalangeal I-V, proximal interphalangeal I-V and knees and is calculated as: $DAS28(CRP) = 0.56 \cdot \sqrt{(TJC28)} + 0.28 \cdot \sqrt{(SJC28)} + 0.014 \cdot GH + 0.36 \cdot \ln(CRP + 1) + 0.96$. Where TJC=Tender joint Count, SJC=Swollen Joint Count, (GH=participant assessment of disease activity and CRP=C reactive Protein (in mg/L). It ranges between 0.96 and 8.61. High score (worse outcome) and low scores (better outcome). Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post-dose visit value from the Baseline. Only those participants with data available at specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary
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End point timeframe:

Baseline and Weeks 1, 2, 4, 6, 8, 12, 16, 20 and 24

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[39]	37 ^[40]	37 ^[41]	37 ^[42]
Units: Scores on a scale				
least squares mean (standard error)				
Week 1; n=35, 36, 33, 35, 34, 37	-0.14 (± 0.114)	-0.47 (± 0.114)	-0.44 (± 0.117)	-0.52 (± 0.114)
Week 2; n=36, 35, 34, 36, 36, 36	-0.37 (± 0.138)	-0.64 (± 0.141)	-0.69 (± 0.142)	-0.78 (± 0.138)
Week 4; n=32, 33, 34, 36, 36, 36	-0.45 (± 0.169)	-0.85 (± 0.169)	-1.01 (± 0.167)	-1.21 (± 0.163)

Week 6; n=35, 34, 34, 36, 33, 36	-0.65 (± 0.184)	-1.07 (± 0.186)	-1.12 (± 0.185)	-1.26 (± 0.181)
Week 8; n=34, 33, 34, 37, 35, 32	-0.61 (± 0.195)	-1.04 (± 0.197)	-1.40 (± 0.196)	-1.44 (± 0.190)
Week 12; n=34, 35, 33, 37, 34, 36	-0.60 (± 0.232)	-1.13 (± 0.231)	-1.48 (± 0.233)	-1.84 (± 0.225)
Week 16; n=8, 16, 20, 24, 18, 36	-0.87 (± 0.335)	-1.16 (± 0.274)	-1.86 (± 0.261)	-1.88 (± 0.247)
Week 20; n=8, 15, 20, 25, 19, 36	-1.23 (± 0.359)	-1.30 (± 0.284)	-1.81 (± 0.260)	-1.89 (± 0.241)
Week 24; n=8, 14, 20, 24, 19, 33	-0.23 (± 0.402)	-1.45 (± 0.322)	-1.76 (± 0.288)	-1.62 (± 0.269)

Notes:

[39] - ITT Population.

[40] - ITT Population.

[41] - ITT Population.

[42] - ITT Population.

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[43]	37 ^[44]		
Units: Scores on a scale				
least squares mean (standard error)				
Week 1; n=35, 36, 33, 35, 34, 37	-0.55 (± 0.116)	-0.63 (± 0.112)		
Week 2; n=36, 35, 34, 36, 36, 36	-0.84 (± 0.139)	-0.88 (± 0.139)		
Week 4; n=32, 33, 34, 36, 36, 36	-1.12 (± 0.164)	-1.46 (± 0.164)		
Week 6; n=35, 34, 34, 36, 33, 36	-1.12 (± 0.185)	-1.51 (± 0.182)		
Week 8; n=34, 33, 34, 37, 35, 32	-1.51 (± 0.194)	-1.72 (± 0.196)		
Week 12; n=34, 35, 33, 37, 34, 36	-1.28 (± 0.230)	-1.87 (± 0.228)		
Week 16; n=8, 16, 20, 24, 18, 36	-1.64 (± 0.265)	-1.98 (± 0.232)		
Week 20; n=8, 15, 20, 25, 19, 36	-2.00 (± 0.263)	-2.03 (± 0.221)		
Week 24; n=8, 14, 20, 24, 19, 33	-1.71 (± 0.291)	-2.05 (± 0.246)		

Notes:

[43] - ITT Population.

[44] - ITT Population.

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.046 ^[45]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	-0.01

Notes:

[45] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
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Statistical analysis description:

Week 1

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.071 ^[46]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	0.03

Notes:

[46] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
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Statistical analysis description:

Week 1

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.022 ^[47]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.69
upper limit	-0.05

Notes:

[47] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.16 ^[48]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	0.11

Notes:

[48] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.103 ^[49]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.71
upper limit	0.07

Notes:

[49] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.034 ^[50]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	-0.03

Notes:

[50] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.096 ^[51]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.87
upper limit	0.07

Notes:

[51] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.02 ^[52]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.02
upper limit	-0.09

Notes:

[52] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001 ^[53]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.22
upper limit	-0.29

Notes:

[53] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.11 ^[54]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	0.1

Notes:

[54] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.076 ^[55]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.98
upper limit	0.05

Notes:

[55] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.02 ^[56]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.11
upper limit	-0.1

Notes:

[56] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.128 ^[57]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.97
upper limit	0.12

Notes:

[57] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005 ^[58]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.33
upper limit	-0.24

Notes:

[58] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003 ^[59]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.36
upper limit	-0.29

Notes:

[59] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 16
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.11 ^[60]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.17
upper limit	0.12

Notes:

[60] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 17
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.008 ^[61]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.53
upper limit	-0.23

Notes:

[61] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 18
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[62]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.88
upper limit	-0.6

Notes:

[62] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 19
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5 ^[63]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.15
upper limit	0.56

Notes:

[63] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 20
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.021 ^[64]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.83
upper limit	-0.15

Notes:

[64] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 21
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.017 ^[65]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.83
upper limit	-0.18

Notes:

[65] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 22
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.871 ^[66]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.98
upper limit	0.83

Notes:

[66] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 23
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.19 ^[67]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.46
upper limit	0.29

Notes:

[67] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 24
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.13 ^[68]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.51
upper limit	0.2

Notes:

[68] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 25
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.019 ^[69]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.24
upper limit	-0.2

Notes:

[69] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 26
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002 ^[70]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.51
upper limit	-0.55

Notes:

[70] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 27
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Statistical analysis description:

Week 24

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005 ^[71]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.34
upper limit	-0.43

Notes:

[71] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 28
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Statistical analysis description:

Week 1

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.013 ^[72]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.73
upper limit	-0.09

Notes:

[72] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 29
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003 ^[73]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	-0.17

Notes:

[73] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 30
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.017 ^[74]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.86
upper limit	-0.09

Notes:

[74] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 31
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.009 ^[75]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	-0.13

Notes:

[75] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 32
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005 ^[76]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.13
upper limit	-0.2

Notes:

[76] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 33
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[77]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.48
upper limit	-0.55

Notes:

[77] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 34
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.073 ^[78]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	0.04

Notes:

[78] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 35
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001 ^[79]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.36
upper limit	-0.34

Notes:

[79] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 36
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001 ^[80]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.43
upper limit	-0.35

Notes:

[80] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 37
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[81]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.65
upper limit	-0.56

Notes:

[81] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 38
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.039 ^[82]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.32
upper limit	-0.03

Notes:

[82] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 39
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[83]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.91
upper limit	-0.63

Notes:

[83] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 40
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.073 ^[84]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.61
upper limit	0.07

Notes:

[84] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 41
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.007 ^[85]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.91
upper limit	-0.3

Notes:

[85] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 42
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Statistical analysis description:

Week 20

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.083 ^[86]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.65
upper limit	0.1

Notes:

[86] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 43
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Statistical analysis description:

Week 20

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.059 ^[87]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.63
upper limit	0.03

Notes:

[87] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 44
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003 ^[88]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.46
upper limit	-0.5

Notes:

[88] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 45
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[89]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.75
upper limit	-0.89

Notes:

[89] - MMRM analysis adjusted for DAS28(CRP) Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Time to first DAS28(CRP) remission

End point title	Time to first DAS28(CRP) remission
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End point description:

DAS28 modification of the original DAS is based on a count of 28 swollen and tender joints used to evaluate a participant's response to treatment. DAS28 CRP utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal- phalangeal I-V, proximal interphalangeal I-V and knees and is calculated as: $\text{DAS28 (CRP)} = 0.56 \times \sqrt{(\text{TJC28}) + 0.28 \times \sqrt{(\text{SJC28}) + 0.014 \times \text{GH} + 0.36 \times \ln(\text{CRP} + 1)} + 0.96$. Where TJC= Tender joint Count, SJC= Swollen Joint Count, (GH= participant assessment of disease activity and CRP= C reactive Protein (in mg/L). It ranges between 0.96 and 8.61. High score (worse outcome) and low scores (better outcome). Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was

value from the Baseline. Only those participants with data available at the time of assessment were analyzed. Median time, to remission has been presented.

End point type	Secondary
End point timeframe:	
Up to Week 62	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[90]	6 ^[91]	11 ^[92]	10 ^[93]
Units: Weeks				
median (full range (min-max))				
Time to DAS (CRP28)	9.10 (6.0 to 20.3)	12.05 (6.1 to 24.3)	16.10 (8.0 to 24.9)	8.10 (4.1 to 16.3)

Notes:

[90] - ITT Population.

[91] - ITT Population.

[92] - ITT Population.

[93] - ITT Population.

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7 ^[94]	18 ^[95]		
Units: Weeks				
median (full range (min-max))				
Time to DAS (CRP28)	19.90 (4.3 to 24.9)	18.20 (2.0 to 64.1)		

Notes:

[94] - ITT Population.

[95] - ITT Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving categorical DAS28(CRP) response (moderate/good [European League against Rheumatism] EULAR response) at all assessment time points

End point title	Percentage of participants achieving categorical DAS28(CRP) response (moderate/good [European League against Rheumatism] EULAR response) at all assessment time points
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End point description:

DAS28(CRP) scores were categorized using EULAR response criteria. Response at a given time point was defined based on the combination of current DAS28 score and the improvement in the current DAS28 score relative to Baseline. The definition of no response, moderate response and good response was as follows: Current DAS28 ≤ 3.2 and DAS28 decrease from Baseline (>1.2 =good response), (>0.6 to ≤ 1.2 = moderate response) and (≤ 0.6 =no response). Current DAS28 >3.2 to ≤ 5.1 and DAS28 decrease from Baseline value (>1.2 =moderate response), (>0.6 to ≤ 1.2 = moderate response) and (≤ 0.6 =no response). Current DAS28 >5.1 and DAS28 decrease from Baseline value (>1.2 =moderate response), (>0.6 to ≤ 1.2 = no response) and (≤ 0.6 =no response). If the post-Baseline DAS28(CRP) score was missing, then the corresponding EULAR category was set to missing.

End point type	Secondary
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End point timeframe:

Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and Week 62 (follow-up)

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[96]	37 ^[97]	37 ^[98]	37 ^[99]
Units: Percentage of participants				
Week 1	5	22	16	24
Week 2	14	19	16	38
Week 4	16	46	38	46
Week 6	24	46	43	51
Week 8	32	43	59	65
Week 12	22	43	51	68
Week 16	22	35	54	59
Week 20	16	35	51	65
Week 24	16	32	46	54
Week 28	3	8	19	19
Week 32	3	8	22	22
Week 36	3	8	19	22
Week 40	3	8	19	22
Week 44	3	8	19	19
Week 48	3	8	19	19
Week 52	3	8	16	16
Week 62 (follow-up)	3	5	16	16

Notes:

[96] - ITT Population

[97] - ITT Population

[98] - ITT Population

[99] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[100]	37 ^[101]		
Units: Percentage of participants				
Week 1	19	27		
Week 2	32	38		
Week 4	43	68		
Week 6	46	65		
Week 8	59	68		
Week 12	49	76		
Week 16	43	73		
Week 20	43	73		
Week 24	43	70		
Week 28	16	78		
Week 32	16	73		
Week 36	16	73		
Week 40	16	65		
Week 44	16	59		

Week 48	16	65		
Week 52	16	51		
Week 62 (follow-up)	16	54		

Notes:

[100] - ITT Population

[101] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Difference to placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.037
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	31.4

Statistical analysis title	Stat 2
Statistical analysis description:	
Difference to placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.144
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	24.7

Statistical analysis title	Stat 3
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Statistical analysis description:

Difference to placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.033
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.3
upper limit	34.5

Statistical analysis title

Stat 4

Statistical analysis description:

Difference to placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.437
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.3
upper limit	22.2

Statistical analysis title

Stat 5

Statistical analysis description:

Difference to placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.755
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	18.9

Statistical analysis title	Stat 6
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Statistical analysis description:

Difference to placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.023
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.2
upper limit	43.4

Statistical analysis title	Stat 7
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Statistical analysis description:

Difference to placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.8
upper limit	49.7

Statistical analysis title	Stat 8
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Statistical analysis description:

Difference to placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.039
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	41.2

Statistical analysis title

Stat 9

Statistical analysis description:

Difference to placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.008
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.8
upper limit	49.7

Statistical analysis title

Stat 10

Statistical analysis description:

Difference to placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.044
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	21.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	42.8

Statistical analysis title	Stat 11
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Statistical analysis description:

Difference to placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.083
Method	Regression, Logistic
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	40

Statistical analysis title	Stat 12
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Statistical analysis description:

Difference to placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.8
upper limit	48.3

Statistical analysis title	Stat 13
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Statistical analysis description:

Difference to placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.2
upper limit	32.8

Statistical analysis title	Stat 14
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Statistical analysis description:

Difference to placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.2
upper limit	48.9

Statistical analysis title	Stat 15
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Statistical analysis description:

Difference to placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	32.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.9
upper limit	54

Statistical analysis title	Stat 16
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Statistical analysis description:

Difference to placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	42.4

Statistical analysis title

Stat 17

Statistical analysis description:

Difference to placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.9
upper limit	50.6

Statistical analysis title

Stat 18

Statistical analysis description:

Difference to placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	45.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.9
upper limit	66

Statistical analysis title	Stat 19
Statistical analysis description:	
Difference to placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	Other: 9 %
sides	2-sided
lower limit	-6.8
upper limit	33.8

Statistical analysis title	Stat 20
Statistical analysis description:	
Difference to placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	32.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.6
upper limit	53.3

Statistical analysis title	Stat 21
Statistical analysis description:	
Difference to placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	37.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	17.2
upper limit	58.5

Statistical analysis title	Stat 22
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Statistical analysis description:

Difference to placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	38.4

Statistical analysis title	Stat 23
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Statistical analysis description:

Difference to placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	35.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.1
upper limit	55.1

Statistical analysis title	Stat 24
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Statistical analysis description:

Difference to placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	48.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.2
upper limit	68.1

Statistical analysis title	Stat 25
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Statistical analysis description:

Difference to placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	35.4

Statistical analysis title	Stat 26
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Statistical analysis description:

Difference to placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.8
upper limit	49.7

Statistical analysis title	Stat 27
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Statistical analysis description:

Difference to placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	37.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.9
upper limit	57.8

Statistical analysis title

Stat 28

Statistical analysis description:

Difference to placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title

Stat 29

Statistical analysis description:

Difference to placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 30
Statistical analysis description:	
Difference to placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 31
Statistical analysis description:	
Difference to placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 32
Statistical analysis description:	
Difference to placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 33
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Statistical analysis description:

Difference to placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 34
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Statistical analysis description:

Difference to placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 35
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Statistical analysis description:

Difference to placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 36
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Statistical analysis description:

Difference to placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 37
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Statistical analysis description:

Difference to placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 38
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Statistical analysis description:

Difference to placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title

Stat 39

Statistical analysis description:

Difference to placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title

Stat 40

Statistical analysis description:

Difference to placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 41
Statistical analysis description:	
Difference to placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 42
Statistical analysis description:	
Difference to placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 43
Statistical analysis description:	
Difference to placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 44
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Statistical analysis description:

Difference to placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 45
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Statistical analysis description:

Difference to placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 46
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Statistical analysis description:

Difference to placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 47
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Statistical analysis description:

Difference to placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 48
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Statistical analysis description:

Difference to placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 49
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Statistical analysis description:

Difference to placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	28.1

Statistical analysis title

Stat 50

Statistical analysis description:

Difference to placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.6
upper limit	37.7

Statistical analysis title

Stat 51

Statistical analysis description:

Difference to placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	37.6

Statistical analysis title	Stat 52
Statistical analysis description:	
Difference to placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.2
upper limit	43.4

Statistical analysis title	Stat 53
Statistical analysis description:	
Difference to placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	46.9

Statistical analysis title	Stat 54
Statistical analysis description:	
Difference to placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	32.2
upper limit	70.5

Statistical analysis title	Stat 55
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Statistical analysis description:

Difference to placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	42.8

Statistical analysis title	Stat 56
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Statistical analysis description:

Difference to placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	40.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.9
upper limit	61.2

Statistical analysis title	Stat 57
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Statistical analysis description:

Difference to placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.2
upper limit	48.9

Statistical analysis title	Stat 58
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Statistical analysis description:

Difference to placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	35.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.8
upper limit	56.5

Statistical analysis title	Stat 59
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Statistical analysis description:

Difference to placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.2
upper limit	47.9

Statistical analysis title	Stat 60
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Statistical analysis description:

Difference to placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	54.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.9
upper limit	73.2

Statistical analysis title

Stat 61

Statistical analysis description:

Difference to placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	42.4

Statistical analysis title

Stat 62

Statistical analysis description:

Difference to placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.8
upper limit	70.9

Statistical analysis title	Stat 63
Statistical analysis description:	
Difference to placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	46.9

Statistical analysis title	Stat 64
Statistical analysis description:	
Difference to placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	56.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	38.2
upper limit	75.4

Statistical analysis title	Stat 65
Statistical analysis description:	
Difference to placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27

Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	46.9

Statistical analysis title	Stat 66
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Statistical analysis description:

Difference to placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	54.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.1
upper limit	73

Statistical analysis title	Stat 67
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Statistical analysis description:

Difference to placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 68
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Statistical analysis description:

Difference to placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	75.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	61.4
upper limit	89.9

Statistical analysis title	Stat 69
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Statistical analysis description:

Difference to placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 70
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Statistical analysis description:

Difference to placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	70.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	55
upper limit	85.5

Statistical analysis title	Stat 71
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Statistical analysis description:

Difference to placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title

Stat 72

Statistical analysis description:

Difference to placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	70.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	55
upper limit	85.5

Statistical analysis title

Stat 73

Statistical analysis description:

Difference to placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 74
Statistical analysis description:	
Difference to placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	62.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	45.9
upper limit	78.4

Statistical analysis title	Stat 75
Statistical analysis description:	
Difference to placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 76
Statistical analysis description:	
Difference to placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	56.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	40.1
upper limit	73.4

Statistical analysis title	Stat 77
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Statistical analysis description:

Difference to placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 78
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Statistical analysis description:

Difference to placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	62.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	45.9
upper limit	78.4

Statistical analysis title	Stat 79
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Statistical analysis description:

Difference to placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 80
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Statistical analysis description:

Difference to placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	48.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.7
upper limit	65.6

Statistical analysis title	Stat 81
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Statistical analysis description:

Difference to placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 82
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Statistical analysis description:

Difference to placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.5
upper limit	68.2

Secondary: Percentage of participants with American College of Rheumatology's (ACR) 20/50/70 response rates at all assessment time points

End point title	Percentage of participants with American College of Rheumatology's (ACR) 20/50/70 response rates at all assessment time points
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End point description:

The ACR definition for calculating improvement in rheumatoid arthritis is calculated as a 20% improvement (ACR20) in both tender and swollen joint counts and 20% improvement in 3 of the 5 remaining ACR-core set measures: participant and physician global assessments, participant's assessment of arthritis pain, disability, and an acute-phase reactant (i.e. CRP value). Similarly, ACR50 and ACR70 were calculated with the respective percent improvement. The specific components of the ACR assessments are as follows: Tender/Painful Joint count 68 (TJC68), Swollen Joint Count 66 (SJC66), Participant's Assessment of Arthritis Pain, Participant's Global Assessment of Arthritis Disease Activity, Physician's Global Assessment of Arthritis, CRP (mg/L) and Health Assessment Questionnaire – Disability Index (HAQ-DI). For all visits, if any of the component scores were missing, then those scores were considered as not having met the criteria for improvement.

End point type	Secondary
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End point timeframe:

Week 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and Week 62 (follow-up)

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[102]	37 ^[103]	37 ^[104]	37 ^[105]
Units: Percentage of participants				
Week 1, ACR 20	0	5	8	11
Week 1, ACR 50	0	0	3	0
Week 1, ACR 70	0	0	0	0
Week 2, ACR 20	5	19	14	16
Week 2, ACR 50	0	3	3	8
Week 2, ACR 70	0	0	0	0
Week 4, ACR 20	8	24	35	32
Week 4, ACR 50	5	5	5	11
Week 4, ACR 70	0	0	0	3
Week 6, ACR 20	22	32	30	32

Week 6, ACR 50	11	5	8	11
Week 6, ACR 70	0	0	3	3
Week 8, ACR 20	16	24	41	46
Week 8, ACR 50	3	11	14	19
Week 8, ACR 70	3	0	3	11
Week 12, ACR 20	11	35	41	51
Week 12, ACR 50	8	11	27	24
Week 12, ACR 70	5	3	14	19
Week 16, ACR 20	16	30	46	51
Week 16, ACR 50	8	22	27	27
Week 16, ACR 70	5	3	14	19
Week 20, ACR 20	16	24	38	54
Week 20, ACR 50	8	11	24	22
Week 20, ACR 70	5	3	16	14
Week 24, ACR 20	14	24	41	57
Week 24, ACR 50	11	11	27	30
Week 24, ACR 70	5	5	14	14
Week 28, ACR 20	3	8	19	19
Week 28, ACR 50	3	8	16	19
Week 28, ACR 70	3	8	14	14
Week 32, ACR 20	3	8	22	22
Week 32, ACR 50	3	8	22	16
Week 32, ACR 70	3	5	19	14
Week 36, ACR 20	3	8	19	16
Week 36, ACR 50	3	5	19	11
Week 36, ACR 70	0	5	19	11
Week 40, ACR 20	3	8	19	22
Week 40, ACR 50	3	8	16	14
Week 40, ACR 70	3	5	16	14
Week 44, ACR 20	3	8	19	19
Week 44, ACR 50	3	8	19	16
Week 44, ACR 70	0	3	19	11
Week 48, ACR 20	3	8	19	19
Week 48, ACR 50	3	8	19	16
Week 48, ACR 70	0	5	19	8
Week 52, ACR 20	3	8	16	16
Week 52, ACR 50	3	8	16	16
Week 52, ACR 70	0	5	16	11
Week 62 (follow-up), ACR 20	3	8	16	11
Week 62 (follow-up), ACR 50	3	5	16	8
Week 62 (follow-up), ACR 70	3	0	16	3

Notes:

[102] - ITT Population

[103] - ITT Population

[104] - ITT Population

[105] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[106]	37 ^[107]		
Units: Percentage of participants				

Week 1, ACR 20	5	19		
Week 1, ACR 50	0	0		
Week 1, ACR 70	0	0		
Week 2, ACR 20	35	43		
Week 2, ACR 50	5	5		
Week 2, ACR 70	0	0		
Week 4, ACR 20	46	46		
Week 4, ACR 50	8	8		
Week 4, ACR 70	0	5		
Week 6, ACR 20	35	46		
Week 6, ACR 50	14	14		
Week 6, ACR 70	3	5		
Week 8, ACR 20	49	51		
Week 8, ACR 50	24	19		
Week 8, ACR 70	8	8		
Week 12, ACR 20	41	51		
Week 12, ACR 50	30	22		
Week 12, ACR 70	8	11		
Week 16, ACR 20	41	68		
Week 16, ACR 50	27	22		
Week 16, ACR 70	11	11		
Week 20, ACR 20	38	59		
Week 20, ACR 50	32	30		
Week 20, ACR 70	24	19		
Week 24, ACR 20	41	59		
Week 24, ACR 50	24	27		
Week 24, ACR 70	19	19		
Week 28, ACR 20	16	68		
Week 28, ACR 50	16	24		
Week 28, ACR 70	11	14		
Week 32, ACR 20	16	54		
Week 32, ACR 50	16	30		
Week 32, ACR 70	14	16		
Week 36, ACR 20	16	59		
Week 36, ACR 50	16	35		
Week 36, ACR 70	16	14		
Week 40, ACR 20	16	54		
Week 40, ACR 50	14	32		
Week 40, ACR 70	11	16		
Week 44, ACR 20	16	54		
Week 44, ACR 50	14	38		
Week 44, ACR 70	11	19		
Week 48, ACR 20	16	57		
Week 48, ACR 50	16	35		
Week 48, ACR 70	14	22		
Week 52, ACR 20	16	51		
Week 52, ACR 50	16	27		
Week 52, ACR 70	14	14		
Week 62 (follow-up), ACR 20	16	43		
Week 62 (follow-up), ACR 50	16	27		
Week 62 (follow-up), ACR 70	14	19		

Notes:

[106] - ITT Population

[107] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description: Week 1, ACR20. Difference to Placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 2
Statistical analysis description: Week 1, ACR20. Difference to Placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 3
Statistical analysis description: Week 1, ACR20. Difference to Placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 4
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Statistical analysis description:

Week 1, ACR50. Difference to Placebo for Week 1 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 5
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	28.1

Statistical analysis title	Stat 6
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	21.3

Statistical analysis title

Stat 7

Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	24.7

Statistical analysis title

Stat 8

Statistical analysis description:

Week 2, ACR20. Difference to Placebo for 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 9
Statistical analysis description: Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 10
Statistical analysis description: Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 11
Statistical analysis description: Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	32.6

Statistical analysis title	Stat 12
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.3
upper limit	44.7

Statistical analysis title	Stat 13
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.9
upper limit	41.8

Statistical analysis title	Stat 14
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	10.3

Statistical analysis title	Stat 15
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	10.3

Statistical analysis title	Stat 16
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	17.8

Statistical analysis title	Stat 17
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Statistical analysis description:

Week 2, ACR20. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 18

Statistical analysis description:

Week 6, ACR20. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	30.9

Statistical analysis title

Stat 19

Statistical analysis description:

Week 6, ACR20. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	27.9

Statistical analysis title	Stat 20
Statistical analysis description:	
Week 6, ACR20. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	30.9

Statistical analysis title	Stat 21
Statistical analysis description:	
Week 6, ACR50. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.8
upper limit	7

Statistical analysis title	Stat 22
Statistical analysis description:	
Week 6, ACR50. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-16
upper limit	10.6

Statistical analysis title	Stat 23
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Statistical analysis description:

Week 6, ACR50. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	14.1

Statistical analysis title	Stat 24
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Statistical analysis description:

Week 6, ACR70. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 25
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Statistical analysis description:

Week 6, ACR70. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 26
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Statistical analysis description:

Week 8, ACR20. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	26.3

Statistical analysis title	Stat 27
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Statistical analysis description:

Week 8, ACR20. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.5
upper limit	44.1

Statistical analysis title	Stat 28
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Statistical analysis description:

Week 8, ACR20. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.8
upper limit	49.7

Statistical analysis title

Stat 29

Statistical analysis description:

Week 8, ACR50. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title

Stat 30

Statistical analysis description:

Week 8, ACR50. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 31
Statistical analysis description:	
Week 8, ACR50. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 32
Statistical analysis description:	
Week 8, ACR70. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 33
Statistical analysis description:	
Week 8, ACR70. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 34
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Statistical analysis description:

Week 8, ACR70. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title	Stat 35
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Statistical analysis description:

Week 12, ACR20. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	6
upper limit	42.7

Statistical analysis title	Stat 36
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Statistical analysis description:

Week 12, ACR20. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Odds ratio (OR)
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	11
upper limit	48.4

Statistical analysis title	Stat 37
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Statistical analysis description:

Week 12, ACR20. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	40.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.6
upper limit	59.5

Statistical analysis title	Stat 38
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Statistical analysis description:

Week 12, ACR50. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	16

Statistical analysis title	Stat 39
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Statistical analysis description:

Week 12, ACR50. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	35.7

Statistical analysis title

Stat 40

Statistical analysis description:

Week 12, ACR50. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	32.6

Statistical analysis title

Stat 41

Statistical analysis description:

Week 12, ACR70. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	6.3

Statistical analysis title	Stat 42
Statistical analysis description:	
Week 12, ACR70. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	21.3

Statistical analysis title	Stat 43
Statistical analysis description:	
Week 12, ACR70. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	28.1

Statistical analysis title	Stat 44
Statistical analysis description:	
Week 12, ACR20. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.4
upper limit	32.4

Statistical analysis title	Stat 45
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Statistical analysis description:

Week 16, ACR20. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.8
upper limit	49.7

Statistical analysis title	Stat 46
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Statistical analysis description:

Week 16, ACR20. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	35.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.1
upper limit	55.1

Statistical analysis title	Stat 47
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Statistical analysis description:

Week 16, ACR20. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	29.4

Statistical analysis title	Stat 48
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Statistical analysis description:

Week 16, ACR50. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	35.7

Statistical analysis title	Stat 49
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Statistical analysis description:

Week 16, ACR50. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	35.7

Statistical analysis title	Stat 50
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Statistical analysis description:

Week 16, ACR70. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	6.3

Statistical analysis title

Stat 51

Statistical analysis description:

Week 16, ACR70. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	21.3

Statistical analysis title

Stat 52

Statistical analysis description:

Week 16, ACR70. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	28.1

Statistical analysis title	Stat 53
Statistical analysis description:	
Week 20, ACR20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	26.3

Statistical analysis title	Stat 54
Statistical analysis description:	
Week 20, ACR20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	41.2

Statistical analysis title	Stat 55
Statistical analysis description:	
Week 20, ACR20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	37.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	17.9
upper limit	57.8

Statistical analysis title	Stat 56
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Statistical analysis description:

Week 20, ACR50. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	16

Statistical analysis title	Stat 57
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Statistical analysis description:

Week 20, ACR50. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	32.6

Statistical analysis title	Stat 58
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Statistical analysis description:

Week 20, ACR50. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	29.4

Statistical analysis title	Stat 59
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Statistical analysis description:

Week 20, ACR70. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	6.3

Statistical analysis title	Stat 60
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Statistical analysis description:

Week 20, ACR70. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	24.7

Statistical analysis title	Stat 61
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Statistical analysis description:

Week 20, ACR70. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	21.3

Statistical analysis title

Stat 62

Statistical analysis description:

Week 24, ACR20. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	28.5

Statistical analysis title

Stat 63

Statistical analysis description:

Week 24, ACR20. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.7
upper limit	46.3

Statistical analysis title	Stat 64
Statistical analysis description:	
Week 24, ACR20. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	43.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.8
upper limit	62.6

Statistical analysis title	Stat 65
Statistical analysis description:	
Week 24, ACR50. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	14.1

Statistical analysis title	Stat 66
Statistical analysis description:	
Week 24, ACR50. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	33.7

Statistical analysis title	Stat 67
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Statistical analysis description:

Week 24, ACR50. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	36.7

Statistical analysis title	Stat 68
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Statistical analysis description:

Week 24, ACR70. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	10.3

Statistical analysis title	Stat 69
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Statistical analysis description:

Week 24, ACR70. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	21.3

Statistical analysis title	Stat 70
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Statistical analysis description:

Week 24, ACR70. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	21.3

Statistical analysis title	Stat 71
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Statistical analysis description:

Week 28, ACR20. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 72
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Statistical analysis description:

Week 28, ACR20. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title

Stat 73

Statistical analysis description:

Week 28, ACR20. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title

Stat 74

Statistical analysis description:

Week 28, ACR50. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 75
Statistical analysis description:	
Week 28, ACR50. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 76
Statistical analysis description:	
Week 28, ACR50. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 77
Statistical analysis description:	
Week 28, ACR70. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 78
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Statistical analysis description:

Week 28, ACR70. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 79
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Statistical analysis description:

Week 28, ACR70. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 80
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Statistical analysis description:

Week 32, ACR20. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 81
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Statistical analysis description:

Week 32, ACR20. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 82
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Statistical analysis description:

Week 32, ACR20. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 83
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Statistical analysis description:

Week 32, ACR50. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title

Stat 84

Statistical analysis description:

Week 32, ACR50. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title

Stat 85

Statistical analysis description:

Week 32, ACR50. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 86
Statistical analysis description:	
Week 32, ACR70. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 87
Statistical analysis description:	
Week 32, ACR70. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 88
Statistical analysis description:	
Week 32, ACR70. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 89
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Statistical analysis description:

Week 36, ACR20. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 90
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Statistical analysis description:

Week 36, ACR20. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 91
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Statistical analysis description:

Week 36, ACR20. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 92
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Statistical analysis description:

Week 36, ACR50. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 93
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Statistical analysis description:

Week 36, ACR50. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 94
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Statistical analysis description:

Week 36, ACR50. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title

Stat 95

Statistical analysis description:

Week 36, ACR70. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 96

Statistical analysis description:

Week 36, ACR70. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.3
upper limit	31.5

Statistical analysis title	Stat 97
Statistical analysis description:	
Week 36, ACR70 Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 98
Statistical analysis description:	
Week 40, ACR20 Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 99
Statistical analysis description:	
Week 40, ACR20 Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 100
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Statistical analysis description:

Week 40, ACR20. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	33.2

Statistical analysis title	Stat 101
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Statistical analysis description:

Week 40, ACR50. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 102
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Statistical analysis description:

Week 40, ACR50. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 103
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Statistical analysis description:

Week 40, ACR50. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 104
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Statistical analysis description:

Week 40, ACR70. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 105
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Statistical analysis description:

Week 40, ACR70. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title

Stat 106

Statistical analysis description:

Week 40, ACR70. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title

Stat 107

Statistical analysis description:

Week 44, ACR20. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 108
Statistical analysis description:	
Week 44, ACR20. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 109
Statistical analysis description:	
Week 44, ACR20. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 110
Statistical analysis description:	
Week 44, ACR50. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 111
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Statistical analysis description:

Week 44, ACR50. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 112
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Statistical analysis description:

Week 44, ACR50. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 113
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Statistical analysis description:

Week 44, ACR70. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 114
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Statistical analysis description:

Week 44, ACR70. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.3
upper limit	31.5

Statistical analysis title	Stat 115
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Statistical analysis description:

Week 44, ACR70. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 116
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Statistical analysis description:

Week 48, ACR20 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title

Stat 117

Statistical analysis description:

Week 48, ACR20 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title

Stat 118

Statistical analysis description:

Week 48, ACR20 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 119
Statistical analysis description:	
Week 48, ACR50 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 120
Statistical analysis description:	
Week 48, ACR50 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 121
Statistical analysis description:	
Week 48, ACR50 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 122
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Statistical analysis description:

Week 48, ACR70 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 123
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Statistical analysis description:

Week 48, ACR70 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.3
upper limit	31.5

Statistical analysis title	Stat 124
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Statistical analysis description:

Week 48, ACR70 Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 125
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Statistical analysis description:

Week 52, ACR20 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 126
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Statistical analysis description:

Week 52, ACR20 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 127
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Statistical analysis description:

Week 52, ACR20 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title

Stat 128

Statistical analysis description:

Week 52, ACR50 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title

Stat 129

Statistical analysis description:

Week 52, ACR50 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 130
Statistical analysis description:	
Week 52, ACR50 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 131
Statistical analysis description:	
Week 52, ACR70 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 132
Statistical analysis description:	
Week 52, ACR70 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.3
upper limit	28.1

Statistical analysis title	Stat 133
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Statistical analysis description:

Week 52, ACR70 Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 134
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Statistical analysis description:

Week 62 (follow-up), ACR20 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 135
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Statistical analysis description:

Week 62 (follow-up), ACR20 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 136
Statistical analysis description: Week 62 (follow-up), ACR20 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title	Stat 137
Statistical analysis description: Week 62 (follow-up), ACR50 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 138
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Statistical analysis description:

Week 62 (follow-up), ACR50 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title

Stat 139

Statistical analysis description:

Week 62 (follow-up), ACR50 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title

Stat 140

Statistical analysis description:

Week 62 (follow-up), ACR70 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 141
Statistical analysis description: Week 62 (follow-up), ACR70 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 142
Statistical analysis description: Week 62 (follow-up), ACR70 Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 143
Statistical analysis description: Week 1, ACR20 Difference to Placebo is presented for Week 1. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 144
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Statistical analysis description:

Week 1, ACR20 Difference to Placebo is presented for Week 1. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.3
upper limit	31.5

Statistical analysis title	Stat 145
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Statistical analysis description:

Week 2, ACR20 Difference to Placebo is presented for Week 2. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.7
upper limit	46.8

Statistical analysis title	Stat 146
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Statistical analysis description:

Week 2, ACR20 Difference to Placebo is presented for Week 2. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	37.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.3
upper limit	55.4

Statistical analysis title	Stat 147
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Statistical analysis description:

Week 2, ACR50 Difference to Placebo is presented for Week 2. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 148
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Statistical analysis description:

Week 2, ACR50 Difference to Placebo is presented for Week 2. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 149
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Statistical analysis description:

Week 4, ACR20 Difference to Placebo is presented for Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	37.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.5
upper limit	56.1

Statistical analysis title

Stat 150

Statistical analysis description:

Week 4, ACR20 Difference to Placebo is presented for Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.5
upper limit	56.1

Statistical analysis title

Stat 151

Statistical analysis description:

Week 4, ACR50 Difference to Placebo is presented for Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	14.1

Statistical analysis title	Stat 152
Statistical analysis description:	
Week 4, ACR50 Difference to Placebo is presented for Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	14.1

Statistical analysis title	Stat 153
Statistical analysis description:	
Week 4, ACR70 Difference to Placebo is presented for Week 4. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 154
Statistical analysis description:	
Week 6, ACR20 Difference to Placebo is presented for Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	33.8

Statistical analysis title	Stat 155
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Statistical analysis description:

Week 6, ACR20 Difference to Placebo is presented for Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.5
upper limit	45.2

Statistical analysis title	Stat 156
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Statistical analysis description:

Week 6, ACR50 Difference to Placebo is presented for Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	17.6

Statistical analysis title	Stat 157
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Statistical analysis description:

Week 6, ACR50 Difference to Placebo is presented for Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	17.6

Statistical analysis title	Stat 158
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Statistical analysis description:

Week 6, ACR70 Difference to Placebo is presented for Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 159
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Statistical analysis description:

Week 6, ACR70 Difference to Placebo is presented for Week 6. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 160
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Statistical analysis description:

Week 8, ACR20 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	32.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.4
upper limit	52.4

Statistical analysis title

Stat 161

Statistical analysis description:

Week 8, ACR20 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	35.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.1
upper limit	55.1

Statistical analysis title

Stat 162

Statistical analysis description:

Week 8, ACR50 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.8
upper limit	36.4

Statistical analysis title	Stat 163
Statistical analysis description:	
Week 8, ACR50 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Statistical analysis title	Stat 164
Statistical analysis description:	
Week 8, ACR70 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 165
Statistical analysis description:	
Week 8, ACR70 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	15.6

Statistical analysis title	Stat 166
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Statistical analysis description:

Week 12, ACR20 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	11
upper limit	48.4

Statistical analysis title	Stat 167
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Statistical analysis description:

Week 12, ACR20 Difference to Placebo is presented for Week 8. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	40.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.6
upper limit	59.5

Statistical analysis title	Stat 168
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Statistical analysis description:

Week 12, ACR50 Difference to Placebo is presented for Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.5
upper limit	38.8

Statistical analysis title	Stat 169
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Statistical analysis description:

Week 12, ACR50 Difference to Placebo is presented for Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	29.4

Statistical analysis title	Stat 170
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Statistical analysis description:

Week 12, ACR70 Difference to Placebo is presented for Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	14.1

Statistical analysis title	Stat 171
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Statistical analysis description:

Week 12, ACR70 Difference to Placebo is presented for Week 12. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	17.8

Statistical analysis title

Stat 172

Statistical analysis description:

Week 16, ACR20 Difference to Placebo is presented for Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.5
upper limit	44.1

Statistical analysis title

Stat 173

Statistical analysis description:

Week 16, ACR20 Difference to Placebo is presented for Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.2
upper limit	70.5

Statistical analysis title	Stat 174
Statistical analysis description:	
Week 16, ACR50 Difference to Placebo is presented for Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	35.7

Statistical analysis title	Stat 175
Statistical analysis description:	
Week 16, ACR50 Difference to Placebo is presented for Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	29.4

Statistical analysis title	Stat 176
Statistical analysis description:	
Week 16, ACR70 Difference to Placebo is presented for Week 16. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	17.8

Statistical analysis title	Stat 177
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Statistical analysis description:

Week 20, ACR20 Difference to Placebo is presented for Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	41.2

Statistical analysis title	Stat 178
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Statistical analysis description:

Week 20, ACR20 Difference to Placebo is presented for Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	43.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.5
upper limit	63

Statistical analysis title	Stat 179
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Statistical analysis description:

Week 20, ACR50 Difference to Placebo is presented for Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.9
upper limit	41.8

Statistical analysis title	Stat 180
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Statistical analysis description:

Week 20, ACR50 Difference to Placebo is presented for Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.5
upper limit	38.8

Statistical analysis title	Stat 181
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Statistical analysis description:

Week 20, ACR70 Difference to Placebo is presented for Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.3
upper limit	34.5

Statistical analysis title	Stat 182
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Statistical analysis description:

Week 20, ACR70 Difference to Placebo is presented for Week 20. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	28.1

Statistical analysis title

Stat 183

Statistical analysis description:

Week 24, ACR20 Difference to Placebo is presented for Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.7
upper limit	46.3

Statistical analysis title

Stat 184

Statistical analysis description:

Week 24, ACR20 Difference to Placebo is presented for Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	45.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.7
upper limit	65.2

Statistical analysis title	Stat 185
Statistical analysis description:	
Week 24, ACR50 Difference to Placebo is presented for Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	30.6

Statistical analysis title	Stat 186
Statistical analysis description:	
Week 24, ACR50 Difference to Placebo is presented for Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	33.7

Statistical analysis title	Stat 187
Statistical analysis description:	
Week 24, ACR70 Difference to Placebo is presented for Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	28.1

Statistical analysis title	Stat 188
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Statistical analysis description:

Week 24, ACR70 Difference to Placebo is presented for Week 24. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	28.1

Statistical analysis title	Stat 189
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Statistical analysis description:

Week 28, ACR20 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 190
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Statistical analysis description:

Week 28, ACR20 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	64.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.9
upper limit	80.8

Statistical analysis title	Stat 191
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Statistical analysis description:

Week 28, ACR50 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 192
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Statistical analysis description:

Week 28, ACR50 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.8
upper limit	36.4

Statistical analysis title	Stat 193
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Statistical analysis description:

Week 28, ACR70 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title

Stat 194

Statistical analysis description:

Week 28, ACR70 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title

Stat 195

Statistical analysis description:

Week 32, ACR20 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 196
Statistical analysis description:	
Week 32, ACR20 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.5
upper limit	68.2

Statistical analysis title	Stat 197
Statistical analysis description:	
Week 32, ACR50 Difference to Placebo is presented for Week 28. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 198
Statistical analysis description:	
Week 32, ACR50 Difference to Placebo is presented for Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	27

Confidence interval	
level	95 %
sides	2-sided
lower limit	11.4
upper limit	42.7

Statistical analysis title	Stat 199
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Statistical analysis description:

Week 32, ACR70 Difference to Placebo is presented for Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 200
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Statistical analysis description:

Week 32, ACR70 Difference to Placebo is presented for Week 32. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 201
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Statistical analysis description:

Week 36, ACR20 Difference to Placebo is presented for Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 202
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Statistical analysis description:

Week 36, ACR20 Difference to Placebo is presented for Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	56.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.1
upper limit	73.4

Statistical analysis title	Stat 203
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Statistical analysis description:

Week 36, ACR50 Difference to Placebo is presented for Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 204
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Statistical analysis description:

Week 36, ACR50 Difference to Placebo is presented for Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	32.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.2
upper limit	48.7

Statistical analysis title

Stat 205

Statistical analysis description:

Week 36, ACR70 Difference to Placebo is presented for Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.3
upper limit	28.1

Statistical analysis title

Stat 206

Statistical analysis description:

Week 36, ACR70 Difference to Placebo is presented for Week 36. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 207
Statistical analysis description:	
Week 40, ACR20 Difference to Placebo is presented for Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 208
Statistical analysis description:	
Week 40, ACR20 Difference to Placebo is presented for Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.5
upper limit	68.2

Statistical analysis title	Stat 209
Statistical analysis description:	
Week 40, ACR50 Difference to Placebo is presented for Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 210
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Statistical analysis description:

Week 40, ACR50 Difference to Placebo is presented for Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.8
upper limit	45.7

Statistical analysis title	Stat 211
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Statistical analysis description:

Week 40, ACR70 Difference to Placebo is presented for Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title	Stat 212
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Statistical analysis description:

Week 40, ACR70 Difference to Placebo is presented for Week 40. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 213
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Statistical analysis description:

Week 44, ACR20 Difference to Placebo is presented for Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 214
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Statistical analysis description:

Week 44, ACR20 Difference to Placebo is presented for Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.5
upper limit	68.2

Statistical analysis title	Stat 215
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Statistical analysis description:

Week 44, ACR50 Difference to Placebo is presented for Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title

Stat 216

Statistical analysis description:

Week 44, ACR50 Difference to Placebo is presented for Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	35.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.7
upper limit	51.6

Statistical analysis title

Stat 217

Statistical analysis description:

Week 44, ACR70 Difference to Placebo is presented for Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 218
Statistical analysis description:	
Week 44, ACR70 Difference to Placebo is presented for Week 44. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.3
upper limit	31.5

Statistical analysis title	Stat 219
Statistical analysis description:	
Week 48, ACR20 Difference to Placebo is presented for Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 220
Statistical analysis description:	
Week 48, ACR20 Difference to Placebo is presented for Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	51.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	37.3
upper limit	70.9

Statistical analysis title	Stat 221
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Statistical analysis description:

Week 48, ACR50 Difference to Placebo is presented for Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 222
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Statistical analysis description:

Week 48, ACR50 Difference to Placebo is presented for Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	32.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.2
upper limit	48.7

Statistical analysis title	Stat 223
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Statistical analysis description:

Week 48, ACR70 Difference to Placebo is presented for Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 224
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Statistical analysis description:

Week 48, ACR70 Difference to Placebo is presented for Week 48. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.4
upper limit	34.9

Statistical analysis title	Stat 225
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Statistical analysis description:

Week 52, ACR20 Difference to Placebo is presented for Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 226
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Statistical analysis description:

Week 52, ACR20 Difference to Placebo is presented for Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	48.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.7
upper limit	65.6

Statistical analysis title

Stat 227

Statistical analysis description:

Week 52, ACR50 Difference to Placebo is presented for Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title

Stat 228

Statistical analysis description:

Week 52, ACR50 Difference to Placebo is presented for Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.1
upper limit	39.6

Statistical analysis title	Stat 229
Statistical analysis description:	
Week 52, ACR70 Difference to Placebo is presented for Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 230
Statistical analysis description:	
Week 52, ACR70 Difference to Placebo is presented for Week 52. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 231
Statistical analysis description:	
Week 62 (follow-up), ACR20 Difference to Placebo is presented for Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 232
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Statistical analysis description:

Week 62 (follow-up), ACR20 Difference to Placebo is presented for Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	40.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.7
upper limit	57.3

Statistical analysis title	Stat 233
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Statistical analysis description:

Week 62 (follow-up), ACR50 Difference to Placebo is presented for Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	26.5

Statistical analysis title	Stat 234
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Statistical analysis description:

Week 62 (follow-up), ACR50 Difference to Placebo is presented for Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.1
upper limit	39.6

Statistical analysis title	Stat 235
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Statistical analysis description:

Week 62 (follow-up), ACR70 Difference to Placebo is presented for Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	23

Statistical analysis title	Stat 236
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Statistical analysis description:

Week 62 (follow-up), ACR70 Difference to Placebo is presented for Week 62 (follow-up). 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	29.9

Secondary: Percentage of participants with Index-based ACR/EULAR remission

rates at all assessment time points

End point title	Percentage of participants with Index-based ACR/EULAR remission rates at all assessment time points
End point description:	
Index-based remission was achieved if the following requirement was met: SDAI ≤ 3.3. If the SDAI value was missing at an individual assessment point, Index-based remission for that assessment was set to missing.	
End point type	Secondary
End point timeframe:	
Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and Week 62 (follow-up)	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[108]	37 ^[109]	37 ^[110]	37 ^[111]
Units: Percentage of participants				
Index based ACR/EULAR, Week 1	0	0	0	0
Index based ACR/EULAR, Week 2	0	0	0	0
Index based ACR/EULAR, Week 4	0	0	0	3
Index based ACR/EULAR, Week 6	0	0	0	3
Index based ACR/EULAR, Week 8	3	0	0	3
Index based ACR/EULAR, Week 12	3	0	0	3
Index based ACR/EULAR, Week 16	0	0	3	14
Index based ACR/EULAR, Week 20	0	0	5	11
Index based ACR/EULAR, Week 24	0	0	5	8
Index based ACR/EULAR, Week 28	0	0	5	11
Index based ACR/EULAR, Week 32	0	0	14	8
Index based ACR/EULAR, Week 36	0	3	11	8
Index based ACR/EULAR, Week 40	0	3	11	8
Index based ACR/EULAR, Week 44	0	3	8	11
Index based ACR/EULAR, Week 48	0	3	11	8
Index based ACR/EULAR, Week 52	0	5	14	5
Index based ACR/EULAR, Week 62 (follow-up)	0	0	8	3

Notes:

[108] - ITT Population

[109] - ITT Population

[110] - ITT Population

[111] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[112]	37 ^[113]		
Units: Percentage of participants				
Index based ACR/EULAR, Week 1	0	0		
Index based ACR/EULAR, Week 2	0	3		
Index based ACR/EULAR, Week 4	0	3		
Index based ACR/EULAR, Week 6	3	3		
Index based ACR/EULAR, Week 8	3	3		
Index based ACR/EULAR, Week 12	3	3		

Index based ACR/EULAR, Week 16	3	5		
Index based ACR/EULAR, Week 20	3	5		
Index based ACR/EULAR, Week 24	8	5		
Index based ACR/EULAR, Week 28	8	14		
Index based ACR/EULAR, Week 32	8	11		
Index based ACR/EULAR, Week 36	14	5		
Index based ACR/EULAR, Week 40	5	14		
Index based ACR/EULAR, Week 44	5	8		
Index based ACR/EULAR, Week 48	11	3		
Index based ACR/EULAR, Week 52	5	8		
Index based ACR/EULAR, Week 62 (follow-up)	5	14		

Notes:

[112] - ITT Population

[113] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
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Statistical analysis description:

Index based ACR/EULAR, Week 4. Difference to Placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 2
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Statistical analysis description:

Index based ACR/EULAR, Week 6. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 3
Statistical analysis description: Index based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 4
Statistical analysis description: Index based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 5
Statistical analysis description: Index based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 6
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Statistical analysis description:

Index based ACR/EULAR, Week 12. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 7
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Statistical analysis description:

Index based ACR/EULAR, Week 12. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 8
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Statistical analysis description:

Index based ACR/EULAR, Week 12. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 9
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Statistical analysis description:

Index based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 10
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Statistical analysis description:

Index based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 11
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Statistical analysis description:

Index based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 12

Statistical analysis description:

Index based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title

Stat 13

Statistical analysis description:

Index based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 14
Statistical analysis description:	
Index based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 15
Statistical analysis description:	
Index based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 16
Statistical analysis description:	
Index based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 17
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Statistical analysis description:

Index based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 18
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Statistical analysis description:

Index based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 19
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Statistical analysis description:

Index based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 20
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Statistical analysis description:

Index based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 21
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Statistical analysis description:

Index based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 22
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Statistical analysis description:

Index based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 23

Statistical analysis description:

Index based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title

Stat 24

Statistical analysis description:

Index based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 25
Statistical analysis description: Index based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 26
Statistical analysis description: Index based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 27
Statistical analysis description: Index based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 28
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Statistical analysis description:

Index based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 29
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Statistical analysis description:

Index based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 30
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Statistical analysis description:

Index based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 31
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Statistical analysis description:

Index based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 32
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Statistical analysis description:

Index based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 33
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Statistical analysis description:

Index based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 34

Statistical analysis description:

Index based ACR/EULAR, Week 62 (follow-up). Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title

Stat 35

Statistical analysis description:

Index based ACR/EULAR, Week 62 (follow-up). Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 36
Statistical analysis description:	
Index based ACR/EULAR, Week 2. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 37
Statistical analysis description:	
Index based ACR/EULAR, Week 4. Difference to Placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 38
Statistical analysis description:	
Index based ACR/EULAR, Week 6. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 39
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Statistical analysis description:

Index based ACR/EULAR, Week 6. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 40
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Statistical analysis description:

Index based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 41
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Statistical analysis description:

Index based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 42
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Statistical analysis description:

Index based ACR/EULAR, Week 12. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 43
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Statistical analysis description:

Index based ACR/EULAR, Week 12. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 44
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Statistical analysis description:

Index based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 45

Statistical analysis description:

Index based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 46

Statistical analysis description:

Index based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	12.7

Statistical analysis title	Stat 47
Statistical analysis description:	
Index based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	68.2

Statistical analysis title	Stat 48
Statistical analysis description:	
Index based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 49
Statistical analysis description:	
Index based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 50
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Statistical analysis description:

Index based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 51
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Statistical analysis description:

Index based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 52
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Statistical analysis description:

Index based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 53
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Statistical analysis description:

Index based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 54
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Statistical analysis description:

Index based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 55
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Statistical analysis description:

Index based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 56

Statistical analysis description:

Index based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 57

Statistical analysis description:

Index based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 58
Statistical analysis description: Index based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 59
Statistical analysis description: Index based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 60
Statistical analysis description: Index based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 61
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Statistical analysis description:

Index based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 62
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Statistical analysis description:

Index based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 63
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Statistical analysis description:

Index based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 64
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 65
Statistical analysis description:	
Index based ACR/EULAR, Week 62 (follow-up). Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Secondary: Percentage of participants with Boolean-based ACR/EULAR remission rates at all assessment time points

End point title	Percentage of participants with Boolean-based ACR/EULAR remission rates at all assessment time points
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End point description:

Boolean-based remission was achieved if all of the following requirements were met at the same time: TJC68 ≤ 1, SJC66 ≤ 1, CRP ≤ 1mg/dL, PtGA ≤ 10. If one of the components was missing at an individual assessment point, Boolean-based remission for that assessment was set to missing.

End point type Secondary

End point timeframe:

Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and Week 62 (follow-up)

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[114]	37 ^[115]	37 ^[116]	37 ^[117]
Units: Percentage of participants				
Boolean based ACR/EULAR, Week 1	0	0	0	0
Boolean based ACR/EULAR, Week 2	0	0	0	0
Boolean based ACR/EULAR, Week 4	0	0	0	0
Boolean based ACR/EULAR, Week 6	0	0	0	0
Boolean based ACR/EULAR, Week 8	0	0	0	3
Boolean based ACR/EULAR, Week 12	0	0	0	8
Boolean based ACR/EULAR, Week 16	0	0	3	5
Boolean based ACR/EULAR, Week 20	0	0	5	8
Boolean based ACR/EULAR, Week 24	0	0	3	8
Boolean based ACR/EULAR, Week 28	0	0	5	8
Boolean based ACR/EULAR, Week 32	0	0	5	5
Boolean based ACR/EULAR, Week 36	0	0	8	5
Boolean based ACR/EULAR, Week 40	0	0	8	8
Boolean based ACR/EULAR, Week 44	0	0	11	8
Boolean based ACR/EULAR, Week 48	0	3	8	3
Boolean based ACR/EULAR, Week 52	0	0	11	3
Boolean based ACR/EULAR, Week 62 (follow-up)	0	0	8	3

Notes:

[114] - ITT Population

[115] - ITT Population

[116] - ITT Population

[117] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[118]	37 ^[119]		
Units: Percentage of participants				
Boolean based ACR/EULAR, Week 1	0	0		
Boolean based ACR/EULAR, Week 2	0	3		
Boolean based ACR/EULAR, Week 4	0	0		
Boolean based ACR/EULAR, Week 6	3	3		
Boolean based ACR/EULAR, Week 8	3	5		
Boolean based ACR/EULAR, Week 12	0	3		
Boolean based ACR/EULAR, Week 16	3	5		
Boolean based ACR/EULAR, Week 20	3	5		
Boolean based ACR/EULAR, Week 24	5	3		

Boolean based ACR/EULAR, Week 28	5	5		
Boolean based ACR/EULAR, Week 32	5	5		
Boolean based ACR/EULAR, Week 36	8	3		
Boolean based ACR/EULAR, Week 40	5	8		
Boolean based ACR/EULAR, Week 44	5	5		
Boolean based ACR/EULAR, Week 48	11	3		
Boolean based ACR/EULAR, Week 52	5	5		
Boolean based ACR/EULAR, Week 62 (follow-up)	3	5		

Notes:

[118] - ITT Population

[119] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Boolean based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 2
Statistical analysis description:	
Boolean based ACR/EULAR, Week 12. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 3
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Statistical analysis description:

Boolean based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 4

Statistical analysis description:

Boolean based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 5

Statistical analysis description:

Boolean based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 6
Statistical analysis description: Boolean based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 7
Statistical analysis description: Boolean based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 8
Statistical analysis description: Boolean based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 9
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Statistical analysis description:

Boolean based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 10
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Statistical analysis description:

Boolean based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 11
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Statistical analysis description:

Boolean based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 12
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Statistical analysis description:

Boolean based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 13
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Statistical analysis description:

Boolean based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 14
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Statistical analysis description:

Boolean based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 15

Statistical analysis description:

Boolean based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title

Stat 16

Statistical analysis description:

Boolean based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 17
Statistical analysis description:	
Boolean based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 18
Statistical analysis description:	
Boolean based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 19
Statistical analysis description:	
Boolean based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 20
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Statistical analysis description:

Boolean based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 21
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Statistical analysis description:

Boolean based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	42.8

Statistical analysis title	Stat 22
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Statistical analysis description:

Boolean based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 23
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Statistical analysis description:

Boolean based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 24
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Statistical analysis description:

Boolean based ACR/EULAR, Week 62 (follow-up). Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 25
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Statistical analysis description:

Boolean based ACR/EULAR, Week 62 (follow-up). Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 26

Statistical analysis description:

Boolean based ACR/EULAR, Week 2. Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 27

Statistical analysis description:

Boolean based ACR/EULAR, Week 6. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 28
Statistical analysis description: Boolean based ACR/EULAR, Week 6. Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 29
Statistical analysis description: Boolean based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 30
Statistical analysis description: Boolean based ACR/EULAR, Week 8. Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 31
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Statistical analysis description:

Boolean based ACR/EULAR, Week 12. Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 32
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Statistical analysis description:

Boolean based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 33
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Statistical analysis description:

Boolean based ACR/EULAR, Week 16. Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 34
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Statistical analysis description:

Boolean based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 35
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Statistical analysis description:

Boolean based ACR/EULAR, Week 20. Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 36
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Statistical analysis description:

Boolean based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 37

Statistical analysis description:

Boolean based ACR/EULAR, Week 24. Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 38

Statistical analysis description:

Boolean based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 39
Statistical analysis description:	
Boolean based ACR/EULAR, Week 28. Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 40
Statistical analysis description:	
Boolean based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 41
Statistical analysis description:	
Boolean based ACR/EULAR, Week 32. Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 42
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Statistical analysis description:

Boolean based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 43
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Statistical analysis description:

Boolean based ACR/EULAR, Week 36. Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 44
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Statistical analysis description:

Boolean based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 135 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 45
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Statistical analysis description:

Boolean based ACR/EULAR, Week 40. Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 46
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Statistical analysis description:

Boolean based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 47
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Statistical analysis description:

Boolean based ACR/EULAR, Week 44. Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 48

Statistical analysis description:

Boolean based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title

Stat 49

Statistical analysis description:

Boolean based ACR/EULAR, Week 48. Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 50
Statistical analysis description: Boolean based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 51
Statistical analysis description: Boolean based ACR/EULAR, Week 52. Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 52
Statistical analysis description: Boolean based ACR/EULAR, Week 62 (follow-up). Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 53
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Statistical analysis description:

Boolean based ACR/EULAR, Week 62 (follow-up). Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Secondary: Percentage of participants with Clinical Disease Activity Index (CDAI) at all assessment time points

End point title	Percentage of participants with Clinical Disease Activity Index (CDAI) at all assessment time points
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End point description:

CDAI combines information relating to the number of swollen and tender joints, in addition to a measure of general health from both the participants and the physician. CDAI utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal- phalangeal I-V, proximal interphalangeal I-V and knees and is calculated using the following formula: $CDAI = TJC28 + SJC28 + GH + GP$ Where TJC – Tender joint Count, SJC= Swollen Joint Count, (GH=participant assessment of disease activity and GP=physician assessment of disease activity using a 10 cm visual analogue scale with 0 = best, 100 = worst). It ranges between 0 and 76. High score indicates worse outcome, low score indicates better outcome.

End point type	Secondary
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End point timeframe:

Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and Week 62 (follow-up)

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[120]	37 ^[121]	37 ^[122]	37 ^[123]
Units: Percentage of participants				
CDAI, Week 1	0	0	0	0
CDAI, Week 2	0	0	0	0
CDAI, Week 4	0	0	0	5

CDAI, Week 6	0	0	0	3
CDAI, Week 8	3	0	0	3
CDAI, Week 12	3	0	0	11
CDAI, Week 16	0	3	3	16
CDAI, Week 20	0	0	3	11
CDAI, Week 24	0	0	5	5
CDAI, Week 28	0	0	3	11
CDAI, Week 32	0	0	14	8
CDAI, Week 36	0	3	11	8
CDAI, Week 40	0	3	11	8
CDAI, Week 44	0	3	11	11
CDAI, Week 48	0	3	14	8
CDAI, Week 52	0	0	14	5
CDAI, Week 62 (follow-up)	0	0	8	3

Notes:

[120] - ITT Population

[121] - ITT Population

[122] - ITT Population

[123] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[124]	37 ^[125]		
Units: Percentage of participants				
CDAI, Week 1	0	0		
CDAI, Week 2	0	5		
CDAI, Week 4	0	3		
CDAI, Week 6	3	3		
CDAI, Week 8	3	3		
CDAI, Week 12	3	5		
CDAI, Week 16	3	5		
CDAI, Week 20	3	5		
CDAI, Week 24	8	5		
CDAI, Week 28	5	14		
CDAI, Week 32	8	11		
CDAI, Week 36	14	5		
CDAI, Week 40	5	14		
CDAI, Week 44	5	5		
CDAI, Week 48	11	8		
CDAI, Week 52	5	8		
CDAI, Week 62 (follow-up)	5	16		

Notes:

[124] - ITT Population

[125] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
CDAI, Week 4, Difference to Placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 2
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Statistical analysis description:

CDAI, Week 6, Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 3
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Statistical analysis description:

CDAI, Week 8, Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 4
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Statistical analysis description:

CDAI, Week 8, Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title

Stat 5

Statistical analysis description:

CDAI, Week 8, Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title

Stat 6

Statistical analysis description:

CDAI, Week 12, Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 7
Statistical analysis description: CDAI, Week 12, Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.5

Statistical analysis title	Stat 8
Statistical analysis description: CDAI, Week 12, Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	19.4

Statistical analysis title	Stat 9
Statistical analysis description: CDAI, Week 16, Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 10
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Statistical analysis description:

CDAI, Week 16, Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 11
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Statistical analysis description:

CDAI, Week 16, Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.3
upper limit	28.1

Statistical analysis title	Stat 12
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Statistical analysis description:

CDAI, Week 20, Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 13
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Statistical analysis description:

CDAI, Week 20, Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 14
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Statistical analysis description:

CDAI, Week 24, Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 15
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Statistical analysis description:

CDAI, Week 24, Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 16

Statistical analysis description:

CDAI, Week 28, Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 17

Statistical analysis description:

CDAI, Week 28, Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 18
Statistical analysis description: CDAI, Week 32, Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 19
Statistical analysis description: CDAI, Week 32, Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 20
Statistical analysis description: CDAI, Week 36, Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 21
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Statistical analysis description:

CDAI, Week 36, Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 22
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Statistical analysis description:

CDAI, Week 36, Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 23
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Statistical analysis description:

CDAI, Week 40, Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 24
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Statistical analysis description:

CDAI, Week 40, Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 25
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Statistical analysis description:

CDAI, Week 40, Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 26
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Statistical analysis description:

CDAI, Week 44, Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 27

Statistical analysis description:

CDAI, Week 44, Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title

Stat 28

Statistical analysis description:

CDAI, Week 44, Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 29
Statistical analysis description: CDAI, Week 48, Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 30
Statistical analysis description: CDAI, Week 48, Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 31
Statistical analysis description: CDAI, Week 48, Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 32
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Statistical analysis description:

CDAI, Week 52, Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 33
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Statistical analysis description:

CDAI, Week 52, Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 34
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Statistical analysis description:

CDAI, Week 62 (follow up), Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 35
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Statistical analysis description:

CDAI, Week 62 (follow up), Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 36
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Statistical analysis description:

CDAI, Week 2, Difference to Placebo for Week 2 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 37
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Statistical analysis description:

CDAI, Week 4, Difference to Placebo for Week 4 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 38

Statistical analysis description:

CDAI, Week 6, Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title

Stat 39

Statistical analysis description:

CDAI, Week 6, Difference to Placebo for Week 6 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 40
Statistical analysis description:	
CDAI, Week 8, Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 41
Statistical analysis description:	
CDAI, Week 8, Difference to Placebo for Week 8 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 42
Statistical analysis description:	
CDAI, Week 12, Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	7.4

Statistical analysis title	Stat 43
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Statistical analysis description:

CDAI, Week 12, Difference to Placebo for Week 12 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	11.7

Statistical analysis title	Stat 44
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Statistical analysis description:

CDAI, Week 16, Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 45
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Statistical analysis description:

CDAI, Week 16, Difference to Placebo for Week 16 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 46
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Statistical analysis description:

CDAI, Week 20, Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	7.9

Statistical analysis title	Stat 47
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Statistical analysis description:

CDAI, Week 20, Difference to Placebo for Week 20 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 48
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Statistical analysis description:

CDAI, Week 24, Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title

Stat 49

Statistical analysis description:

CDAI, Week 24, Difference to Placebo for Week 24 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title

Stat 50

Statistical analysis description:

CDAI, Week 28, Difference to Placebo for Week 28 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 51
Statistical analysis description:	
CDAI, Week 32, Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 52
Statistical analysis description:	
CDAI, Week 32, Difference to Placebo for Week 32 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title	Stat 53
Statistical analysis description:	
CDAI, Week 36, Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 54
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Statistical analysis description:

CDAI, Week 36, Difference to Placebo for Week 36 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 55
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Statistical analysis description:

CDAI, Week 40, Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 56
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Statistical analysis description:

CDAI, Week 40, Difference to Placebo for Week 40 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	24.5

Statistical analysis title	Stat 57
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Statistical analysis description:

CDAI, Week 44, Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 58
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Statistical analysis description:

CDAI, Week 44, Difference to Placebo for Week 44 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 59
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Statistical analysis description:

CDAI, Week 48, Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	20.8

Statistical analysis title

Stat 60

Statistical analysis description:

CDAI, Week 48, Difference to Placebo for Week 48 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title

Stat 61

Statistical analysis description:

CDAI, Week 52, Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 62
Statistical analysis description: CDAI, Week 52, Difference to Placebo for Week 52 is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.9

Statistical analysis title	Stat 63
Statistical analysis description: CDAI, Week 62 (follow-up), Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	5.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	12.7

Statistical analysis title	Stat 64
Statistical analysis description: CDAI, Week 62 (follow-up), Difference to Placebo for Week 62 (follow-up) is presented. 95% CI were constructed using asymptotic Wald confidence limits without correction.	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference
Point estimate	16.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.3
upper limit	28.1

Secondary: Change from Baseline in SDAI at all assessment time points

End point title	Change from Baseline in SDAI at all assessment time points
End point description:	
SDAI combines information relating to the number of swollen and tender joints, in addition to a measure of general health from both the participants and the physician and acute phase reactants. SDAI utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal-phalangeal I-V, proximal interphalangeal I-V and knees and calculated using the following formula: SDAI = TJC28+SJC28+GH+GP+CRP Where TJC=Tender joint Count, SJC=Swollen Joint Count, (GH=participant assessment, GP=physician assessment of disease activity), and CRP=C reactive Protein (in mg/L). It ranges between 0.1 and 86. High score (worse outcome), low score (better outcome). Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=x in the category titles).	
End point type	Secondary
End point timeframe:	
Baseline and Weeks 1, 2, 4, 6, 8, 12, 16, 20 and 24	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[126]	37 ^[127]	37 ^[128]	37 ^[129]
Units: Scores on a scale				
least squares mean (standard error)				
SDAI, Week 1,n=35,36,32,35, 34, 37	-1.53 (± 1.470)	-5.62 (± 1.466)	-5.20 (± 1.527)	-5.86 (± 1.470)
SDAI, Week 2,n=35,34,34,36,36,36	-4.56 (± 1.821)	-8.62 (± 1.848)	-9.28 (± 1.851)	-10.03 (± 1.804)
SDAI, Week 4,n=32,33,34,35, 36, 36	-5.53 (± 2.095)	-12.30 (± 2.092)	-12.81 (± 2.073)	-14.76 (± 2.037)
SDAI, Week 6,n=35,34,33,36,32, 36	-8.70 (± 2.132)	-14.36 (± 2.152)	-14.99 (± 2.163)	-15.50 (± 2.095)
SDAI, Week 8,n=34,33,34,37, 35, 32	-8.08 (± 2.349)	-14.66 (± 2.367)	-17.23 (± 2.353)	-16.95 (± 2.281)
SDAI, Week 12,n=34,35,33,37, 34, 36	-7.05 (± 2.729)	-13.95 (± 2.712)	-17.41 (± 2.741)	-21.20 (± 2.640)
SDAI, Week 16,n=8,16,20,23, 18, 36	-15.64 (± 3.222)	-17.53 (± 2.707)	-22.64 (± 2.605)	-22.91 (± 2.484)
SDAI, Week 20,n=8,15,20,25, 18, 35	-17.47 (± 3.523)	-16.67 (± 2.835)	-23.17 (± 2.621)	-23.47 (± 2.437)
SDAI, Week 24,n=8,14,20,24, 19, 33	-5.40 (± 4.484)	-16.05 (± 3.569)	-21.77 (± 3.165)	-21.07 (± 2.945)

Notes:

[126] - ITT Population

[127] - ITT Population

[128] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[130]	37 ^[131]		
Units: Scores on a scale				
least squares mean (standard error)				
SDAI, Week 1,n=35,36,32,35, 34, 37	-6.31 (± 1.495)	-9.30 (± 1.448)		
SDAI, Week 2,n=35,34,34,36,36,36	-11.22 (± 1.819)	-11.40 (± 1.808)		
SDAI, Week 4,n=32,33,34,35, 36, 36	-13.97 (± 2.042)	-18.03 (± 2.032)		
SDAI, Week 6,n=35,34,33,36,32, 36	-15.70 (± 2.165)	-18.86 (± 2.109)		
SDAI, Week 8,n=34,33,34,37, 35, 32	-19.26 (± 2.329)	-22.09 (± 2.358)		
SDAI, Week 12,n=34,35,33,37, 34, 36	-16.73 (± 2.708)	-23.90 (± 2.676)		
SDAI, Week 16,n=8,16,20,23, 18, 36	-21.68 (± 2.632)	-25.08 (± 2.351)		
SDAI, Week 20,n=8,15,20,25, 18, 35	-24.06 (± 2.670)	-26.17 (± 2.263)		
SDAI, Week 24,n=8,14,20,24, 19, 33	-21.28 (± 3.200)	-26.27 (± 2.667)		

Notes:

[130] - ITT Population

[131] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Week 1, SDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.05 ^[132]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.18
upper limit	0

Notes:

[132] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
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Statistical analysis description:

Week 1, SDAI

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.086 ^[133]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.84
upper limit	0.52

Notes:

[133] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
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Statistical analysis description:

Week 2, SDAI

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.119 ^[134]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.18
upper limit	1.05

Notes:

[134] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
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Statistical analysis description:

Week 1, SDAI

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.038 ^[135]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.33

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.43
upper limit	-0.23

Notes:

[135] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
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Statistical analysis description:

Week 2, SDAI

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.071 ^[136]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.85
upper limit	0.4

Notes:

[136] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
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Statistical analysis description:

Week 4, SDAI

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.023 ^[137]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.61
upper limit	-0.94

Notes:

[137] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
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Statistical analysis description:

Week 2, SDAI

Comparison groups	Placebo v GSK3196165 90 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.034 ^[138]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.53
upper limit	-0.42

Notes:

[138] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
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Statistical analysis description:

Week 4, SDAI

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002 ^[139]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.99
upper limit	-3.47

Notes:

[139] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
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Statistical analysis description:

Week 4, SDAI

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.014 ^[140]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.09
upper limit	-1.47

Notes:

[140] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
Statistical analysis description:	
Week 6, SDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.063 ^[141]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.62
upper limit	0.32

Notes:

[141] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
Statistical analysis description:	
Week 6, SDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.04 ^[142]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.28
upper limit	-0.3

Notes:

[142] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
Week 8, SDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.05 ^[143]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.15
upper limit	-0.01

Notes:

[143] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
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Statistical analysis description:

Week 6, SDAI

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.024 ^[144]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.69
upper limit	-0.9

Notes:

[144] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
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Statistical analysis description:

Week 8, SDAI

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006 ^[145]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.71
upper limit	-2.6

Notes:

[145] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
Statistical analysis description:	
Week 8, SDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.007 ^[146]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.32
upper limit	-2.41

Notes:

[146] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 16
Statistical analysis description:	
Week 12, SDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.074 ^[147]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.49
upper limit	0.68

Notes:

[147] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 17
Statistical analysis description:	
Week 12, SDAI	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.008 ^[148]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-10.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.99
upper limit	-2.74

Notes:

[148] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 18
Statistical analysis description:	
Week 12, SDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[149]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-14.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.64
upper limit	-6.67

Notes:

[149] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 19
Statistical analysis description:	
Week 16, SDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.656 ^[150]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.19
upper limit	6.43

Notes:

[150] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 21
Statistical analysis description: Week 16,SDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.076 ^[151]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.3
upper limit	0.78

Notes:

[151] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 20
Statistical analysis description: Week 16,SDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.093 ^[152]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.19
upper limit	1.19

Notes:

[152] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 22
Statistical analysis description: Week 20,SDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.86 ^[153]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.14
upper limit	9.74

Notes:

[153] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 23
Statistical analysis description:	
Week 20,SDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.196 ^[154]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.4
upper limit	2.99

Notes:

[154] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 24
Statistical analysis description:	
Week 20,SDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.164 ^[155]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.48
upper limit	2.48

Notes:

[155] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 25
Statistical analysis description: Week 24,SDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.066 ^[156]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-10.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.99
upper limit	0.69

Notes:

[156] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 26
Statistical analysis description: Week 24,SDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003 ^[157]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-16.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.25
upper limit	-5.49

Notes:

[157] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 27
Statistical analysis description: Week 24,SDAI	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[158]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-15.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.3
upper limit	-5.03

Notes:

[158] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 28
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Statistical analysis description:

Week 1,SDAI

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.024 ^[159]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.91
upper limit	-0.65

Notes:

[159] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 29
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Statistical analysis description:

Week 1,SDAI

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[160]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.84
upper limit	-3.7

Notes:

[160] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 30
Statistical analysis description: Week 2,SDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.01 ^[161]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.74
upper limit	-1.6

Notes:

[161] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 31
Statistical analysis description: Week 2,SDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.008 ^[162]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.91
upper limit	-1.78

Notes:

[162] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 32
Statistical analysis description: Week 4,SDAI	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[163]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.2
upper limit	-2.67

Notes:

[163] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 33
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Statistical analysis description:

Week 4,SDAI

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[164]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-12.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.26
upper limit	-6.75

Notes:

[164] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 34
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Statistical analysis description:

Week 6,SDAI

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.022 ^[165]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.99
upper limit	-1.01

Notes:

[165] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 35
Statistical analysis description:	
Week 6,SDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[166]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-10.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.07
upper limit	-4.24

Notes:

[166] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 37
Statistical analysis description:	
Week 8,SDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[167]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.57
upper limit	-7.44

Notes:

[167] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 36
Statistical analysis description:	
Week 8,SDAI	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[168]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-11.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.7
upper limit	-4.66

Notes:

[168] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 39
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Statistical analysis description:

Week 12,SDAI

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[169]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-16.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.39
upper limit	-9.32

Notes:

[169] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 38
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Statistical analysis description:

Week 12,SDAI

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.013 ^[170]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.26
upper limit	-2.11

Notes:

[170] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 41
Statistical analysis description:	
Week 16,SDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.019 ^[171]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.32
upper limit	-1.55

Notes:

[171] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 40
Statistical analysis description:	
Week 16,SDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.149 ^[172]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.24
upper limit	2.18

Notes:

[172] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 43
Statistical analysis description:	
Week 20,SDAI	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.04 ^[173]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.99
upper limit	-0.42

Notes:

[173] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 42
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Statistical analysis description:

Week 20,SDAI

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.138 ^[174]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.32
upper limit	2.14

Notes:

[174] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 44
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Statistical analysis description:

Week 24,SDAI

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005 ^[175]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-15.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.77
upper limit	-4.98

Notes:

[175] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 45
Statistical analysis description: Week 24,SDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[176]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-20.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.2
upper limit	-10.53

Notes:

[176] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Change from Baseline in CDAI at all assessment time points

End point title	Change from Baseline in CDAI at all assessment time points
End point description: CDAI combines information relating to the number of swollen and tender joints, in addition to a measure of general health from both the participants and the physician. CDAI utilizing joint scores from the following 28 joints: elbows, shoulders, elbow, wrists, metacarpal- phalangeal I-V, proximal interphalangeal I-V and knees and is calculated using the following formula: CDAI =TJC28 + SJC28 + GH + GP Where TJC – Tender joint Count, SJC= Swollen Joint Count, (GH=participant assessment of disease activity and GP=physician assessment of disease). It ranges between 0 and 76. High score indicates worse outcome, low score indicates better outcome. Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=x in the category titles).	
End point type	Secondary
End point timeframe: Baseline and Weeks 1, 2, 4, 6, 8, 12, 16, 20 and 24	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[177]	37 ^[178]	37 ^[179]	37 ^[180]
Units: Scores on a scale				
least squares mean (standard error)				
CDAI, Week 1, n=36,36,33,36, 35, 37	-1.34 (± 1.449)	-5.18 (± 1.455)	-5.18 (± 1.497)	-5.76 (± 1.448)
CDAI, Week 2,n=35,34,36,37, 36, 37	-4.25 (± 1.782)	-8.42 (± 1.807)	-7.72 (± 1.771)	-9.45 (± 1.752)
CDAI, Week 4,n=33,33,35,36, 36, 36	-4.95 (± 2.013)	-12.15 (± 2.024)	-11.68 (± 1.978)	-14.15 (± 1.958)

CDAI, Week 6,n=35,35,33,37, 34, 36	-8.20 (± 2.089)	-13.68 (± 2.094)	-14.05 (± 2.101)	-14.83 (± 2.042)
CDAI, Week 8,n=34,33,35,37, 35, 34	-7.57 (± 2.298)	-13.98 (± 2.315)	-16.17 (± 2.270)	-16.31 (± 2.232)
CDAI, Week 12,n=34,35,35,37, 35, 36	-6.59 (± 2.658)	-13.40 (± 2.640)	-16.39 (± 2.621)	-20.47 (± 2.571)
CDAI, Week 16,n=8,16,21,23, 18, 36	-15.61 (± 3.077)	-17.30 (± 2.586)	-21.94 (± 2.445)	-22.05 (± 2.371)
CDAI, Week 20,n=8,15,21,25, 18, 35	-16.91 (± 3.419)	-15.87 (± 2.730)	-22.31 (± 2.470)	-22.81 (± 2.334)
CDAI, Week 24,n=8,14,21,24, 19, 33	-5.77 (± 4.267)	-15.14 (± 3.389)	-20.88 (± 2.947)	-20.67 (± 2.791)

Notes:

[177] - ITT Population

[178] - ITT Population

[179] - ITT Population

[180] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[181]	37 ^[182]		
Units: Scores on a scale				
least squares mean (standard error)				
CDAI, Week 1, n=36,36,33,36, 35, 37	-5.23 (± 1.469)	-8.73 (± 1.438)		
CDAI, Week 2,n=35,34,36,37, 36, 37	-10.35 (± 1.777)	-11.10 (± 1.755)		
CDAI, Week 4,n=33,33,35,36, 36, 36	-12.88 (± 1.974)	-17.14 (± 1.965)		
CDAI, Week 6,n=35,35,33,37, 34, 36	-13.82 (± 2.094)	-18.37 (± 2.065)		
CDAI, Week 8,n=34,33,35,37, 35, 34	-17.94 (± 2.276)	-21.36 (± 2.279)		
CDAI, Week 12,n=34,35,35,37, 35, 36	-16.26 (± 2.625)	-23.23 (± 2.604)		
CDAI, Week 16,n=8,16,21,23, 18, 36	-21.14 (± 2.508)	-24.47 (± 2.245)		
CDAI, Week 20,n=8,15,21,25, 18, 35	-23.46 (± 2.564)	-25.58 (± 2.158)		
CDAI, Week 24,n=8,14,21,24, 19, 33	-21.19 (± 3.037)	-25.65 (± 2.529)		

Notes:

[181] - ITT Population

[182] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Week 1,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.063 ^[183]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.89
upper limit	0.2

Notes:

[183] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
Statistical analysis description:	
Week 1,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.067 ^[184]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.95
upper limit	0.28

Notes:

[184] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
Statistical analysis description:	
Week 1,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.032 ^[185]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.46
upper limit	-0.39

Notes:

[185] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
Statistical analysis description: Week 2,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.102 ^[186]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.17
upper limit	0.84

Notes:

[186] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
Statistical analysis description: Week 2,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.17 ^[187]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.43
upper limit	1.49

Notes:

[187] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
Statistical analysis description: Week 2,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.039 ^[188]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.13
upper limit	-0.27

Notes:

[188] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
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Statistical analysis description:

Week 4,CDAI

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.012 ^[189]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.82
upper limit	-1.57

Notes:

[189] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
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Statistical analysis description:

Week 4,CDAI

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.018 ^[190]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.3
upper limit	-1.16

Notes:

[190] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
Statistical analysis description: Week 4,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001 ^[191]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.73
upper limit	-3.66

Notes:

[191] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
Statistical analysis description: Week 6,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.065 ^[192]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.31
upper limit	0.35

Notes:

[192] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
Statistical analysis description: Week 6,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.05 ^[193]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.69
upper limit	0

Notes:

[193] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
Statistical analysis description:	
Week 6,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.024 ^[194]
Method	MMRM
Parameter estimate	Mean difference (final values)
Point estimate	-6.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.38
upper limit	-0.87

Notes:

[194] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
Week 8,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.051 ^[195]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.84
upper limit	0.02

Notes:

[195] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
Statistical analysis description: Week 8,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.008 ^[196]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.97
upper limit	-2.22

Notes:

[196] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
Statistical analysis description: Week 8,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.007 ^[197]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.06
upper limit	-2.43

Notes:

[197] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 16
Statistical analysis description: Week 12,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.071 ^[198]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.19
upper limit	0.58

Notes:

[198] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 17
Statistical analysis description:	
Week 12,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.009 ^[199]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.17
upper limit	-2.44

Notes:

[199] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 18
Statistical analysis description:	
Week 12,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[200]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.17
upper limit	-6.59

Notes:

[200] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 19
Statistical analysis description: Week 16,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.676 ^[201]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.63
upper limit	6.26

Notes:

[201] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 20
Statistical analysis description: Week 16,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.11 ^[202]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.11
upper limit	1.44

Notes:

[202] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 21
Statistical analysis description: Week 16,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.099 ^[203]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.12
upper limit	1.23

Notes:

[203] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 22
Statistical analysis description:	
Week 20,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.812 ^[204]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.61
upper limit	9.69

Notes:

[204] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 23
Statistical analysis description:	
Week 20,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.204 ^[205]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.75
upper limit	2.96

Notes:

[205] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 24
Statistical analysis description: Week 20,CDAI	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.157 ^[206]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.09
upper limit	2.3

Notes:

[206] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 25
Statistical analysis description: Week 24,CDAI	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.088 ^[207]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.15
upper limit	1.42

Notes:

[207] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 26
Statistical analysis description: Week 24,CDAI	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[208]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-15.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.4
upper limit	-4.83

Notes:

[208] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 27
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Statistical analysis description:

Week 24,CDAI

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[209]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-14.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.01
upper limit	-4.8

Notes:

[209] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 28
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Statistical analysis description:

Week 1,CDAI

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.06 ^[210]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.96
upper limit	0.17

Notes:

[210] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 29
Statistical analysis description:	
Week 1,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[211]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.42
upper limit	-3.36

Notes:

[211] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 30
Statistical analysis description:	
Week 2,CDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.016 ^[212]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.06
upper limit	-1.14

Notes:

[212] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 31
Statistical analysis description:	
Week 2,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.007 ^[213]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.78
upper limit	-1.91

Notes:

[213] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 32
Statistical analysis description:	
Week 4,CDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005 ^[214]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.48
upper limit	-2.37

Notes:

[214] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 33
Statistical analysis description:	
Week 4,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[215]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-12.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.74
upper limit	-6.64

Notes:

[215] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 34
Statistical analysis description: Week 6,CDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.059 ^[216]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.45
upper limit	0.21

Notes:

[216] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 35
Statistical analysis description: Week 6,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[217]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-10.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.97
upper limit	-4.38

Notes:

[217] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 36
Statistical analysis description: Week 8,CDAI	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002 ^[218]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-10.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.75
upper limit	-4

Notes:

[218] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 37
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Statistical analysis description:

Week 8,CDAI

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[219]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.18
upper limit	-7.41

Notes:

[219] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 38
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Statistical analysis description:

Week 12,CDAI

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.01 ^[220]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.03
upper limit	-2.31

Notes:

[220] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 39
Statistical analysis description:	
Week 12,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 [221]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-16.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.97
upper limit	-9.3

Notes:

[221] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 40
Statistical analysis description:	
Week 16,CDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.165 [222]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.37
upper limit	2.3

Notes:

[222] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 41
Statistical analysis description:	
Week 16,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.022 ^[223]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.39
upper limit	-1.32

Notes:

[223] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 42
Statistical analysis description:	
Week 20,CDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.127 ^[224]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.99
upper limit	1.89

Notes:

[224] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 43
Statistical analysis description:	
Week 20,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.034 ^[225]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.67
upper limit	-0.67

Notes:

[225] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 44
Statistical analysis description: Week 24,CDAI	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[226]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-15.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.78
upper limit	-5.07

Notes:

[226] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 45
Statistical analysis description: Week 24,CDAI	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[227]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-19.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.7
upper limit	-10.06

Notes:

[227] - MMRM analysis adjusted for CDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Change from Baseline in Health Assessment Questionnaire – Disability Index (HAQ-DI) at all assessment time points

End point title	Change from Baseline in Health Assessment Questionnaire – Disability Index (HAQ-DI) at all assessment time points
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End point description:

HAQ-DI is 20-question instrument that assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas; dressing and grooming, arising, eating, walking, hygiene, reach, grip, and common daily activities. Each functional area contains at least 2 questions. For each question, there is a 4 level response set that is scored ranging from 0 (without any difficulty) to 3 (unable to do). If aids/devices/physical assistance are used for a specific functional area and the maximum response of this functional area is 0/1 the according value is increased to a score of 2. HAQ-DI is only calculated if at

least 6 functional area scores available. Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=x in the category titles).

End point type	Secondary
End point timeframe:	
Baseline and Weeks 1, 2, 4, 6, 8, 12, 16, 20 and 24	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[228]	37 ^[229]	37 ^[230]	37 ^[231]
Units: Scores on a scale				
least squares mean (standard error)				
HAQ-DI, Week 1,n=36,36,35,36, 36, 37	-0.09 (± 0.054)	-0.08 (± 0.054)	-0.08 (± 0.054)	-0.10 (± 0.054)
HAQ-DI, Week 2,n=36,35,37,37, 36, 37	-0.17 (± 0.062)	-0.13 (± 0.063)	-0.16 (± 0.062)	-0.23 (± 0.062)
HAQ-DI, Week 4,n=34,34,36,37, 36, 36	-0.22 (± 0.073)	-0.18 (± 0.073)	-0.17 (± 0.072)	-0.29 (± 0.071)
HAQ-DI, Week 6,n=35,35,35,37, 36, 36	-0.23 (± 0.077)	-0.22 (± 0.077)	-0.27 (± 0.077)	-0.33 (± 0.076)
HAQ-DI, Week 8,n=34,34,35,37, 35, 34	-0.22 (± 0.082)	-0.18 (± 0.082)	-0.33 (± 0.081)	-0.31 (± 0.080)
HAQ-DI, Week 12,n=34,35, 35, 37,35, 36	-0.26 (± 0.091)	-0.31 (± 0.091)	-0.30 (± 0.090)	-0.37 (± 0.89)
HAQ-DI, Week 16,n=8,16,21,24, 18, 36	-0.49 (± 0.141)	-0.33 (± 0.111)	-0.38 (± 0.102)	-0.57 (± 0.098)
HAQ-DI, Week 20,n=8,15,21,25, 19, 36	-0.35 (± 0.139)	-0.37 (± 0.112)	-0.42 (± 0.103)	-0.51 (± 0.097)
HAQ-DI, Week 24,n=8,14,21,24, 19, 34	-0.34 (± 0.143)	-0.32 (± 0.116)	-0.41 (± 0.104)	-0.43 (± 0.099)

Notes:

[228] - ITT Population

[229] - ITT Population

[230] - ITT Population

[231] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[232]	37 ^[233]		
Units: Scores on a scale				
least squares mean (standard error)				
HAQ-DI, Week 1,n=36,36,35,36, 36, 37	-0.13 (± 0.054)	-0.17 (± 0.053)		
HAQ-DI, Week 2,n=36,35,37,37, 36, 37	-0.25 (± 0.063)	-0.26 (± 0.062)		
HAQ-DI, Week 4,n=34,34,36,37, 36, 36	-0.29 (± 0.072)	-0.40 (± 0.072)		
HAQ-DI, Week 6,n=35,35,35,37, 36, 36	-0.21 (± 0.077)	-0.43 (± 0.076)		
HAQ-DI, Week 8,n=34,34,35,37, 35, 34	-0.35 (± 0.081)	-0.42 (± 0.081)		

HAQ-DI, Week 12,n=34,35, 35, 37,35, 36	-0.38 (± 0.090)	-0.50 (± 0.090)		
HAQ-DI, Week 16,n=8,16,21,24, 18, 36	-0.40 (± 0.106)	-0.50 (± 0.090)		
HAQ-DI, Week 20,n=8,15,21,25, 19, 36	-0.49 (± 0.105)	-0.56 (± 0.091)		
HAQ-DI, Week 24,n=8,14,21,24, 19, 34	-0.42 (± 0.107)	-0.54 (± 0.092)		

Notes:

[232] - ITT Population

[233] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.938 [234]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.16

Notes:

[234] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.981 [235]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.15

Notes:

[235] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.857 ^[236]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.14

Notes:

[236] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.592 ^[237]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.22

Notes:

[237] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.917 ^[238]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.18

Notes:

[238] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
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Statistical analysis description:

Week 2

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.545 ^[239]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.05

Confidence interval

level	95 %
sides	2-sided
lower limit	-0.23
upper limit	0.12

Notes:

[239] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.707 ^[240]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.04

Confidence interval

level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.24

Notes:

[240] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.603 ^[241]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.26

Notes:

[241] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.473 ^[242]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.13

Notes:

[242] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.987 ^[243]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.21
upper limit	0.22

Notes:

[243] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.713 [244]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.17

Notes:

[244] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.748 [245]
Method	MMRM
Parameter estimate	Mean difference (final values)
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.26

Notes:

[245] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.357 ^[246]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.31
upper limit	0.11

Notes:

[246] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.327 ^[247]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	0.11

Notes:

[247] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.395 ^[248]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.32
upper limit	0.13

Notes:

[248] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 16
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.71 [249]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.21

Notes:

[249] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 17
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.74 [250]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.21

Notes:

[250] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 18
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.398 ^[251]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	0.14

Notes:

[251] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 19
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.364 ^[252]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.52

Notes:

[252] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 20
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.503 ^[253]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	0.46

Notes:

[253] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 21
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.647 [254]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	0.26

Notes:

[254] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 22
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.91 [255]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	0.33

Notes:

[255] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 23
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.66 ^[256]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	0.26

Notes:

[256] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 24
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.34 ^[257]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.17

Notes:

[257] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 25
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.902 ^[258]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	0.39

Notes:

[258] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 26
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.687 [259]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	0.28

Notes:

[259] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 27
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.599 [260]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.44
upper limit	0.25

Notes:

[260] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 28
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.588 ^[261]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.11

Notes:

[261] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 29
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.259 ^[262]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	0.06

Notes:

[262] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 30
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.358 ^[263]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.09

Notes:

[263] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 31
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.325 [264]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.09

Notes:

[264] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 32
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.473 [265]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	0.13

Notes:

[265] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 33
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.085 ^[266]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	0.02

Notes:

[266] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 34
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.897 ^[267]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.23

Notes:

[267] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 35
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.065 ^[268]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	0.01

Notes:

[268] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 36
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.238 ^[269]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	0.09

Notes:

[269] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 37
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.071 ^[270]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.44
upper limit	0.02

Notes:

[270] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 38
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.34 ^[271]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	0.13

Notes:

[271] - MMRM analysis adjusted for SDAI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 39
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Statistical analysis description:

Week 12

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.059 ^[272]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	0.01

Notes:

[272] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 40
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Statistical analysis description:

Week 16

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.607 ^[273]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.44

Notes:

[273] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 41
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.959 [274]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	0.32

Notes:

[274] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 42
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.401 [275]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	0.2

Notes:

[275] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 43
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.207 ^[276]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	0.12

Notes:

[276] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 44
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Statistical analysis description:

Week 24

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.637 ^[277]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.44
upper limit	0.27

Notes:

[277] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 45
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Statistical analysis description:

Week 24

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.251 ^[278]
Method	MMRM
Parameter estimate	Mean difference (final values)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	0.14

Notes:

[278] - MMRM analysis adjusted for HAQ-DI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Change from Baseline in pain score at all assessment time points

End point title	Change from Baseline in pain score at all assessment time points
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End point description:

Participants assessed the severity of their current arthritis pain using a 100 unit visual analog scale (VAS) by placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponds to the magnitude of their pain. Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=x in the category titles).

End point type	Secondary
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End point timeframe:

Baseline and Weeks 1, 2, 4, 6, 8, 12, 16, 20 and Week 24

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	37	37	37
Units: Scores on a scale				
least squares mean (standard error)				
Week 1,n=36,36,35,36, 36,37	-2.25 (± 2.625)	-4.71 (± 2.648)	-5.02 (± 2.656)	-9.96 (± 2.626)
Week 2,n=36,35,37,37,36,37	-3.79 (± 2.818)	-6.71 (± 2.870)	-9.77 (± 2.797)	-11.37 (± 2.791)
Week 4,n=34,34,36,37, 36,36	-5.44 (± 3.081)	-8.47 (± 3.107)	-14.83 (± 3.029)	-17.65 (± 2.995)
Week 6,n=35,35,35,37, 36, 36	-6.69 (± 3.334)	-11.18 (± 3.357)	-14.71 (± 3.319)	-15.05 (± 3.262)
Week 8,n=34,34,35,37, 35,34	-3.98 (± 3.555)	-9.60 (± 3.577)	-18.55 (± 3.517)	-17.92 (± 3.461)
Week 12,n=34,35,35,37, 35, 36	-7.07 (± 3.705)	-14.09 (± 3.702)	-21.22 (± 3.659)	-25.25 (± 3.593)
Week 16,n=8,16,21,24, 18, 16	-12.60 (± 6.077)	-17.50 (± 4.768)	-28.56 (± 4.361)	-26.46 (± 4.187)
Week 20,n=8,15,21,25, 19,36	-13.95 (± 5.589)	-14.64 (± 4.495)	-27.12 (± 4.068)	-27.44 (± 3.870)
Week 24,n=8,14,21,24, 19, 34	-13.38 (± 6.484)	-19.76 (± 5.231)	-23.52 (± 4.620)	-25.45 (± 4.409)

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	37		
Units: Scores on a scale				
least squares mean (standard error)				
Week 1,n=36,36,35,36, 36,37	-7.18 (± 2.637)	-7.89 (± 2.619)		
Week 2,n=36,35,37,37,36,37	-11.63 (± 2.829)	-14.22 (± 2.810)		

Week 4,n=34,34,36,37, 36,36	-13.39 (± 3.036)	-19.40 (± 3.038)		
Week 6,n=35,35,35,37, 36, 36	-14.05 (± 3.306)	-19.12 (± 3.311)		
Week 8,n=34,34,35,37, 35,34	-20.49 (± 3.523)	-24.38 (± 3.541)		
Week 12,n=34.35,35,37, 35, 36	-19.07 (± 3.662)	-25.01 (± 3.650)		
Week 16,n=8,16,21,24, 18, 16	-25.80 (± 4.549)	-24.48 (± 3.807)		
Week 20,n=8,15,21,25, 19,36	-27.86 (± 4.179)	-27.17 (± 3.584)		
Week 24,n=8,14,21,24, 19, 34	-26.61 (± 4.756)	-30.08 (± 4.048)		

Statistical analyses

Statistical analysis title	Stat 1
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Statistical analysis description:

Week 1

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.511 ^[279]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.81
upper limit	4.9

Notes:

[279] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
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Statistical analysis description:

Week 1

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.461 ^[280]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.76

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.13
upper limit	4.6

Notes:

[280] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
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Statistical analysis description:

Week 1

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.039 ^[281]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.03
upper limit	-0.39

Notes:

[281] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
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Statistical analysis description:

Week 2

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.469 ^[282]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.86
upper limit	5.01

Notes:

[282] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
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Statistical analysis description:

Week 2

Comparison groups	Placebo v GSK3196165 45 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.133 ^[283]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.82
upper limit	1.85

Notes:

[283] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
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Statistical analysis description:

Week 2

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.057 ^[284]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.4
upper limit	0.23

Notes:

[284] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.49 ^[285]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.67
upper limit	5.61

Notes:

[285] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.031 ^[286]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-9.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.91
upper limit	-0.86

Notes:

[286] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005 ^[287]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-12.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.67
upper limit	-3.74

Notes:

[287] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.345 ^[288]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.83
upper limit	4.85

Notes:

[288] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
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Statistical analysis description:

Week 6

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.09 ^[289]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.3
upper limit	1.26

Notes:

[289] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
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Statistical analysis description:

Week 6

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.074 ^[290]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-8.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.55
upper limit	0.83

Notes:

[290] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[291]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-14.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.43
upper limit	-4.7

Notes:

[291] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
Week 8	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.268 ^[292]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.57
upper limit	4.34

Notes:

[292] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 16
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.182 ^[293]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.36
upper limit	3.32

Notes:

[293] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
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Statistical analysis description:

Week 8

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005 ^[294]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.72
upper limit	-4.16

Notes:

[294] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 17
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Statistical analysis description:

Week 12

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.007 ^[295]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-14.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.42
upper limit	-3.87

Notes:

[295] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 18
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 [296]
Method	MMRM
Parameter estimate	Mean difference (final values)
Point estimate	-18.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.35
upper limit	-8.01

Notes:

[296] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 19
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.527 [297]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.15
upper limit	10.36

Notes:

[297] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 20
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 45 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.034 ^[298]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-15.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.72
upper limit	-1.19

Notes:

[298] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 21
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.062 ^[299]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.42
upper limit	0.7

Notes:

[299] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 22
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.924 ^[300]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.85
upper limit	13.47

Notes:

[300] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 23
Statistical analysis description:	
Week 20	
Comparison groups	GSK3196165 45 mg v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.058 ^[301]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.82
upper limit	0.48

Notes:

[301] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 24
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.049 ^[302]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.91
upper limit	-0.08

Notes:

[302] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 25
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.445 ^[303]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-6.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.84
upper limit	10.07

Notes:

[303] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 26
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Statistical analysis description:

Week 24

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.205 ^[304]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-10.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.87
upper limit	5.58

Notes:

[304] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 27
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Statistical analysis description:

Week 24

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.125 ^[305]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-12.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.55
upper limit	3.41

Notes:

[305] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 28
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.187 ^[306]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-4.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.26
upper limit	2.41

Notes:

[306] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 29
Statistical analysis description:	
Week 1	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.13 ^[307]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-5.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.93
upper limit	1.67

Notes:

[307] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 30
Statistical analysis description:	
Week 2	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.051 ^[308]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.72
upper limit	0.03

Notes:

[308] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 31
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Statistical analysis description:

Week 2

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.009 ^[309]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-10.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.27
upper limit	-2.6

Notes:

[309] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 32
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068 ^[310]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.47
upper limit	0.58

Notes:

[310] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 33
Statistical analysis description:	
Week 4	
Comparison groups	GSK3196165 180 mg v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001 ^[311]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.47
upper limit	-5.44

Notes:

[311] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 34
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.118 ^[312]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-7.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.62
upper limit	1.89

Notes:

[312] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 35
Statistical analysis description:	
Week 6	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.009 ^[313]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-12.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.68
upper limit	-3.19

Notes:

[313] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 36
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Statistical analysis description:

Week 8

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001 ^[314]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-16.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.38
upper limit	-6.65

Notes:

[314] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 37
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Statistical analysis description:

Week 8

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[315]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-20.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.27
upper limit	-10.52

Notes:

[315] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 38
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.022 ^[316]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.27
upper limit	-1.73

Notes:

[316] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 39
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[317]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-17.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.18
upper limit	-7.7

Notes:

[317] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 40
Statistical analysis description:	
Week 16	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.084 ^[318]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.18
upper limit	1.79

Notes:

[318] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 42
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Statistical analysis description:

Week 20

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.048 ^[319]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.68
upper limit	-0.14

Notes:

[319] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 41
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Statistical analysis description:

Week 16

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.099 ^[320]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-11.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.02
upper limit	2.27

Notes:

[320] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 44
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.102 ^[321]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.11
upper limit	2.64

Notes:

[321] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 43
Statistical analysis description:	
Week 20	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.048 ^[322]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-13.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.32
upper limit	-0.13

Notes:

[322] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 45
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.03 ^[323]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-16.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.79
upper limit	-1.62

Notes:

[323] - MMRM analysis adjusted for Pain Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Change from Baseline in physical and mental component scores (PCS, MCS) and in domain scores of short form 36 (SF-36) at all assessment time points

End point title	Change from Baseline in physical and mental component scores (PCS, MCS) and in domain scores of short form 36 (SF-36) at all assessment time points
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End point description:

SF-36 (generic health survey) yields an 8-scale profile of functional health and well-being scores as well as PCS and MCS health summary scores. The version 2, 1-week recall questionnaire was used. Recoding, calculations and standardization were done as per the User's manual of SF-36. All raw domain scores were transformed on a 0–100 scale (transformed domain scores) and then standardized into norm-based scores using Z-score. Following the transformation of the 8 domain scores into z-scores, the MCS and PCS were aggregated (AGG) using weights as PCS/MCS=50+(AGG_PHYS *10/AGG_MENT *10). High score (worse outcome) and low score (better outcome). Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=x in the category titles).

End point type	Secondary
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End point timeframe:

Baseline and Weeks 4, 12, 24

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[324]	37 ^[325]	37 ^[326]	37 ^[327]
Units: Scores on a scale				
least squares mean (standard error)				
PCS, Week 4,n=34,34,36,37,36,36,	1.86 (± 1.046)	2.46 (± 1.048)	5.05 (± 1.020)	4.47 (± 1.007)
PCS Week 12,n=34,35,35,37,35,36	3.42 (± 1.203)	4.88 (± 1.192)	5.84 (± 1.186)	5.15 (± 1.158)
PCS, Week 24,n=8,14,21,24,19,34	5.34 (± 2.058)	7.03 (± 1.631)	6.63 (± 1.404)	7.80 (± 1.335)
MCS, Week 4,n=34,34,36,37,36,36,	3.36 (± 1.488)	2.86 (± 1.488)	3.81 (± 1.453)	2.82 (± 1.434)
MCS, Week 12,n=34,35,35,37,35,36,	3.54 (± 1.558)	4.86 (± 1.542)	5.00 (± 1.535)	4.66 (± 1.501)
MCS, Week 24,n=8,14,21,24,19,34	4.07 (± 2.560)	4.50 (± 2.039)	6.36 (± 1.755)	3.02 (± 1.669)
Bodily pain, Week 4,n=34,34,36,37,36,36,	2.52 (± 1.071)	2.41 (± 1.071)	6.24 (± 1.043)	5.44 (± 1.029)
Bodily pain, Week 12,n=34,35,35,37,35,36	3.90 (± 1.294)	5.43 (± 1.280)	6.72 (± 1.273)	5.99 (± 1.243)
Bodily pain, Week 24,n=8,14,21,24,19,34	4.15 (± 2.580)	7.01 (± 1.996)	9.20 (± 1.682)	7.36 (± 1.593)

General Health, Week 4,n=34,34,36,37,36,36	1.78 (± 1.079)	1.27 (± 1.079)	2.77 (± 1.055)	1.90 (± 1.039)
General health, Week 12,n=34,35,35,37,35,36	2.44 (± 1.102)	3.07 (± 1.090)	4.30 (± 1.088)	3.02 (± 1.061)
General health, Week 24,n=8,14,21,24,19,34	2.07 (± 2.248)	5.36 (± 1.762)	4.83 (± 1.514)	4.60 (± 1.420)
Mental health, Week 4,n=34,34,36,37,36,36	3.64 (± 1.451)	3.77 (± 1.449)	4.52 (± 1.413)	3.62 (± 1.395)
Mental health, Week 12,n=34,35,35,37,35,36	2.27 (± 1.601)	4.87 (± 1.581)	5.49 (± 1.575)	4.77 (± 1.539)
Mental health, Week 24,n=8,14,21,24,19,34	2.81 (± 2.619)	4.13 (± 2.073)	6.09 (± 1.777)	3.42 (± 1.684)
Physical functioning, Week 4,n=34,34,36,37,36,36	3.30 (± 1.206)	3.97 (± 1.208)	5.68 (± 1.174)	4.84 (± 1.159)
Physical functioning, Week 12,n=34,35,35,37,35,36	2.98 (± 1.390)	5.80 (± 1.375)	5.99 (± 1.368)	5.98 (± 1.333)
Physical functioning, Week 24,n=8,14,21,24,19,34	6.93 (± 2.100)	6.29 (± 1.700)	6.52 (± 1.490)	7.16 (± 1.426)
Role emotional, Week 4,n=34,34,36,37,36,36	4.37 (± 1.489)	3.09 (± 1.488)	3.08 (± 1.452)	3.35 (± 1.432)
Role emotional, Week 12,n=34,35,35,37,35,36	4.85 (± 1.595)	5.19 (± 1.574)	5.52 (± 1.570)	5.10 (± 1.532)
Role emotional, Week 24,n=8,14,21,24,19,34	5.66 (± 2.674)	6.57 (± 2.102)	6.16 (± 1.794)	4.36 (± 1.704)
Role physical, Week 4,n=34,34,36,37,36,36	2.15 (± 1.128)	3.01 (± 1.124)	4.04 (± 1.097)	4.56 (± 1.082)
Role physical, Week 12,n=34,35,35,37,35,36	4.56 (± 1.270)	5.16 (± 1.255)	6.28 (± 1.251)	5.49 (± 1.221)
Role physical, Week 24,n=8,14,21,24,19,34	6.38 (± 2.235)	7.65 (± 1.738)	6.27 (± 1.481)	7.50 (± 1.408)
Social functioning, Week 4,n=34,34,36,37,36,36	2.27 (± 1.512)	1.95 (± 1.512)	5.44 (± 1.475)	2.84 (± 1.455)
Social functioning, Week 12,n=34,35,35,37,35,36	4.34 (± 1.529)	4.90 (± 1.513)	4.34 (± 1.507)	4.62 (± 1.471)
Social functioning, Week 24,n=8,14,21,24,19,34	8.31 (± 2.841)	5.41 (± 2.221)	7.87 (± 1.871)	4.52 (± 1.773)
Vitality, Week 4,n=34,34,36,37,36,36	1.91 (± 1.389)	2.94 (± 1.386)	5.48 (± 1.352)	4.54 (± 1.334)
Vitality, Week 12,n=34,35,35,37,35,36	4.19 (± 1.445)	6.16 (± 1.429)	7.10 (± 1.421)	6.37 (± 1.389)
Vitality, Week 24,n=8,14,21,24,19,34	4.68 (± 2.775)	6.62 (± 2.175)	7.83 (± 1.854)	7.65 (± 1.758)

Notes:

[324] - ITT Population

[325] - ITT Population

[326] - ITT Population

[327] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[328]	37 ^[329]		
Units: Scores on a scale				
least squares mean (standard error)				
PCS, Week 4,n=34,34,36,37,36,36,	4.80 (± 1.021)	5.97 (± 1.028)		
PCS Week 12,n=34,35,35,37,35,36	5.31 (± 1.188)	6.97 (± 1.182)		
PCS, Week 24,n=8,14,21,24,19,34	7.50 (± 1.454)	6.99 (± 1.211)		
MCS, Week 4,n=34,34,36,37,36,36,	4.52 (± 1.453)	3.46 (± 1.453)		
MCS, Week 12,n=34,35,35,37,35,36,	5.51 (± 1.535)	6.79 (± 1.521)		
MCS, Week 24,n=8,14,21,24,19,34	5.42 (± 1.817)	7.86 (± 1.503)		

Bodily pain, Week 4, n=34,34,36,37,36,36	5.97 (± 1.046)	7.60 (± 1.045)		
Bodily pain, Week 12, n=34,35,35,37,35,36	6.01 (± 1.277)	7.34 (± 1.263)		
Bodily pain, Week 24, n=8,14,21,24,19,34	8.87 (± 1.752)	9.35 (± 1.387)		
General Health, Week 4, n=34,34,36,37,36,36	3.43 (± 1.053)	3.72 (± 1.054)		
General health, Week 12, n=34,35,35,37,35,36	3.14 (± 1.087)	4.73 (± 1.077)		
General health, Week 24, n=8,14,21,24,19,34	3.84 (± 1.562)	5.42 (± 1.265)		
Mental health, Week 4, n=34,34,36,37,36,36	3.49 (± 1.413)	3.69 (± 1.413)		
Mental health, Week 12, n=34,35,35,37,35,36	4.68 (± 1.576)	5.72 (± 1.558)		
Mental health, Week 24, n=8,14,21,24,19,34	4.96 (± 1.844)	7.82 (± 1.504)		
Physical functioning, Week 4, n=34,34,36,37,36,36	5.18 (± 1.179)	5.75 (± 1.180)		
Physical functioning, Week 12, n=34,35,35,37,35,36	5.84 (± 1.373)	7.76 (± 1.358)		
Physical functioning, Week 24, n=8,14,21,24,19,34	7.40 (± 1.539)	7.58 (± 1.309)		
Role emotional, Week 4, n=34,34,36,37,36,36	4.96 (± 1.451)	3.77 (± 1.451)		
Role emotional, Week 12, n=34,35,35,37,35,36	5.93 (± 1.570)	7.54 (± 1.552)		
Role emotional, Week 24, n=8,14,21,24,19,34	6.06 (± 1.863)	8.18 (± 1.518)		
Role physical, Week 4, n=34,34,36,37,36,36	4.02 (± 1.097)	4.80 (± 1.099)		
Role physical, Week 12, n=34,35,35,37,35,36	5.99 (± 1.253)	7.91 (± 1.241)		
Role physical, Week 24, n=8,14,21,24,19,34	7.59 (± 1.538)	7.25 (± 1.250)		
Social functioning, Week 4, n=34,34,36,37,36,36	5.22 (± 1.476)	5.67 (± 1.475)		
Social functioning, Week 12, n=34,35,35,37,35,36	6.32 (± 1.508)	8.69 (± 1.491)		
Social functioning, Week 24, n=8,14,21,24,19,34	7.97 (± 1.951)	8.60 (± 1.551)		
Vitality, Week 4, n=34,34,36,37,36,36	6.55 (± 1.352)	5.25 (± 1.353)		
Vitality, Week 12, n=34,35,35,37,35,36	6.83 (± 1.421)	8.16 (± 1.408)		
Vitality, Week 24, n=8,14,21,24,19,34	8.04 (± 1.924)	7.81 (± 1.560)		

Notes:

[328] - ITT Population

[329] - ITT Population

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Week 4, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.	
Comparison groups	Placebo v GSK3196165 22.5 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.683 ^[330]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.31
upper limit	3.52

Notes:

[330] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
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Statistical analysis description:

Week 4, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.03 ^[331]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	6.07

Notes:

[331] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
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Statistical analysis description:

Week 4, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.074 ^[332]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.61

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	5.47

Notes:

[332] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
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Statistical analysis description:

Week 12, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.39 ^[333]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.46

Confidence interval

level	95 %
sides	2-sided
lower limit	-1.88
upper limit	4.8

Notes:

[333] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
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Statistical analysis description:

Week 12, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.154 ^[334]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.42

Confidence interval

level	95 %
sides	2-sided
lower limit	-0.91
upper limit	5.75

Notes:

[334] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
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Statistical analysis description:

Week 12, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.302 ^[335]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.56
upper limit	5.02

Notes:

[335] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
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Statistical analysis description:

Week 24, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.521 ^[336]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	6.88

Notes:

[336] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
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Statistical analysis description:

Week 24, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.606 ^[337]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.28

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.63
upper limit	6.2

Notes:

[337] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
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Statistical analysis description:

Week 4, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.811 ^[338]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.65
upper limit	3.64

Notes:

[338] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
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Statistical analysis description:

Week 24, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.32 ^[339]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.41
upper limit	7.32

Notes:

[339] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
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Statistical analysis description:

Week 4, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.83 ^[340]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.65
upper limit	4.55

Notes:

[340] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
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Statistical analysis description:

Week 4, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.795 ^[341]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.61
upper limit	3.54

Notes:

[341] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
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Statistical analysis description:

Week 12, , MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.548 ^[342]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	5.64

Notes:

[342] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
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Statistical analysis description:

Week 12, , MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.505 ^[343]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.46

Confidence interval

level	95 %
sides	2-sided
lower limit	-2.85
upper limit	5.77

Notes:

[343] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
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Statistical analysis description:

Week 12, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.605 ^[344]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.12

Confidence interval

level	95 %
sides	2-sided
lower limit	-3.15
upper limit	5.39

Notes:

[344] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 16
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Statistical analysis description:

Week 24, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.895 ^[345]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.03
upper limit	6.9

Notes:

[345] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 17
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Statistical analysis description:

Week 24, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.461 ^[346]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.84
upper limit	8.42

Notes:

[346] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 18
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Statistical analysis description:

Week 24, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.732 ^[347]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	4.99

Notes:

[347] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 19
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Statistical analysis description:

Week 4, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.941 ^[348]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.11

Confidence interval

level	95 %
sides	2-sided
lower limit	-3.11
upper limit	2.88

Notes:

[348] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 20
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Statistical analysis description:

Week 4, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.013 ^[349]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.73

Confidence interval

level	95 %
sides	2-sided
lower limit	0.78
upper limit	6.67

Notes:

[349] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 21
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Statistical analysis description:

Week 4, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.051 ^[350]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	5.84

Notes:

[350] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 22
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Statistical analysis description:

Week 12, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.403 ^[351]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.07
upper limit	5.12

Notes:

[351] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 23
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Statistical analysis description:

Week 12, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.122 ^[352]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.82

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	6.4

Notes:

[352] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 24
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Statistical analysis description:

Week 12, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.247 ^[353]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.45
upper limit	5.62

Notes:

[353] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 25
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Statistical analysis description:

Week 24, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.384 ^[354]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.61
upper limit	9.32

Notes:

[354] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 26
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Statistical analysis description:

Week 24, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.105 ^[355]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	5.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.07
upper limit	11.16

Notes:

[355] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 27
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Statistical analysis description:

Week 24, Bodily Pain MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.29 ^[356]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.76
upper limit	9.17

Notes:

[356] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 28
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Statistical analysis description:

Week 4, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.738 ^[357]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.51

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.52
upper limit	2.5

Notes:

[357] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 29
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Statistical analysis description:

Week 4, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.513 ^[358]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.99
upper limit	3.97

Notes:

[358] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 30
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Statistical analysis description:

Week 4, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.934 ^[359]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.83
upper limit	3.08

Notes:

[359] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 31
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Statistical analysis description:

Week 12, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.687 ^[360]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.43
upper limit	3.68

Notes:

[360] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 32
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Statistical analysis description:

Week 12, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.233 ^[361]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	4.91

Notes:

[361] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 33
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Statistical analysis description:

Week 12, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.708 ^[362]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.57

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.44
upper limit	3.59

Notes:

[362] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 34
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Statistical analysis description:

Week 24, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.25 ^[363]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.34
upper limit	8.93

Notes:

[363] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 35
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Statistical analysis description:

Week 24, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.307 ^[364]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.57
upper limit	8.09

Notes:

[364] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 36
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Statistical analysis description:

Week 24, General Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.345 ^[365]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.74
upper limit	7.79

Notes:

[365] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 37
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Statistical analysis description:

Week 4, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.95 ^[366]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.52

Notes:

[366] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 38
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Statistical analysis description:

Week 4, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.664 ^[367]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.88

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.11
upper limit	4.87

Notes:

[367] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 39
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Statistical analysis description:

Week 4, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.994 ^[368]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.01

Confidence interval

level	95 %
sides	2-sided
lower limit	-3.99
upper limit	3.96

Notes:

[368] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 40
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Statistical analysis description:

Week 12, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.25 ^[369]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.6

Confidence interval

level	95 %
sides	2-sided
lower limit	-1.84
upper limit	7.03

Notes:

[369] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 41
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Statistical analysis description:

Week 12, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.154 ^[370]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.22
upper limit	7.64

Notes:

[370] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 42
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Statistical analysis description:

Week 12, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.262 ^[371]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.88
upper limit	6.89

Notes:

[371] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 43
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Statistical analysis description:

Week 24, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.693 ^[372]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.28
upper limit	7.93

Notes:

[372] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 44
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Statistical analysis description:

Week 24, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.302 ^[373]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.98
upper limit	9.54

Notes:

[373] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 45
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Statistical analysis description:

Week 24, Mental Health MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.844 ^[374]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.54
upper limit	6.77

Notes:

[374] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 46
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Statistical analysis description:

Week 4, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.698 ^[375]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.71
upper limit	4.04

Notes:

[375] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 47
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Statistical analysis description:

Week 4, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.159 ^[376]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	5.7

Notes:

[376] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 48
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Statistical analysis description:

Week 4, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.36 ^[377]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.53

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.76
upper limit	4.83

Notes:

[377] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 49
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Statistical analysis description:

Week 12, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.151 ^[378]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	6.69

Notes:

[378] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 50
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Statistical analysis description:

Week 12, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.124 ^[379]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	6.86

Notes:

[379] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 51
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Statistical analysis description:

Week 12, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.12 ^[380]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.79
upper limit	6.8

Notes:

[380] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 52
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Statistical analysis description:

Week 24, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.814 ^[381]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.98
upper limit	4.7

Notes:

[381] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 53
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Statistical analysis description:

Week 24, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.873 ^[382]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.49
upper limit	4.67

Notes:

[382] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 54
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Statistical analysis description:

Week 24, Physical Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.928 ^[383]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	5.26

Notes:

[383] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 55
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Statistical analysis description:

Week 4, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.541 ^[384]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.44
upper limit	2.86

Notes:

[384] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 56
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Statistical analysis description:

Week 4, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.535 ^[385]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.39
upper limit	2.81

Notes:

[385] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 58
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Statistical analysis description:

Week 12, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.881 ^[386]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.08
upper limit	4.76

Notes:

[386] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 57
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Statistical analysis description:

Week 4, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.62 ^[387]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	3.05

Notes:

[387] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 59
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Statistical analysis description:

Week 12, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.767 ^[388]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.74
upper limit	5.07

Notes:

[388] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 60
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Statistical analysis description:

Week 12, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.913 ^[389]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.12
upper limit	4.61

Notes:

[389] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 61
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Statistical analysis description:

Week 24, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.79 ^[390]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.81
upper limit	7.63

Notes:

[390] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 62
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Statistical analysis description:

Week 24, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.876 ^[391]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.86
upper limit	6.87

Notes:

[391] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 63
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Statistical analysis description:

Week 24, Role Emotional MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.684 ^[392]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.59
upper limit	4.99

Notes:

[392] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 65
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Statistical analysis description:

Week 4, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.229 ^[393]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.9

Confidence interval

level	95 %
sides	2-sided
lower limit	-1.21
upper limit	5

Notes:

[393] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 64
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Statistical analysis description:

Week 4, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.588 ^[394]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.86

Confidence interval

level	95 %
sides	2-sided
lower limit	-2.28
upper limit	4.01

Notes:

[394] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 66
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Statistical analysis description:

Week 4, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.125 ^[395]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	5.49

Notes:

[395] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 67
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Statistical analysis description:

Week 12, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.736 ^[396]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.92
upper limit	4.12

Notes:

[396] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 68
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Statistical analysis description:

Week 12, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.338 ^[397]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	5.23

Notes:

[397] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 69
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Statistical analysis description:

Week 12, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6 [398]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.55
upper limit	4.4

Notes:

[398] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 70
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Statistical analysis description:

Week 24, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.657 [399]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.34
upper limit	6.86

Notes:

[399] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 71
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Statistical analysis description:

Week 24, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.965 ^[400]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.41
upper limit	5.17

Notes:

[400] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 72
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Statistical analysis description:

Week 24, Role Physical MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.675 ^[401]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.14
upper limit	6.37

Notes:

[401] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 73
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Statistical analysis description:

Week 4, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.88 ^[402]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.54
upper limit	3.89

Notes:

[402] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 74
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Statistical analysis description:

Week 4, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.135 ^[403]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	7.33

Notes:

[403] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 75
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Statistical analysis description:

Week 4, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.785 ^[404]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.56
upper limit	4.71

Notes:

[404] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 76
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Statistical analysis description:

Week 12, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.797 ^[405]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.69
upper limit	4.8

Notes:

[405] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 77
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Statistical analysis description:

Week 12, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	> 0.999 ^[406]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.23
upper limit	4.23

Notes:

[406] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 78
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Statistical analysis description:

Week 12, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.896 ^[407]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.28

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.91
upper limit	4.46

Notes:

[407] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 79
-----------------------------------	---------

Statistical analysis description:

Week 24, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.424 ^[408]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-2.89

Confidence interval

level	95 %
sides	2-sided
lower limit	-10.02
upper limit	4.24

Notes:

[408] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 80
-----------------------------------	---------

Statistical analysis description:

Week 24, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.898 ^[409]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.44

Confidence interval

level	95 %
sides	2-sided
lower limit	-7.16
upper limit	6.29

Notes:

[409] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 81
-----------------------------------	---------

Statistical analysis description:

Week 24, Social Functioning MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.26 ^[410]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-3.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.42
upper limit	2.84

Notes:

[410] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 82
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Statistical analysis description:

Week 4, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.603 ^[411]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.85
upper limit	4.9

Notes:

[411] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 83
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Statistical analysis description:

Week 4, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068 ^[412]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.56

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	7.39

Notes:

[412] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 84
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Statistical analysis description:

Week 4, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.174 ^[413]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.17
upper limit	6.43

Notes:

[413] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 85
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Statistical analysis description:

Week 12, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.334 ^[414]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.04
upper limit	5.98

Notes:

[414] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 86
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Statistical analysis description:

Week 12, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.153 ^[415]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.09
upper limit	6.91

Notes:

[415] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 87
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Statistical analysis description:

Week 12, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.279 ^[416]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.78
upper limit	6.13

Notes:

[416] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 88
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Statistical analysis description:

Week 24, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.584 ^[417]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.04
upper limit	8.91

Notes:

[417] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 89
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Statistical analysis description:

Week 24, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.346 ^[418]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.44
upper limit	9.73

Notes:

[418] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 90
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Statistical analysis description:

Week 24, Vitality MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.37 ^[419]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.55
upper limit	9.48

Notes:

[419] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 91
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Statistical analysis description:

Week 4, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.045 ^[420]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	5.83

Notes:

[420] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 92
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Statistical analysis description:

Week 4, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006 ^[421]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	4.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.22
upper limit	7.01

Notes:

[421] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 93
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Statistical analysis description:

Week 12, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.264 ^[422]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.89

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.44
upper limit	5.23

Notes:

[422] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 94
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Statistical analysis description:

Week 12, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.037 ^[423]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	6.88

Notes:

[423] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 95
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Statistical analysis description:

Week 24, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.392 ^[424]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.81
upper limit	7.14

Notes:

[424] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 96
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Statistical analysis description:

Week 24, PCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.493 ^[425]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.09
upper limit	6.39

Notes:

[425] - MMRM analysis adjusted for PCS Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 97
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Statistical analysis description:

Week 4, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.577 ^[426]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.94
upper limit	5.26

Notes:

[426] - MMRM analysis adjusted for MCS Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 98
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Statistical analysis description:

Week 4, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.964 ^[427]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.01
upper limit	4.2

Notes:

[427] - MMRM analysis adjusted for MCS Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 99
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Statistical analysis description:

Week 12, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.37 ^[428]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.35
upper limit	6.28

Notes:

[428] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 100
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Statistical analysis description:

Week 12, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.138 ^[429]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.05
upper limit	7.54

Notes:

[429] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 101
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Statistical analysis description:

Week 24, MCS MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.667 ^[430]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.85
upper limit	7.56

Notes:

[430] - MMRM analysis adjusted for Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 102
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Statistical analysis description:

Week 24, MCS MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.203 ^[431]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.85
upper limit	7.56

Notes:

[431] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 104
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Statistical analysis description:

Week 4, Bodily pain MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[432]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	5.08

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.14
upper limit	8.03

Notes:

[432] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 103
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Statistical analysis description:

Week 4, Bodily pain MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.023 ^[433]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	6.41

Notes:

[433] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 105
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Statistical analysis description:

Week 12, Bodily pain MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.249 ^[434]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.49
upper limit	5.7

Notes:

[434] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 106
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Statistical analysis description:

Week 12, Bodily pain MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.059 ^[435]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	6.99

Notes:

[435] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 107
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Statistical analysis description:

Week 24, Bodily pain MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.134 ^[436]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	4.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.47
upper limit	10.9

Notes:

[436] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 108
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Statistical analysis description:

Week 24, Bodily pain MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.078 ^[437]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	5.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.58
upper limit	10.97

Notes:

[437] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 109
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Statistical analysis description:

Week 4, General health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.275 ^[438]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.32
upper limit	4.62

Notes:

[438] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 110
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Statistical analysis description:

Week 4, General health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.199 ^[439]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	4.91

Notes:

[439] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 112
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Statistical analysis description:

Week 12, General health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.138 ^[440]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	5.33

Notes:

[440] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 111
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Statistical analysis description:

Week 12, General health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.654 ^[441]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.36
upper limit	3.74

Notes:

[441] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 113
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Statistical analysis description:

Week 24, General health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.516 ^[442]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.77

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.62
upper limit	7.17

Notes:

[442] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 114
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Statistical analysis description:

Week 24, General health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.198 ^[443]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.77
upper limit	8.46

Notes:

[443] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 115
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Statistical analysis description:

Week 4, Mental health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.941 ^[444]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.15
upper limit	3.84

Notes:

[444] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 116
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Statistical analysis description:

Week 4, Mental health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.979 ^[445]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.94
upper limit	4.05

Notes:

[445] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 117
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Statistical analysis description:

Week 12, Mental health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.287 ^[446]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.03
upper limit	6.84

Notes:

[446] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 118
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Statistical analysis description:

Week 12, Mental health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.125 ^[447]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.96
upper limit	7.85

Notes:

[447] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 120
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Statistical analysis description:

Week 24, Mental health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.099 ^[448]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	5.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.96
upper limit	10.98

Notes:

[448] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 119
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Statistical analysis description:

Week 24, Mental health MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.503 ^[449]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.18
upper limit	8.49

Notes:

[449] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 121
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Statistical analysis description:

Week 4, Physical functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.268 ^[450]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.45
upper limit	5.21

Notes:

[450] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 122
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Statistical analysis description:

Week 4, Physical functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.147 ^[451]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.87
upper limit	5.77

Notes:

[451] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 123
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Statistical analysis description:

Week 12, Physical functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.145 ^[452]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.87

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	6.73

Notes:

[452] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 124
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Statistical analysis description:

Week 12, Physical functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.014 ^[453]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	4.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	8.61

Notes:

[453] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 125
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Statistical analysis description:

Week 24, Physical functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.856 ^[454]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.66
upper limit	5.61

Notes:

[454] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 126
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Statistical analysis description:

Week 24, Physical functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.793 ^[455]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.24
upper limit	5.55

Notes:

[455] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 127
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Statistical analysis description:

Week 4, Role emotional MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.778 ^[456]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.51
upper limit	4.69

Notes:

[456] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 128
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Statistical analysis description:

Week 4, Role emotional MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.773 ^[457]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.7
upper limit	3.5

Notes:

[457] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 129
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Statistical analysis description:

Week 12, Role emotional MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.631 ^[458]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.34
upper limit	5.49

Notes:

[458] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 130
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Statistical analysis description:

Week 12, Role emotional MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.23 ^[459]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.71
upper limit	7.07

Notes:

[459] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 132
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Statistical analysis description:

Week 24, Role emotional MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.412 ^[460]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.54
upper limit	8.59

Notes:

[460] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 131
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Statistical analysis description:

Week 24, Role emotional MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.901 ^[461]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.03
upper limit	6.84

Notes:

[461] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 134
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Statistical analysis description:

Week 4, Role physical MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.094 ^[462]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.66

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	5.77

Notes:

[462] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 133
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Statistical analysis description:

Week 4, Role physical MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.234 ^[463]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.22
upper limit	4.98

Notes:

[463] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 135
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Statistical analysis description:

Week 12, Role physical MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.423 ^[464]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.08
upper limit	4.94

Notes:

[464] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 136
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Statistical analysis description:

Week 12, Role physical MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.061 ^[465]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	6.86

Notes:

[465] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 137
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Statistical analysis description:

Week 24, Role physical MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.657 ^[466]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.16
upper limit	6.57

Notes:

[466] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 138
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Statistical analysis description:

Week 24, Role physical MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.737 ^[467]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.87

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.22
upper limit	5.95

Notes:

[467] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 139
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Statistical analysis description:

Week 4, Social Functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.165 ^[468]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.22
upper limit	7.11

Notes:

[468] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 140
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Statistical analysis description:

Week 4, Social Functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.109 ^[469]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	7.56

Notes:

[469] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 141
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Statistical analysis description:

Week 12, Social Functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.359 ^[470]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.26
upper limit	6.21

Notes:

[470] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 142
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Statistical analysis description:

Week 12, Social Functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.043 ^[471]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	4.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.14
upper limit	8.56

Notes:

[471] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 143
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Statistical analysis description:

Week 24, Social Functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.923 ^[472]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.33

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.15
upper limit	6.49

Notes:

[472] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 144
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Statistical analysis description:

Week 24, Social Functioning MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.927 ^[473]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.11
upper limit	6.7

Notes:

[473] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 145
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Statistical analysis description:

Week 4, Vitality MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.018 ^[474]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	4.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	8.46

Notes:

[474] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 146
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Statistical analysis description:

Week 4, Vitality MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.087 ^[475]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	7.17

Notes:

[475] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 147
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Statistical analysis description:

Week 12, Vitality MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.193 ^[476]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.35
upper limit	6.64

Notes:

[476] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 148
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Statistical analysis description:

Week 12, Vitality MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.051 ^[477]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	7.95

Notes:

[477] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 149
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Statistical analysis description:

Week 24, Vitality MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.321 ^[478]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.31
upper limit	10.02

Notes:

[478] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions

Statistical analysis title	Stat 150
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Statistical analysis description:

Week 24, Vitality MMRM analysis adjusted for baseline, treatment group, visit, treatment group by visit and baseline by visit interactions.

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.328 ^[479]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.18
upper limit	9.44

Notes:

[479] - MMRM analysis adjusted for Baseline, treatment group, visit, treatment group by visit and Baseline by visit interactions.

Secondary: Change from Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue at all assessment time points

End point title	Change from Baseline in Functional Assessment of Chronic
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End point description:

FACIT-fatigue questionnaire is a participant reported measure developed to assess fatigue consisting of 13 statements using a numeric rating scale ranging from 0 to 4. For only 2 of the items (i.e. Answer 5 [An5] and An7) a higher value represents a lower fatigue; 11 of the item scores (i.e. HI7, HI12, An1, An2, An3, An4, An8, An12, An14, An15, An16) have to be reversed by subtracting the captured value from 4 (0 is turned to a 4; 1 into 3; 3 into 1; 4 into 0). The final score ranges from 0 to 52 with higher values representing a lower fatigue (better quality of life). Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=x in the category titles).

End point type	Secondary
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End point timeframe:

Baseline and Weeks 4, 12, 24

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[480]	37 ^[481]	37 ^[482]	37 ^[483]
Units: Scores on a scale				
least squares mean (standard error)				
Week 4, n=34,34,36,37, 36, 36	3.16 (± 1.192)	2.51 (± 1.191)	4.66 (± 1.164)	5.71 (± 1.148)
Week 12, n=34,35,35,37, 35, 36	3.37 (± 1.291)	5.29 (± 1.278)	5.91 (± 1.273)	6.44 (± 1.244)
Week 24, n=8,14,21,24, 19, 34	7.56 (± 2.439)	8.31 (± 1.946)	7.09 (± 1.680)	6.74 (± 1.595)

Notes:

[480] - ITT Population.

[481] - ITT Population.

[482] - ITT Population.

[483] - ITT Population.

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[484]	37 ^[485]		
Units: Scores on a scale				
least squares mean (standard error)				
Week 4, n=34,34,36,37, 36, 36	6.73 (± 1.165)	5.97 (± 1.165)		
Week 12, n=34,35,35,37, 35, 36	7.28 (± 1.274)	8.70 (± 1.262)		
Week 24, n=8,14,21,24, 19, 34	8.28 (± 1.737)	9.43 (± 1.443)		

Notes:

[484] - ITT Population.

[485] - ITT Population.

Statistical analyses

Statistical analysis title	Stat 1
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.701 ^[486]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.97
upper limit	2.67

Notes:

[486] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.37 ^[487]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.79
upper limit	4.78

Notes:

[487] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.125 ^[488]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.71
upper limit	5.81

Notes:

[488] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.292 ^[489]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.66
upper limit	5.5

Notes:

[489] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.163 ^[490]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	6.11

Notes:

[490] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.087 ^[491]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	6.61

Notes:

[491] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
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Statistical analysis description:

Week 24

Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.808 ^[492]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.4
upper limit	6.92

Notes:

[492] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
-----------------------------------	--------

Statistical analysis description:

Week 24

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.874 ^[493]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.31
upper limit	5.38

Notes:

[493] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.78 [494]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.58
upper limit	4.95

Notes:

[494] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.033 [495]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	6.85

Notes:

[495] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 180 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.094 ^[496]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	2.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	6.1

Notes:

[496] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.032 ^[497]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	3.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	7.49

Notes:

[497] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[498]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	5.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.77
upper limit	8.89

Notes:

[498] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.808 ^[499]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.19
upper limit	6.64

Notes:

[499] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.511 ^[500]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	1.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.74
upper limit	7.48

Notes:

[500] - MMRM analysis adjusted for FACIT Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Change from Baseline in Brief Fatigue Inventory (BFI) Question 3 at all assessment time points

End point title	Change from Baseline in Brief Fatigue Inventory (BFI) Question 3 at all assessment time points
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End point description:

BFI is a self-reported instrument consisting of nine questions which correlate well with quality-of-life measures. For this study, Question 3 only was used which asked about fatigue severity at its worst in the last 24 hours. A discrete 11 unit numeric reporting scale was used where 0 =No fatigue, and 10=As bad as you can imagine. Baseline was defined as the last available assessment prior to the start of study treatment. Change from Baseline was calculated by subtracting the post dose visit value from the Baseline value. Only those participants available at the specified time points were analyzed (represented

by n=x in the category titles).

End point type	Secondary
End point timeframe:	
Baseline and Weeks 4, 12, 24	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[501]	37 ^[502]	37 ^[503]	37 ^[504]
Units: Scores on a scale				
least squares mean (standard error)				
Week 4,n=34,34,36,37, 36, 36	-0.60 (± 0.348)	-0.67 (± 0.348)	-1.10 (± 0.339)	-1.60 (± 0.335)
Week 12,n=34,35,35,37, 35, 36	-0.63 (± 0.346)	-1.26 (± 0.342)	-1.83 (± 0.341)	-2.02 (± 0.333)
Week 24,n=8,14,21,24, 19, 34	-1.83 (± 0.635)	-2.19 (± 0.496)	-1.76 (± 0.418)	-2.03 (± 0.395)

Notes:

[501] - ITT Population.

[502] - ITT Population.

[503] - ITT Population.

[504] - ITT Population.

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[505]	37 ^[506]		
Units: Scores on a scale				
least squares mean (standard error)				
Week 4,n=34,34,36,37, 36, 36	-1.86 (± 0.339)	-1.53 (± 0.341)		
Week 12,n=34,35,35,37, 35, 36	-2.07 (± 0.341)	-2.20 (± 0.339)		
Week 24,n=8,14,21,24, 19, 34	-2.59 (± 0.435)	-2.41 (± 0.353)		

Notes:

[505] - ITT Population.

[506] - ITT Population.

Statistical analyses

Statistical analysis title	Stat 1
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.888 ^[507]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	0.9

Notes:

[507] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 2
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.307 ^[508]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.46
upper limit	0.46

Notes:

[508] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 3
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.041 ^[509]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.95
upper limit	-0.04

Notes:

[509] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 4
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Statistical analysis description:

Week 12

Comparison groups	Placebo v GSK3196165 22.5 mg
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Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.191 ^[510]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	0.32

Notes:

[510] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 5
-----------------------------------	--------

Statistical analysis description:

Week 12

Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.014 ^[511]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.16
upper limit	-0.24

Notes:

[511] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 6
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Statistical analysis description:

Week 12

Comparison groups	Placebo v GSK3196165 90 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[512]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.34
upper limit	-0.45

Notes:

[512] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 7
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 22.5 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.656 ^[513]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.94
upper limit	1.23

Notes:

[513] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 8
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 45 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.928 ^[514]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.43
upper limit	1.57

Notes:

[514] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 9
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 90 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.788 ^[515]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.68
upper limit	1.28

Notes:

[515] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 10
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.01 ^[516]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.22
upper limit	-0.3

Notes:

[516] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 11
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Statistical analysis description:

Week 4

Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.059 ^[517]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.89
upper limit	0.03

Notes:

[517] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 12
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 135 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003 ^[518]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	-0.48

Notes:

[518] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 13
Statistical analysis description:	
Week 12	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001 ^[519]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-1.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.53
upper limit	-0.62

Notes:

[519] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 14
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 135 mg

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.324 ^[520]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.28
upper limit	0.76

Notes:

[520] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Statistical analysis title	Stat 15
Statistical analysis description:	
Week 24	
Comparison groups	Placebo v GSK3196165 180 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.432 ^[521]
Method	MMRM
Parameter estimate	Mean difference (net)
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	0.87

Notes:

[521] - MMRM analysis adjusted for BFI Baseline score, treatment group, visit and treatment group by visit and Baseline by visit interactions.

Secondary: Number of participants with adverse events (AEs) and serious AEs (SAEs)

End point title	Number of participants with adverse events (AEs) and serious AEs (SAEs)
End point description:	
An AE is any untoward medical occurrence in a participant or clinical investigation participants, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, is associated with liver injury and impaired liver function or any other situations as per Medical or Scientific judgment. Overall AEs and SAEs for the entire study duration until follow-up have been presented.	
End point type	Secondary
End point timeframe:	
Up to 62 weeks	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[522]	37 ^[523]	37 ^[524]	37 ^[525]
Units: Participants				
Any AE	26	24	26	28
Any SAE	1	2	1	2

Notes:

[522] - ITT Population

[523] - ITT Population

[524] - ITT Population

[525] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[526]	37 ^[527]		
Units: Participants				
Any AE	28	24		
Any SAE	2	0		

Notes:

[526] - ITT Population

[527] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with serious infections

End point title	Number of participants with serious infections
End point description:	
An AE is any untoward medical occurrence in a participant or clinical investigation participants, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Serious infections were categorized as AE of special interest. The number of participants with overall serious infections have been presented.	
End point type	Secondary
End point timeframe:	
Up to 62 weeks	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[528]	37 ^[529]	37 ^[530]	37 ^[531]
Units: Participants				
number (not applicable)	0	1	0	0

Notes:

[528] - ITT Population

[529] - ITT Population

[530] - ITT Population

[531] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[532]	37 ^[533]		
Units: Participants				
number (not applicable)	0	0		

Notes:

[532] - ITT Population

[533] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with opportunistic infections

End point title	Number of participants with opportunistic infections
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End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation participants, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Opportunistic infections were categorized as AE of special interest. The number of participants with overall opportunistic infections have been presented.

End point type	Secondary
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End point timeframe:

Up to 62 weeks

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[534]	37 ^[535]	37 ^[536]	37 ^[537]
Units: Participants				
number (not applicable)	0	0	0	0

Notes:

[534] - ITT Population

[535] - ITT Population

[536] - ITT Population

[537] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[538]	37 ^[539]		
Units: Participants				
number (not applicable)	0	0		

Notes:

[538] - ITT Population

[539] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with pulmonary events

End point title	Number of participants with pulmonary events
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End point description:

Pulmonary assessments were performed to determine the number of participants with pulmonary events including persistent cough, persistent dyspnea, and persistent Diffusing capacity of the lung for carbon monoxide (DLCO). Persistent is defined as any event with duration ≥ 15 days. Baseline was defined as the last available assessment prior to the start of study treatment. The number of participants experiencing pulmonary events have been reported.

End point type	Secondary
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End point timeframe:

Up to 62 weeks

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[540]	37 ^[541]	37 ^[542]	37 ^[543]
Units: Participants				
Persistent Cough	1	0	0	0
Persistent Dyspnea	1	0	0	1
Persistent DLCO decrease >15% from Baseline	2	3	1	0

Notes:

[540] - ITT Population

[541] - ITT Population

[542] - ITT Population

[543] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[544]	37 ^[545]		
Units: Participants				
Persistent Cough	0	0		
Persistent Dyspnea	0	0		
Persistent DLCO decrease >15% from Baseline	3	1		

Notes:

[544] - ITT Population

[545] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with worst-case Post-Baseline results for Pulse Oximetry

End point title	Number of participants with worst-case Post-Baseline results for Pulse Oximetry
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End point description:

Oxygen saturation measures the capacity of blood to transport oxygen to other parts of the body. Oxygen binds to hemoglobin in red blood cells when moving through the lungs. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage of hemoglobin in the blood that is saturated with oxygen, that is called as blood oxygen saturation. Baseline was defined as the last

available assessment prior to the start of study treatment. The number of participants with blood oxygen level < 80%, 80% to <90% and >=90% have been reported. Only those participants with data available at specified time point were analyzed (represented by n=x in category titles).

End point type	Secondary
End point timeframe:	
Up to 62 weeks	

End point values	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg	GSK3196165 90 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[546]	37 ^[547]	37 ^[548]	37 ^[549]
Units: Participants				
< 80%; n=37, 36, 37, 37, 36, 37	0	0	0	0
80% to <90%; n=37, 36, 37, 37, 36, 37	0	0	0	0
>= 90%; n=37, 36, 37, 37, 36, 37	37	36	37	37

Notes:

[546] - ITT Population

[547] - ITT Population

[548] - ITT Population

[549] - ITT Population

End point values	GSK3196165 135 mg	GSK3196165 180 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37 ^[550]	37 ^[551]		
Units: Participants				
< 80%; n=37, 36, 37, 37, 36, 37	0	0		
80% to <90%; n=37, 36, 37, 37, 36, 37	1	0		
>= 90%; n=37, 36, 37, 37, 36, 37	35	37		

Notes:

[550] - ITT Population

[551] - ITT Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 62 weeks

Adverse event reporting additional description:

ITT Population was used for the analysis of safety data.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received placebo liquid (sterile 0.9% weight/volume) sodium chloride solution) 0.6 mL drawn into a small (1 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 22.5 mg
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Reporting group description:

Participants received GSK3196165 22.5 mg (0.15 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 45 mg
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Reporting group description:

Participants received GSK3196165 45 mg (0.3 mL) liquid drawn into a small (0.3 mL/0.5 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 90 mg
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Reporting group description:

Participants received GSK3196165 90 mg (0.6 mL) liquid drawn into a small (1 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 135 mg
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Reporting group description:

Participants received GSK3196165 135 mg (0.9 mL) liquid drawn into a small (1 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule (orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Reporting group title	GSK3196165 180 mg
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Reporting group description:

Participants received GSK3196165 180 mg (1.2 mL) liquid drawn into a small (2 mL/3 mL syringe) administered subcutaneous in the thigh/abdomen up to 52 weeks in combination with MTX tablets (orally)/liquid (subcutaneous injection) at a dose of 7.5 to 25 mg/week and folic acid tablet/capsule

(orally) at a dose of ≥ 5 mg/week. MTX was taken as a single weekly dose/divided weekly dose, folic acid was taken the day after and at least 12 hours following MTX administration. Safety was monitored for 1 hour after the injection, for the first 3 injections, then for 30 minutes thereafter.

Serious adverse events	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 37 (2.70%)	2 / 37 (5.41%)	1 / 37 (2.70%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 37 (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
Foot fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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			
Oesophageal spasm			

subjects affected / exposed	0 / 37 (0.00%)	1 / 37 (2.70%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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
Rheumatoid arthritis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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
Infections and infestations			
Pyelonephritis acute			
subjects affected / exposed	0 / 37 (0.00%)	1 / 37 (2.70%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK3196165 90 mg	GSK3196165 135 mg	GSK3196165 180 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 37 (5.41%)	2 / 37 (5.41%)	0 / 37 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 37 (0.00%)	1 / 37 (2.70%)	0 / 37 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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
Foot fracture			

subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 37 (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
Gastrointestinal disorders			
Oesophageal spasm			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 37 (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
Rheumatoid arthritis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 37 (2.70%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pyelonephritis acute			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 37 (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

Non-serious adverse events	Placebo	GSK3196165 22.5 mg	GSK3196165 45 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 37 (35.14%)	12 / 37 (32.43%)	13 / 37 (35.14%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 37 (5.41%)	1 / 37 (2.70%)	3 / 37 (8.11%)
occurrences (all)	2	1	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 37 (0.00%)	3 / 37 (8.11%)	1 / 37 (2.70%)
occurrences (all)	0	3	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 37 (21.62%)	5 / 37 (13.51%)	7 / 37 (18.92%)
occurrences (all)	8	6	11
Upper respiratory tract infection			
subjects affected / exposed	3 / 37 (8.11%)	5 / 37 (13.51%)	3 / 37 (8.11%)
occurrences (all)	3	6	3

Non-serious adverse events	GSK3196165 90 mg	GSK3196165 135 mg	GSK3196165 180 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 37 (24.32%)	18 / 37 (48.65%)	13 / 37 (35.14%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 37 (8.11%)	3 / 37 (8.11%)	0 / 37 (0.00%)
occurrences (all)	3	4	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 37 (0.00%)	3 / 37 (8.11%)	5 / 37 (13.51%)
occurrences (all)	0	5	5
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 37 (13.51%)	8 / 37 (21.62%)	9 / 37 (24.32%)
occurrences (all)	6	8	12
Upper respiratory tract infection			
subjects affected / exposed	2 / 37 (5.41%)	7 / 37 (18.92%)	3 / 37 (8.11%)
occurrences (all)	2	9	4

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 February 2015	This amendment includes removal of the Medical Monitor Contact Information on the Sponsor Information page, missing assessments in Section 7.1, and removal of example PRO Questionnaires as Appendix 12.7.
13 March 2015	This amendment includes revision of the study title on the Title page, clarification that actigraphy will only be at participating sites in Section 3, Section 7.2, Section 7.3, Section 7.10.5, Section 7.10.6, Appendix 12.7, minor revisions to placebo and comedication information in Section 6.1, changes to the guidance on dosing instructions in Section 6.1, and revisions of anchors for Global Assessment of Arthritis in Section 7.3.2.
01 May 2015	This amendment includes removal of flow cytometry assessments from Section 3, 7.1 and Section 7.7, clarification of biomarkers in Section 3, corrections to neutropenia levels in Section 4.7.1, clarification of Tuberculosis (TB) testing in Section 5.1 and Section 7.2, changes to administration of MTX in Section 6.1 and Section 6.9.2, clarification of unblinded administrator in Section 6.5, compliance of MTX in Section 6.8, and corrected Routine Laboratory Assessments in Section 7.4.11 (Table 2).
01 May 2015	This amendment includes removal of blank line in Section 7.1.
20 October 2015	This amendment includes additional criteria for continuation or withdrawal in the study at Week 38 in Section 4.2 and Section 5.4, clarification that SoC is standard of care in Section 4.5, clarification of rescreening procedure in Section 5.3.1, Section 5.3.2.2, clarification of DLCO retesting in Section 5.3.2, addition of lipid measurements in Section 7.1 and Section 7.4.11 (Table 2), clarification of header version numbers and footnotes in Section 7.1, clarification of eligibility in Section 7.3.5, clarification of pregnancy in Section 7.4.7, additions to Appendix 12.1, revisions of Appendix 12.2 and Appendix 12.5, and added Appendix 12.9 to track all protocol text changes.
25 November 2015	This amendment includes clarification that the DLCO tests may be repeated twice within the screening period in Section 5.1, clarification that only Fridericia's formula (QTcF) will be used in Section 5.2 and Section 5.4.2, clarification that the screening ECG test may be repeated once in Section 5.3.2.3, clarification of footnotes in Section 7.1, removal of biomarker interleukin 22 (IL-22) measurement in Section 7.7, and reinsertion of contraception guidance inadvertently deleted in Appendix 12.2 of previous Amendment 5.
11 March 2016	This amendment includes correction of the example formula to calculate the EULAR good/moderate response at Week 12 and Week 36 in Section 4.2 and Section 6.4; confirmation of mandatory chest HRCT if DLCO $\geq 60\%$ to $< 70\%$ predicted in Section 5.1, Section 5.3.2.2, Section 7.1 and Section 7.4.1; update to investigator brochure (IB) document number and added reference in Section 11.
08 June 2016	Germany only: This local amendment revised Inclusion Criterion number 13 to DLCO $\geq 70\%$ predicted in Section 5.1.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported