



Clinical trial results:

A Multi-Centre Long-term Extension Study to Assess the Safety and Efficacy of GSK3196165 in the Treatment of Rheumatoid Arthritis

Summary

EudraCT number	2019-000878-30
Trial protocol	LT GB CZ HU EE DE LV BG BE
Global end of trial date	24 February 2023

Results information

Result version number	v2 (current)
This version publication date	06 March 2024
First version publication date	14 December 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	209564
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04333147
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	GreatWestRoad, Brentford,Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, +1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, +1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 May 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 February 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the long-term safety of GSK3196165 at weekly doses of 90 milligram (mg) or 150 mg for the treatment of participants with moderately to severely active rheumatoid arthritis (RA).

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 October 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 803
Country: Number of subjects enrolled	Argentina: 387
Country: Number of subjects enrolled	United States: 344
Country: Number of subjects enrolled	Japan: 207
Country: Number of subjects enrolled	Russian Federation: 195
Country: Number of subjects enrolled	Ukraine: 165
Country: Number of subjects enrolled	Mexico: 124
Country: Number of subjects enrolled	South Africa: 93
Country: Number of subjects enrolled	China: 85
Country: Number of subjects enrolled	Czechia: 83
Country: Number of subjects enrolled	India: 82
Country: Number of subjects enrolled	Bulgaria: 58
Country: Number of subjects enrolled	Hungary: 57
Country: Number of subjects enrolled	Estonia: 38
Country: Number of subjects enrolled	Lithuania: 35
Country: Number of subjects enrolled	Colombia: 34
Country: Number of subjects enrolled	Korea, Republic of: 27
Country: Number of subjects enrolled	Germany: 23
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	Serbia: 17
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	Latvia: 7

Country: Number of subjects enrolled	Thailand: 7
Country: Number of subjects enrolled	Malaysia: 5
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	Australia: 2
Country: Number of subjects enrolled	Belgium: 1
Worldwide total number of subjects	2915
EEA total number of subjects	1126

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)	2275
From 65 to 84 years	639
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The participants with Rheumatoid Arthritis (RA) who completed the treatment phase of a qualifying Otilimab clinical study (201790 [ContrAst 1], 201791 [ContrAst 2] and 202018 [ContrAst 3]) and who, in the investigator's and participant's judgement would have benefited from extended treatment with Otilimab were enrolled.

Pre-assignment

Screening details:

Participants from 202018, 201790, 201791 who consented, was enrolled. Participants who received Otilimab, continued on same dose. Participants who received comparator were randomized in ratio of 1:1 to either Otilimab 90 mg or 150 mg. One participant withdrew from 150mg GSK3196165 before receiving intervention due to Physician Decision (N=1459).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Otilimab 90 mg

Arm description:

Participants who received Otilimab 90mg in a qualifying study and continued on Otilimab 90mg in study 209564 or participants who received either tofacitinib 5mg (study 201790 or 201791) or sarilumab 200mg (study 202018) in a qualifying study and were exposed for the first time to Otilimab 90mg in study 209564. Otilimab 90mg was administered through subcutaneous (SC) injection once weekly.

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

Dosage and administration details:

Participants received GSK3196165 90 mg subcutaneous (SC) injection.

Arm title	Otilimab 150 mg
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Arm description:

Participants who received Otilimab 150mg in a qualifying study and continued on Otilimab 150mg in study 209564 or participants who received either tofacitinib 5mg (study 201790 or 201791) or sarilumab 200mg (study 202018) in a qualifying study and were exposed for the first time to Otilimab 150mg in study 209564. Otilimab 150mg was administered through subcutaneous (SC) injection once weekly.

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

Dosage and administration details:

Participants received GSK3196165 150 mg subcutaneous (SC) injection.

Number of subjects in period 1	Otilimab 90 mg	Otilimab 150 mg
Started	1456	1459
Completed	0	0
Not completed	1456	1459
Physician decision	17	20
Consent withdrawn by subject	65	68
Adverse event, non-fatal	43	40
STUDY TERMINATED BY SPONSOR	1251	1256
INVESTIGATOR SITE CLOSED	6	2
PROTOCOL-SPECIFIED WITHDRAWAL CRITERION MET	6	9
Lost to follow-up	19	16
Lack of efficacy	49	48

Baseline characteristics

Reporting groups

Reporting group title	Otilimab 90 mg
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Reporting group description:

Participants who received Otilimab 90mg in a qualifying study and continued on Otilimab 90mg in study 209564 or participants who received either tofacitinib 5mg (study 201790 or 201791) or sarilumab 200mg (study 202018) in a qualifying study and were exposed for the first time to Otilimab 90mg in study 209564. Otilimab 90mg was administered through subcutaneous (SC) injection once weekly.

Reporting group title	Otilimab 150 mg
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Reporting group description:

Participants who received Otilimab 150mg in a qualifying study and continued on Otilimab 150mg in study 209564 or participants who received either tofacitinib 5mg (study 201790 or 201791) or sarilumab 200mg (study 202018) in a qualifying study and were exposed for the first time to Otilimab 150mg in study 209564. Otilimab 150mg was administered through subcutaneous (SC) injection once weekly.

Reporting group values	Otilimab 90 mg	Otilimab 150 mg	Total
Number of subjects	1456	1459	2915
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)	1138	1137	2275
From 65-84 years	318	321	639
85 years and over	0	1	1
Sex: Female, Male			
Units: Participants			
Female	1158	1181	2339
Male	298	278	576
Race/Ethnicity, Customized			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	40	53	93
ASIAN	223	206	429
BLACK OR AFRICAN AMERICAN	33	28	61
WHITE	1147	1157	2304
MULTIPLE	13	15	28
Age, Customized			
Units: Subjects			
18-49	453	402	855
50-64	685	735	1420
>=65	318	322	640

Age, Continuous			
Units: YEARS			
arithmetic mean	55.2	55.7	
standard deviation	± 11.38	± 10.91	-

End points

End points reporting groups

Reporting group title	Otilimab 90 mg
Reporting group description: Participants who received Otilimab 90mg in a qualifying study and continued on Otilimab 90mg in study 209564 or participants who received either tofacitinib 5mg (study 201790 or 201791) or sarilumab 200mg (study 202018) in a qualifying study and were exposed for the first time to Otilimab 90mg in study 209564. Otilimab 90mg was administered through subcutaneous (SC) injection once weekly.	
Reporting group title	Otilimab 150 mg
Reporting group description: Participants who received Otilimab 150mg in a qualifying study and continued on Otilimab 150mg in study 209564 or participants who received either tofacitinib 5mg (study 201790 or 201791) or sarilumab 200mg (study 202018) in a qualifying study and were exposed for the first time to Otilimab 150mg in study 209564. Otilimab 150mg was administered through subcutaneous (SC) injection once weekly.	

Primary: Number of participants with adverse events (AEs), serious adverse events (SAEs) and adverse events of special interest (AESI)

End point title	Number of participants with adverse events (AEs), serious adverse events (SAEs) and adverse events of special interest (AESI) ^[1]
End point description: An AE is defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. SAEs are defined as any untoward medical occurrence that, at any dose: results in death, cause life threatening events which requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability or incapacity and birth defect or congenital anomaly. Protocol defined AESIs were included. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment.	
End point type	Primary
End point timeframe: Up to approximately 145 Weeks	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1456	1459		
Units: Participants				
Participants with AEs, n=1456,1459	902	931		
Participants with SAEs, n=1456,1459	123	114		
Participants with AESI, n=1456,1459	120	95		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Platelet Count at Week 24

End point title	Change from Baseline in Hematology Parameter of Platelet Count at Week 24 ^[2]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter platelet count. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 24

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1180	1204		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)	-11.9 (± 66.86)	-9.7 (± 66.82)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Hemoglobin at Week 48

End point title	Change from Baseline in Hematology Parameter of Hemoglobin at Week 48 ^[3]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter hemoglobin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 48

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	713	706		
Units: Gram Per Liter (g/L)				
arithmetic mean (standard deviation)	-0.5 (± 10.38)	-1.1 (± 10.62)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Hemoglobin at Week 24

End point title	Change from Baseline in Hematology Parameter of Hemoglobin at Week 24 ^[4]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter hemoglobin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 24

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1195	1212		
Units: Gram Per Liter (g/L)				
arithmetic mean (standard deviation)	0.4 (± 10.10)	0.3 (± 9.89)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Platelet Count at Week 144

End point title	Change from Baseline in Hematology Parameter of Platelet Count at Week 144 ^[5]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter platelet count. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 144

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1 ^[6]	2		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)	17.0 (± 0)	-37.5 (± 40.31)		

Notes:

[6] - The Standard Deviation was not derived as only one participant was analyzed.

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Platelet Count at Week 96

End point title	Change from Baseline in Hematology Parameter of Platelet Count at Week 96 ^[7]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter platelet count. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 96

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	117		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)	-13.8 (± 60.72)	-5.7 (± 72.81)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Platelet Count at Week 48

End point title	Change from Baseline in Hematology Parameter of Platelet
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter platelet count. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 48

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	706	702		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)	-12.5 (± 66.47)	-7.6 (± 71.36)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Hemoglobin at Week 96

End point title	Change from Baseline in Hematology Parameter of Hemoglobin at Week 96 ^[9]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter hemoglobin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 96

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	119		
Units: Gram Per Liter (g/L)				
arithmetic mean (standard deviation)	1.0 (± 11.37)	1.2 (± 10.24)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter of Hemoglobin at Week 144

End point title	Change from Baseline in Hematology Parameter of Hemoglobin at Week 144 ^[10]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter hemoglobin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 144

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1 ^[11]	2		
Units: Gram Per Liter (g/L)				
arithmetic mean (standard deviation)	-1.0 (± 0)	2.0 (± 2.83)		

Notes:

[11] - The Standard Deviation was not derived as only one participant was analyzed.

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 24

End point title	Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 24 ^[12]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameters including White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 24

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1350	1212		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)				
Neutrophils, n=1182, 1208	-0.348 (± 2.18)	-0.390 (± 2.13)		
Lymphocytes, n=1182, 1208	-0.001 (± 0.55)	-0.012 (± 0.55)		
Monocytes, n=1182, 1208	0.003 (± 0.18)	0.00 (± 0.194)		
Eosinophils, n=1182, 666	0.027 (± 0.1623)	0.022 (± 0.171)		
Basophils, n=1350, 1208	-0.001 (± 0.0405)	-0.001 (± 0.04)		
Total WBC, n=1188, 1212	-0.32 (± 2.212)	-0.38 (± 2.230)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 48

End point title	Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 48 ^[13]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameters including White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 48

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	709	703		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)				
Neutrophils, n=703, 698	-0.318 (± 2.2215)	-0.541 (± 2.1426)		
Lymphocytes, n=703, 698	-0.022 (± 0.5385)	-0.051 (± 0.5725)		
Monocytes, n=703, 698	-0.002 (± 0.1871)	-0.013 (± 0.2461)		

Eosinophils, n=703, 698	0.018 (± 0.1435)	0.028 (± 0.1844)		
Basophils, n=703, 698	-0.004 (± 0.0391)	-0.006 (± 0.0403)		
Total WBC, n=709, 703	-0.33 (± 2.283)	-0.58 (± 2.262)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 96

End point title	Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 96 ^[14]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameters including White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 96

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	119		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)				
Neutrophils, n=127,44	-0.243 (± 1.8851)	-0.555 (± 2.3580)		
Lymphocytes, n=127,118	0.090 (± 0.6453)	0.018 (± 0.5816)		
Monocytes, n=127,118	-0.042 (± 0.2001)	-0.001 (± 0.2035)		
Eosinophils, n=127,118	0.025 (± 0.1725)	0.029 (± 0.1526)		
Basophils, n=127,118	-0.007 (± 0.0423)	-0.013 (± 0.0346)		
Total WBC, n=127,119	-0.18 (± 2.043)	-0.53 (± 2.568)		

Statistical analyses

Primary: Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 144

End point title	Change from Baseline in White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils at Week 144 ^[15]
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End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameters including White Blood Cell (WBC) Count with Differential i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 144

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1 ^[16]	2 ^[17]		
Units: Giga cells per liter (10 ⁹ cells/L)				
arithmetic mean (standard deviation)				
Neutrophils, n=1,0	-0.360 (± 0)	0 (± 0)		
Lymphocytes, n=1,2	-0.320 (± 0)	0.010 (± 0.3253)		
Monocytes, n=1,2	-0.220 (± 0)	0.010 (± 0.0424)		
Eosinophils, n=1,0	-0.130 (± 0)	0 (± 0)		
Basophils, n=1,2	0.000 (± 0)	0.000 (± 0.0141)		
Total WBC, n=1,2	-1.00 (± 0)	-0.85 (± 1.061)		

Notes:

[16] - The Standard Deviation was not derived as only one participant was analyzed.

[17] - There is no data to disclose as no participant was analyzed for some of the analytes.

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 24

End point title	Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 24 ^[18]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including AST, ALT, AP, GGT, CPK. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
End point timeframe:	
Baseline (Day 01) and Week 24	
Notes:	
[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: This endpoint was descriptive; hence no statistical analysis to report.	

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1232	1402		
Units: International units per liter (IU/L)				
arithmetic mean (standard deviation)				
Aspartate Aminotransferase (AST), n=1231,1242	1.0 (± 11.09)	0.8 (± 9.70)		
Alanine Aminotransferase (ALT), n=1232,1243	0.0 (± 15.80)	-0.1 (± 15.20)		
Alkaline Phosphatase (AP), n=1232,12423	3.0 (± 18.85)	3.1 (± 21.05)		
Gamma Glutamyl Transferase (GGT), n=1230,1402	-0.9 (± 20.32)	-0.4 (± 18.94)		
Creatine Kinase (CPK), n=1230,1242	5.4 (± 103.03)	-3.8 (± 66.66)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 96

End point title	Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 96 ^[19]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including AST, ALT, AP, GGT, CPK. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
End point timeframe:	
Baseline (Day 01) and Week 96	
Notes:	
[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: This endpoint was descriptive; hence no statistical analysis to report.	

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	122		
Units: International units per liter (IU/L)				
arithmetic mean (standard deviation)				
Aspartate Aminotransferase (AST), n=128,44	0.1 (± 11.65)	2.0 (± 7.47)		
Alanine Aminotransferase (ALT), n=128,44	-2.4 (± 19.02)	-1.1 (± 9.33)		
Alkaline Phosphatase (AP), n=128,122	0.0 (± 18.98)	8.6 (± 27.79)		
Gamma Glutamyl Transferase (GGT), n=128,122	-1.9 (± 18.52)	-0.1 (± 19.67)		
Creatine Kinase (CPK), n=128,122	1.4 (± 39.73)	3.6 (± 93.29)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 48

End point title	Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 48 ^[20]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including AST, ALT, AP, GGT, CPK. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 48

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	762	749		
Units: International units per liter (IU/L)				
arithmetic mean (standard deviation)				
Aspartate Aminotransferase (AST), n=761,749	0.4 (± 11.11)	0.4 (± 11.32)		
Alanine Aminotransferase (ALT), n=762,748	-0.9 (± 16.35)	-1.2 (± 16.26)		
Alkaline Phosphatase (AP), n=762,748	5.4 (± 20.07)	5.2 (± 21.32)		
Gamma Glutamyl Transferase (GGT), n=762,748	-0.0 (± 22.44)	-0.4 (± 22.14)		
Creatine Kinase (CPK), n=762,748	7.8 (± 153.24)	-3.7 (± 71.52)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 144

End point title	Change from Baseline in Clinical Chemistry Parameter of Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase (AP), Gamma Glutamyl Transferase (GGT), Creatine Kinase (CPK) at Week 144 ^[21]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including AST, ALT, AP, GGT, CPK. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 144

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1 ^[22]	2 ^[23]		
Units: International units per liter (IU/L)				
arithmetic mean (standard deviation)				
Aspartate Aminotransferase (AST), n=1,2	-8.0 (± 0)	2.0 (± 0.0)		
Alanine Aminotransferase (ALT), n=1,0	-14.0 (± 0)	0 (± 0)		
Alkaline Phosphatase (AP), n=1,2	39.0 (± 0)	-1.5 (± 6.36)		
Gamma Glutamyl Transferase (GGT), n=1,2	-21.0 (± 0)	5.0 (± 14.14)		
Creatine Kinase (CPK), n=1,2	-47.0 (± 0)	-2.5 (± 31.82)		

Notes:

[22] - The Standard Deviation was not derived as only one participant was analyzed.

[23] - There is no data to disclose as no participant was analyzed for some of the analytes.

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Lipid Profile Parameter of Cholesterol, Low-Density Lipoprotein (LDL) Cholesterol, High-Density Lipoprotein-Cholesterol (HDL), Triglycerides at Week 24

End point title	Change from Baseline in Lipid Profile Parameter of Cholesterol,
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End point description:

Blood samples was collected for the assessment of clinical chemistry parameters including Cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein-cholesterol (HDL), Triglycerides. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type Primary

End point timeframe:

Baseline (Day 01) and Week 24

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1183	1204		
Units: Millimoles per liter (mmol/L)				
arithmetic mean (standard deviation)				
Cholesterol, n=1183,1201	-0.038 (± 0.8542)	-0.011 (± 0.9685)		
HDL Cholesterol, Direct, n=1183,1201	-0.020 (± 0.2703)	-0.022 (± 0.2869)		
LDL Cholesterol, n=1171,1190	-0.031 (± 0.7239)	0.010 (± 0.7818)		
Triglycerides, n=1183, 1204	0.033 (± 0.6503)	0.011 (± 0.7895)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Lipid Profile Parameter of Cholesterol, Low-Density Lipoprotein (LDL) Cholesterol, High-Density Lipoprotein-Cholesterol (HDL), Triglycerides at Week 48

End point title Change from Baseline in Lipid Profile Parameter of Cholesterol, Low-Density Lipoprotein (LDL) Cholesterol, High-Density Lipoprotein-Cholesterol (HDL), Triglycerides at Week 48^[25]

End point description:

Blood samples was collected for the assessment of clinical chemistry parameters including Cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein-cholesterol (HDL), Triglycerides. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type Primary

End point timeframe:

Baseline (Day 01) and Week 48

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	730	719		
Units: Millimoles per liter (mmol/L)				
arithmetic mean (standard deviation)				
Cholesterol, n=730,718	-0.053 (± 0.9271)	-0.078 (± 0.9826)		
HDL Cholesterol, Direct, n=730,718	-0.021 (± 0.2979)	-0.027 (± 0.2959)		
LDL Cholesterol, n=728,708	-0.038 (± 0.7865)	-0.034 (± 0.7899)		
Triglycerides, n=730,719	0.015 (± 0.6772)	-0.019 (± 0.7376)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Lipid Profile Parameter of Cholesterol, Low-Density Lipoprotein (LDL) Cholesterol, High-Density Lipoprotein-Cholesterol (HDL), Triglycerides at Week 96

End point title	Change from Baseline in Lipid Profile Parameter of Cholesterol, Low-Density Lipoprotein (LDL) Cholesterol, High-Density Lipoprotein-Cholesterol (HDL), Triglycerides at Week 96 ^[26]
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End point description:

Blood samples was collected for the assessment of clinical chemistry parameters including Cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein-cholesterol (HDL), Triglycerides. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 96

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	100		
Units: Millimoles per liter (mmol/L)				
arithmetic mean (standard deviation)				
Cholesterol, n=113,100	-0.178 (± 1.0350)	-0.130 (± 1.0570)		
HDL Cholesterol, Direct, n=113,100	-0.032 (± 0.2665)	-0.058 (± 0.3233)		
LDL Cholesterol, n=112,99	-0.159 (± 0.8948)	-0.031 (± 0.8546)		
Triglycerides, n=113,100	0.009 (± 0.8042)	-0.056 (± 0.7262)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Lipid Profile Parameter of Cholesterol, Low-Density Lipoprotein (LDL) Cholesterol, High-Density Lipoprotein-Cholesterol (HDL), Triglycerides at Week 144

End point title	Change from Baseline in Lipid Profile Parameter of Cholesterol, Low-Density Lipoprotein (LDL) Cholesterol, High-Density Lipoprotein-Cholesterol (HDL), Triglycerides at Week 144 ^[27]
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End point description:

Blood samples was collected for the assessment of clinical chemistry parameters including Cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein-cholesterol (HDL), Triglycerides. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 144

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1 ^[28]	2		
Units: Millimoles per liter (mmol/L)				
arithmetic mean (standard deviation)				
Cholesterol, n=1,2	-2.360 (± 0)	-2.240 (± 2.8709)		
HDL Cholesterol, Direct, n=1,2	0.160 (± 0)	-0.095 (± 0.0212)		
LDL Cholesterol, n=1,2	-2.250 (± 0)	-1.750 (± 2.4183)		
Triglycerides, n=1,2	-0.580 (± 0)	-0.865 (± 0.9687)		

Notes:

[28] - The Standard Deviation was not derived as only one participant was analyzed.

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 24

End point title	Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 24 ^[29]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including total bilirubin, direct bilirubin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 24

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1232	1243		
Units: Micromoles per liter (umol/L)				
arithmetic mean (standard deviation)				
Total Bilirubin, n=1232,1243	0.3 (± 2.87)	0.3 (± 2.92)		
Direct Bilirubin, n=1224,1235	0.053 (± 0.764)	0.027 (± 0.641)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 48

End point title	Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 48 ^[30]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including total bilirubin, direct bilirubin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 48

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	762	749		
Units: Micromoles per liter (umol/L)				
arithmetic mean (standard deviation)				
Total Bilirubin, n=762,749	-0.0 (± 2.85)	0.1 (± 3.04)		

Direct Bilirubin, n=757,743	0.011 (± 0.777)	0.040 (± 0.690)		
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Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with National Cancer Institute-Common terminology criteria for adverse events (NCI-CTCAE) ≥ Grade 3 hematological/clinical chemistry abnormalities

End point title	Number of participants with National Cancer Institute-Common terminology criteria for adverse events (NCI-CTCAE) ≥ Grade 3 hematological/clinical chemistry abnormalities ^[31]
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End point description:

Number of participants with NCI-CTCAE ≥ Grade 3 hematological/clinical chemistry abnormalities were summarized. Hematological and Clinical chemistry parameters were summarized according to the NCI-CTCAE, version 5.0: Grade 1: mild; Grade 2: moderate; Grade 3: severe; Grade 4: life-threatening or disabling. Higher grade indicates more severity. Data is presented for only those parameters for which participants had worst case ≥ Grade 3 shifts from Baseline.

End point type	Primary
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End point timeframe:

Up to approximately 145 Weeks

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1456	1459		
Units: Participants				
Hypercalcemia, Total, Grade 3	1	0		
Hyperkalemia, Total, Grade 4	2	0		
Hypernatremia, Total, Grade 3	1	0		
Hypernatremia, Total, Grade 4	0	1		
Chronic Kidney Disease, Total, Grade 3	0	1		
Creatinine increased, Total, Grade 3	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 96

End point title	Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 96 ^[32]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including total bilirubin, direct bilirubin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 96

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	123		
Units: Micromoles per liter (umol/L)				
arithmetic mean (standard deviation)				
Total Bilirubin, n=128, 123	-0.2 (± 3.22)	0.5 (± 3.49)		
Direct Bilirubin, n=127, 122	0.047 (± 0.815)	0.041 (± 0.827)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 144

End point title	Change from Baseline in Clinical Chemistry Parameter Total Bilirubin, Direct Bilirubin at Week 144 ^[33]
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End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters including total bilirubin, direct bilirubin. The analysis was performed on the Safety Set that includes all randomized participants who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Primary
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End point timeframe:

Baseline (Day 01) and Week 144

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1 ^[34]	2		
Units: Micromoles per liter (umol/L)				
arithmetic mean (standard deviation)				
Total Bilirubin, n=1,2	4.0 (± 0)	4.5 (± 6.36)		

Direct Bilirubin, n=1,2	2.000 (± 0)	1.500 (± 0.707)		
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Notes:

[34] - The Standard Deviation was not derived as only one participant was analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving Clinical Disease Activity Index (CDAI) total score lesser than or equal to (\leq)10 (CDAI) low disease activity (LDA) at Week 24, 48, 96 and 144

End point title	Percentage of participants achieving Clinical Disease Activity Index (CDAI) total score lesser than or equal to (\leq)10 (CDAI) low disease activity (LDA) at Week 24, 48, 96 and 144
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End point description:

CDAI total score is a composite score consisting of the sum of Swollen Joint Count 28 (SJC28), Tender Joint Count 28 (TJC28), Patient's Global Assessment of Arthritis Disease Activity (PtGA) (visual analogue scale with values from 0=best to 100=worst) and Physician Global Assessment of Arthritis Disease Activity (PhGA) (visual analogue scale with values from 0=best to 100=worst). PtGA and PhGA are transformed to a 0-10 scale before computing the CDAI total score. CDAI total score ranges from 0 to 76 with higher values representing higher disease activity. Low disease activity (LDA) is achieved when CDAI total score \leq 10. Percentage values are rounded off. The analysis was performed on the intent to treat (ITT) set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1206 ^[35]	1212		
Units: Percentage of participants				
number (not applicable)				
Week 24, n=1206,1212	47.0	46.0		
Week 48, n=757,749	44.0	47.0		
Week 96, n=124,112	40.0	47.0		
Week 144, n=0,1	0	0.0		

Notes:

[35] - There is no data to disclose as no participant was analyzed at Week 144.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving Clinical Disease Activity Index (CDAI) total score \leq 2.8 (CDAI Remission) at Week 24, 48, 96 and 144

End point title	Percentage of participants achieving Clinical Disease Activity Index (CDAI) total score \leq 2.8 (CDAI Remission) at Week 24,
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End point description:

CDAI total score is a composite score consisting of the sum of Swollen Joint Count 28 (SJC28), Tender Joint Count 28 (TJC28), Patient's Global Assessment of Arthritis Disease Activity (PtGA) (visual analogue scale with values from 0=best to 100=worst) and Physician Global Assessment of Arthritis Disease Activity (PhGA) (visual analogue scale with values from 0=best to 100=worst). PtGA and PhGA are transformed to a 0-10 scale before computing the CDAI total score. CDAI total score ranges from 0 to 76 with higher values representing higher disease activity. CDAI remission is achieved when CDAI total score ≤ 2.8 . Percentage values are rounded off. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1206 ^[36]	1212		
Units: Percentage of participants				
number (not applicable)				
Week 24, n=1206,1212	11.0	10.0		
Week 48, n=757,749	12.0	9.0		
Week 96, n=124,112	13.0	9.0		
Week 144, n=0,1	0	0.0		

Notes:

[36] - There is no data to disclose as no participant was analyzed at Week 144.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving Disease Activity Score using 28 joint count and C-Reactive Protein (DAS28-CRP) < 2.6 at Week 24, 48, 96 and 144

End point title	Percentage of participants achieving Disease Activity Score using 28 joint count and C-Reactive Protein (DAS28-CRP) < 2.6 at Week 24, 48, 96 and 144
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End point description:

The DAS28-CRP is a measure of RA disease activity calculated using Tender Joint Count 28 (TJC28), Swollen Joint Count 28 (SJC28), C-reactive protein (CRP) (in mg/L), Patient's Global Assessment of Arthritis Disease Activity (PtGA) (visual analogue scale with values from 0=best to 100=worst). PtGA is transformed to a 0-10 scale before computing the total score. DAS28-CRP scores range from 1.0 to 9.4, where lower scores indicates less disease activity. Low disease activity (LDA) is achieved when DAS28-CRP greater than or equal to (\leq) 3.2. A negative change from baseline in DAS28-CRP indicates an improvement. Percentage values are rounded off. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1190	1190		
Units: Percentage of participants				
number (not applicable)				
Week 24, n=1190,1190	26.0	25.0		
Week 48, n=719,715	25.0	25.0		
Week 96, n=108,99	26.0	28.0		
Week 144, n=0,1	0	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving American College of Rheumatology (ACR)/ European league against rheumatism (EULAR) remission at Week 24, 48, 96 and 144

End point title	Percentage of participants achieving American College of Rheumatology (ACR)/ European league against rheumatism (EULAR) remission at Week 24, 48, 96 and 144
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End point description:

Boolean-based ACR/EULAR remission is achieved if all of the following requirements are met at the same timepoint: Tender Joint Count 68 (TJC68) ≤ 1 , Swollen Joint Count 66 (SJC66) ≤ 1 , high sensitivity C-reactive Protein (hsCRP) ≤ 1 mg/dl and patient's global assessment of disease activity (PtGA) ≤ 10 . Simple Disease Activity Index based ACR/EULAR remission is achieved if a has SDAI ≤ 3.3 . The SDAI is the sum of the tender/painful joint count and swollen joint count, employing 28 joints; PtGA and PhGA (on a scale of 0-10); and hsCRP (mg/L). Percentage values are rounded off. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1190	1199		
Units: Percentage of participants				
number (not applicable)				
Boolean-based ACR/EULAR, Week 24, n=1190,1199	7.0	6.0		
Boolean-based ACR/EULAR, Week 48, n=719,715	8.0	4.0		
Boolean-based ACR/EULAR, Week 96, n=108,99	8.0	9.0		

Boolean-based ACR/EULAR, Week 144, n=0,1	0.0	0.0		
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Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving Disease Activity Score using 28 joint count and Erythrocyte Sedimentation Rate (ESR) <2.6 (DAS28-ESR Remission) at Week 24, 48, 96 and 132

End point title	Percentage of participants achieving Disease Activity Score using 28 joint count and Erythrocyte Sedimentation Rate (ESR) <2.6 (DAS28-ESR Remission) at Week 24, 48, 96 and 132
End point description:	
The DAS28-ESR is a measure of RA disease activity calculated using TJC28,SJC28, ESR (in mm/hr), Patient's Global Assessment of Arthritis Disease Activity (PtGA) (visual analogue scale with values from 0=best to 100=worst). PtGA is transformed to a 0-10 scale before computing the total score. DAS28-ESR scores range from 1.0 to 9.4, where lower scores indicate less disease activity. Remission is achieved when DAS28-ESR <2.6. A negative change from baseline in DAS28-ESR indicates an improvement. Percentage values are rounded off. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.	
End point type	Secondary
End point timeframe:	
Week 24, 48, 96 and 132	

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1084	1085		
Units: Percentage of participants				
number (not applicable)				
Week 24, n=1084,1085	15.0	14.0		
Week 48, n=676,672	14.0	13.0		
Week 96, n=95,91	16.0	12.0		
Week 132, n=1,3	0.0	33.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values for Clinical Disease Activity Index (CDAI) total score

End point title	Absolute Values for Clinical Disease Activity Index (CDAI) total score
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End point description:

CDAI total score is a composite score consisting of the sum of TJC28, SJC28, PtGA (visual analogue scale with values from 0=best to 100=worst) and PhGA (visual analogue scale with values from 0=best to 100=worst). PtGA and PhGA are transformed to a 0-10 scale before computing the CDAI total score. CDAI total score ranges from 0 to 76 with higher values representing higher disease activity. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1206 ^[37]	1212 ^[38]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24, n=1206,1212	13.42 (± 10.669)	14.26 (± 11.637)		
Week 48, n=757,749	13.85 (± 10.612)	14.07 (± 11.186)		
Week 96, n=124,112	14.62 (± 11.443)	15.22 (± 13.997)		
Week 144, n=0,1	0 (± 0)	11.30 (± 0.0)		

Notes:

[37] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[38] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values for Disease Activity Score using 28 joint count and C-Reactive Protein (DAS28-CRP)

End point title	Absolute Values for Disease Activity Score using 28 joint count and C-Reactive Protein (DAS28-CRP)
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End point description:

The DAS28-CRP is a measure of RA disease activity calculated using Tender Joint Count 28 (TJC28), Swollen Joint Count 28 (SJC28), C-reactive protein (CRP) (in mg/L), Patient's Global Assessment of Arthritis Disease Activity (PtGA) (visual analogue scale with values from 0=best to 100=worst). PtGA is transformed to a 0-10 scale before computing the total score. DAS28- CRP scores range from 1.0 to 9.4, where lower scores indicate less disease activity. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1338 ^[39]	1199 ^[40]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24, n=1338,1199	3.49 (± 1.237)	3.55 (± 1.269)		
Week 48, n=719,715	3.51 (± 1.224)	3.54 (± 1.232)		
Week 96, n=108,99	3.44 (± 1.188)	3.52 (± 1.389)		
Week 144, n=0,1	0.0 (± 0.0)	3.21 (± 0.0)		

Notes:

[39] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[40] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values for Disease Activity Score using 28 joint count and Erythrocyte Sedimentation Rate (DAS28-ESR)

End point title	Absolute Values for Disease Activity Score using 28 joint count and Erythrocyte Sedimentation Rate (DAS28-ESR)
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End point description:

The DAS28-ESR is a measure of RA disease activity calculated using Tender Joint Count 28 (TJC28), Swollen Joint Count 28 (SJC28), Erythrocyte sedimentation rate (ESR) (in millimeter [mm]/hour[hr]), Patient's Global Assessment of Arthritis Disease Activity (PtGA) (visual analogue scale with values from 0=best to 100=worst). PtGA is transformed to a 0-10 scale before computing the total score. DAS28-ESR scores range from 1.0 to 9.4, where lower scores indicate less disease activity. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 132

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1084 ^[41]	1085		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24, n=1084,1085	3.97 (± 1.295)	4.01 (± 1.333)		
Week 48, n=676,672	4.02 (± 1.284)	4.05 (± 1.306)		
Week 96, n=95,91	3.92 (± 1.216)	4.04 (± 1.470)		
Week 132, n=1,3	3.77 (± 0)	4.26 (± 1.560)		

Notes:

[41] - At Week 132, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values of Van der Heijde modified total sharp scores (mTSS)

End point title	Absolute values of Van der Heijde modified total sharp scores (mTSS)
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End point description:

Van der Heijde mTSS is utilized for scoring radiographs of hands and feet in rheumatoid arthritis. This method includes 16 areas of erosions, and 15 areas for joint space narrowing (JSN) in each hand, and 6 areas for erosions and 6 areas JSN in each foot. The total mTSS score is the sum of erosion (maximum of 280) and JSN (maximum of 168) scores. The score ranges from 0 to 448 for mTSS with higher values representing higher disease activity. The analysis was performed on the ITT set that includes participants from qualifying studies 201790 and 201791 only who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24 and 48

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	46		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24, n=66,46	23.26 (± 34.191)	30.31 (± 40.236)		
Week 48, n=66,46	23.27 (± 33.953)	30.34 (± 40.432)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for Health Assessment Questionnaire Disability Index (HAQ-DI)

End point title	Absolute values for Health Assessment Questionnaire Disability Index (HAQ-DI)
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End point description:

The HAQ-DI includes 20 questions which assesses difficulty in performing activities of daily living. The questionnaire assesses eight domains of physical functioning: Dressing and Grooming, Hygiene, Arising, Reach, Eating, Grip, Walking, Common Daily Activities. The questions assess domain scores ranging from 0 "without any difficulty" to 3 "unable to do." Scores on each domain were summed and averaged to provide an overall score ranging from 0 to 3, where higher score reflected worse status and a lower score indicates better quality of life.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1228 ^[42]	1239 ^[43]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24, n=1228,1239	1.045 (± 0.6764)	1.060 (± 0.6849)		
Week 48, n=768,764	1.072 (± 0.6679)	1.096 (± 0.6691)		
Week 96, n=126,120	1.074 (± 0.6852)	1.156 (± 0.7582)		
Week 144, n=0,1	0 (± 0)	2.00 (± 0)		

Notes:

[42] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[43] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for Arthritis pain VAS

End point title	Absolute values for Arthritis pain VAS
End point description:	
For the Arthritis Pain VAS, participants assess the severity of their current arthritis pain using a continuous visual analogue scale (VAS) with anchors at "0" (no pain) and "100" (most severe pain). A negative change from baseline indicates an improvement. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.	
End point type	Secondary
End point timeframe:	
Week 24, 48, 96 and 144	

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1230 ^[44]	1239 ^[45]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24, n=1230,1239	34.6 (± 23.51)	36.6 (± 23.85)		
Week 48, n=768,765	37.0 (± 23.55)	36.0 (± 23.88)		
Week 96, n=127,119	39.3 (± 24.62)	38.1 (± 27.08)		
Week 144, n=0,1	0 (± 0)	26.0 (± 0)		

Notes:

[44] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[45] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values Short form (SF)-36 Mental Component Scores (MCS)

End point title	Absolute values Short form (SF)-36 Mental Component Scores (MCS)
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End point description:

SF-36 is health-related survey that assesses quality of life covering 8 domains: physical functioning, bodily pain, role limitations due to physical/emotional problems, general health, mental health (MH), social functioning (SF), vitality. Each of 8 domains is scored using average, 0-100; higher score represents better health. MCS was aggregated across the domains and scaled to T-score with mean of 50 and SD of 10; higher score represents better health. MCS is primarily derived from 4 domains (SF, vitality, MH, role-emotional) representing overall mental health. Quality Metric software was used for scoring. - The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1228 ^[46]	1237 ^[47]		
Units: T-score				
arithmetic mean (standard deviation)				
Week 24, n=1228,1237	49.14 (± 10.386)	49.44 (± 10.384)		
Week 48, n=768,764	49.54 (± 10.577)	49.70 (± 10.557)		
Week 96, n=126,119	48.66 (± 11.483)	49.75 (± 11.351)		
Week 144, n=0,1	0 (± 0)	42.55 (± 0)		

Notes:

[46] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[47] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values SF-36 domain scores

End point title	Absolute values SF-36 domain scores
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End point description:

SF-36 is a health-related survey that assesses quality of life covering 8 domains: physical functioning, bodily pain, role limitations due to physical and emotional problems, general health, mental health, social functioning, vitality. MCS consists of 4 domains (social functioning, vitality, mental health, and role-emotional domains) and PCS consists of 4 domains (physical functioning, role-physical, bodily pain and general health). The individual question items are first summed for each item under the various sections. Then, those domain scores are weighted to a scale between 0 to 100, where higher score represents better health. Quality Metric software was used for scoring for SF-36. The analysis was performed on ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on treatment the subject was randomized to. Number of subjects analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 24, 48, 96 and 144

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1228 ^[48]	1237 ^[49]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Bodily Pain at Week 24, n=1228,1237	54.49 (± 21.457)	53.83 (± 21.158)		
Bodily Pain at Week 48, n=768,764	52.22 (± 21.099)	52.94 (± 21.158)		
Bodily Pain at Week 96, n=126,119	49.90 (± 20.943)	51.11 (± 21.983)		
Bodily Pain at Week 144, n=0,1	0 (± 0)	41.00 (± 0)		
General Health at week 24, n=1228,1237	51.00 (± 18.744)	50.30 (± 17.980)		
General Health at week 48, n=768,764	50.35 (± 18.817)	49.44 (± 17.645)		
General Health at week 96, n=126,119	48.44 (± 20.029)	46.73 (± 18.543)		
General Health at week 144, n=0,1	0 (± 0)	45.00 (± 0)		
Mental Health at week 24, n=1228,1237	67.47 (± 19.387)	68.05 (± 19.150)		
Mental Health at week 48, n=768,764	67.64 (± 19.701)	67.97 (± 19.636)		
Mental Health at week 96, n=126,119	66.90 (± 20.860)	68.49 (± 20.217)		
Mental Health at week 144, n=0,1	0 (± 0)	50.00 (± 0)		
Physical Function at week 24, n=1228,1237	56.20 (± 25.644)	55.28 (± 25.615)		
Physical Function at week 48, n=768,764	54.23 (± 26.222)	53.98 (± 25.397)		
Physical Function at week 96, n=126,119	51.87 (± 25.735)	50.92 (± 26.175)		
Physical Function at week 144, n=0,1	0 (± 0)	35.00 (± 0)		
Role Emotional At week 24, n=1228,1237	74.79 (± 24.653)	75.09 (± 24.760)		
Role Emotional At week 48, n=768,764	75.31 (± 24.008)	76.18 (± 24.163)		
Role Emotional At week 96, n=126,119	73.35 (± 25.188)	74.44 (± 26.324)		
Role Emotional At week 144, n=0,1	0 (± 0)	50.00 (± 0)		
Role Physical at week 24, n=1228,1237	58.58 (± 23.155)	57.78 (± 23.514)		
Role Physical at week 48, n=768,764	56.49 (± 23.645)	57.57 (± 23.463)		
Role Physical at week 96, n=126,119	54.27 (± 23.818)	55.15 (± 24.956)		
Role Physical at week 144, n=0,1	0 (± 0)	25.00 (± 0)		
Social Function at week 24, n=1228,1237	71.20 (± 24.001)	71.39 (± 23.936)		
Social Function at week 48, n=768,764	70.88 (± 24.596)	71.29 (± 24.123)		
Social Function at week 96, n=126,119	68.25 (± 24.065)	69.43 (± 26.526)		
Social Function at week 144, n=0,1	0 (± 0)	62.50 (± 0)		

Vitality at week 24, n=1228,1237	55.77 (± 20.690)	55.18 (± 20.593)		
Vitality at week 48, n=768,764	55.24 (± 20.972)	54.49 (± 21.262)		
Vitality at week 96, n=126,119	51.04 (± 23.127)	54.25 (± 22.738)		
Vitality at week 144, n=0,1	0 (± 0)	50.00 (± 0)		

Notes:

[48] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[49] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values SF-36 Physical Component Scores (PCS)

End point title	Absolute values SF-36 Physical Component Scores (PCS)
End point description:	
SF-36 is health-related survey that assesses quality of life covering 8 domains:physical functioning(PF),bodily pain(BP),role limitations due to physical/emotional problems,general health(GH),mental health,social functioning,vitality.Each of 8 domains is scored using average, 0-100; higher score represents better health.PCS was aggregated across the domains and scaled to T-score with mean of 50 and SD of 10; higher score represents better health.PCS is primarily derived from 4 domains(PF,role-physical,BP,GH) representing overall physical health. Quality Metric software was used for scoring. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for	
End point type	Secondary
End point timeframe:	
Week 24, 48, 96 and 144	

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1228 ^[50]	1237 ^[51]		
Units: T-Score				
arithmetic mean (standard deviation)				
Week 24, n=1228,1237	41.19 (± 8.173)	40.67 (± 8.232)		
Week 48, n=768,764	40.17 (± 8.586)	40.13 (± 8.271)		
Week 96, n=126,119	39.18 (± 9.280)	38.86 (± 8.879)		
Week 144, n=0,1	0 (± 0)	35.03 (± 0)		

Notes:

[50] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[51] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values Functional assessment of chronic illness therapy (FACIT)-Fatigue

End point title	Absolute values Functional assessment of chronic illness therapy (FACIT)-Fatigue
End point description: The Functional Assessment of Chronic Illness Therapy (FACIT)-fatigue is a validated patient-reported measure of 13 statements regarding the feeling of fatigue. The total score ranges from 0 to 52 with higher values representing a lower fatigue and a better quality of life. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.	
End point type	Secondary
End point timeframe: Week 24, 48, 96 and 144	

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1229 ^[52]	1238 ^[53]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24, n=1229,1238	36.0 (± 10.33)	35.9 (± 10.25)		
Week 48, n=767,764	35.5 (± 10.53)	35.4 (± 10.59)		
Week 96, n=126,119	35.2 (± 10.77)	34.8 (± 11.87)		
Week 144, n=0,1	0 (± 0)	26.0 (± 0)		

Notes:

[52] - At Week 144, there were 0 participant analyzed, there is no data to disclose.

[53] - At Week 144, as only single participant was analyzed the standard deviation was be derived.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with anti-GSK3196165 antibodies

End point title	Number of participants with anti-GSK3196165 antibodies
End point description: Serum samples were collected for the determination of anti- GSK3196165 antibodies (ADA) using a validated electrochemiluminescence (ECL) immunoassay. The assay involved screening, confirmation and titration steps. If serum samples tested positive in the screening assay, they were considered 'potentially positive' and were further analyzed for the specificity using the confirmation assay. Samples that confirmed positive in the confirmation assay were reported as 'positive'. Confirmed positive ADA samples were further characterized in the titration assay to quasi-quantitate the amount of ADA in the sample. Additionally, confirmed positive ADA samples were also tested in a validated neutralizing antibody assay to determine the potential neutralizing activity of the ADA. The analysis was performed on the ITT set that includes all randomized participants who received at least one dose of study treatment. This population was based on the treatment the subject was randomized to.	
End point type	Secondary
End point timeframe: Week 120	

End point values	Otilimab 90 mg	Otilimab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1456	1459		
Units: Participants	11	10		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AE and SAE were collected from the start of the study intervention. Initially the study was planned for 4 years approx. 208 weeks however due to early termination by sponsor data for all Adverse event was collected up to approximately 145 weeks only.

Assessment type	Systematic
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Dictionary used

Dictionary name	Medra
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Dictionary version	25.0
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Reporting groups

Reporting group title	Otilimab 150 mg
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Reporting group description:

Participants received 150mg Otilimab prior to this study 209564 and received either tofacitinib (study 201790 or 201791) or sarilumab (study 202018) in the qualifying studies and were exposed for the first time to Otilimab through subcutaneous (SC) injection once weekly.

Reporting group title	Otilimab 90 mg
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Reporting group description:

Participants received 90mg Otilimab prior to this study 209564 and received either tofacitinib (study 201790 or 201791) or sarilumab (study 202018) in the qualifying studies and were exposed for the first time to Otilimab through subcutaneous (SC) injection once weekly.

Serious adverse events	Otilimab 150 mg	Otilimab 90 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	114 / 1459 (7.81%)	123 / 1456 (8.45%)	
number of deaths (all causes)	9	10	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of appendix			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Adenocarcinoma pancreas			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Anogenital warts			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoproliferative disorder			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer stage III			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neoplasm			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neuroendocrine tumour			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the cervix			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			

subjects affected / exposed	1 / 1459 (0.07%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary-mucinous carcinoma of pancreas			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic vein thrombosis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	2 / 1459 (0.14%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein thrombosis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

Asthenia	subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
	occurrences causally related to treatment / all	0 / 0	0 / 1	
	deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia	subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
	occurrences causally related to treatment / all	0 / 0	0 / 1	
	deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome	subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
	occurrences causally related to treatment / all	0 / 1	0 / 0	
	deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia	subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
	occurrences causally related to treatment / all	0 / 0	0 / 2	
	deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death	subjects affected / exposed	1 / 1459 (0.07%)	2 / 1456 (0.14%)	
	occurrences causally related to treatment / all	0 / 1	0 / 2	
	deaths causally related to treatment / all	0 / 1	0 / 2	
Reproductive system and breast disorders				
Cystocele	subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
	occurrences causally related to treatment / all	0 / 1	0 / 0	
	deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexal torsion	subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
	occurrences causally related to treatment / all	0 / 0	0 / 1	
	deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia	subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
	occurrences causally related to treatment / all	0 / 0	0 / 1	
	deaths causally related to treatment / all	0 / 0	0 / 0	

Endometrial hyperplasia			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menstrual disorder			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cyst			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Acute respiratory failure			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal ulceration			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	3 / 1459 (0.21%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			

Generalised anxiety disorder			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient psychosis			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device physical property issue			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental poisoning			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acetabulum fracture			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns first degree			

subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dislocation of vertebra			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	3 / 1459 (0.21%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	3 / 1459 (0.21%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament injury			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic osteolysis			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	3 / 1459 (0.21%)	3 / 1456 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	2 / 1459 (0.14%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myocardial infarction			
subjects affected / exposed	2 / 1459 (0.14%)	3 / 1456 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Atrial fibrillation			
subjects affected / exposed	1 / 1459 (0.07%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			

subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	3 / 1459 (0.21%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			

subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilia			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Meniere's disease			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinal artery occlusion			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	2 / 1459 (0.14%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jejunal perforation			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flatulence			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal rupture			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Omental haemorrhage			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 1459 (0.14%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 1459 (0.07%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	2 / 1459 (0.14%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intervertebral disc degeneration			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint destruction			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	8 / 1459 (0.55%)	6 / 1456 (0.41%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			

subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	4 / 1459 (0.27%)	7 / 1456 (0.48%)	
occurrences causally related to treatment / all	1 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	2 / 1459 (0.14%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess bacterial			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic infection			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			

subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	10 / 1459 (0.69%)	8 / 1456 (0.55%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 1	
Cellulitis			
subjects affected / exposed	0 / 1459 (0.00%)	3 / 1456 (0.21%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter bacteraemia			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster disseminated			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Latent tuberculosis			
subjects affected / exposed	1 / 1459 (0.07%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 1459 (0.14%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	5 / 1459 (0.34%)	5 / 1456 (0.34%)	
occurrences causally related to treatment / all	2 / 5	2 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19			
subjects affected / exposed	1 / 1459 (0.07%)	4 / 1456 (0.27%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	2 / 1459 (0.14%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subcutaneous abscess			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubo-ovarian abscess			
subjects affected / exposed	1 / 1459 (0.07%)	0 / 1456 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 1459 (0.00%)	2 / 1456 (0.14%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral sinusitis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 1459 (0.00%)	1 / 1456 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Otilimab 150 mg	Otilimab 90 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	308 / 1459 (21.11%)	279 / 1456 (19.16%)	
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
subjects affected / exposed	129 / 1459 (8.84%)	118 / 1456 (8.10%)	
occurrences (all)	175	158	
Infections and infestations			
COVID-19			
subjects affected / exposed	141 / 1459 (9.66%)	141 / 1456 (9.68%)	
occurrences (all)	148	153	
Upper respiratory tract infection			
subjects affected / exposed	88 / 1459 (6.03%)	65 / 1456 (4.46%)	
occurrences (all)	100	74	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported