Clinical trial results:
Phase 3, Multicenter, Randomized, Double-blinded, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Intravenous MLN0002 (300 mg) Infusion in Induction and Maintenance Therapy in Japanese Subjects with Moderate or Severe Ulcerative Colitis

Summary

EudraCT number	2019-001198-10
Trial protocol	Outside EU/EEA
Global end of trial date	28 June 2018

Results information

Result version number	v1 (current)
This version publication date	16 June 2019
First version publication date	16 June 2019

Trial information

Trial identification

Sponsor protocol code	MLN0002/CCT-101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02039505
WHO universal trial number (UTN)	U1111-1151-6762
Other trial identifiers	JapicCTI: JapicCTI-142403

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	1-1, Doshomachi 4-chome, Chuo-ku, Osaka-shi, Osaka, Japan, 540-8645
Public contact	Medical Director, Takeda, +1877 8253327, trialdisclosures@takeda.com
Scientific contact	Medical Director, Takeda, +1877 8253327, trialdisclosures@takeda.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 October 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 February 2018
Global end of trial reached?	Yes
Global end of trial date	28 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the trial is to examine the efficacy, safety, and pharmacokinetics of intravenous Vedolizumab (300 mg) infusion in induction and maintenance therapy in Japanese patients with moderately or severely active ulcerative colitis (UC).

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 February 2014
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	Japan: 292
Worldwide total number of subjects	292
EEA total number of subjects	0

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)	4
Adults (18-64 years)	288
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 86 investigative sites in Japan from 04 February 2014 to 28 June 2018.

Pre-assignment

Screening details:

Participants with moderate to severe UC were enrolled. 292 participants enrolled in induction phase, 109 participants entered maintenance phase and 259 participants entered open-label cohort and received placebo or vedolizumab 300 mg and 188 completed. Open-label cohort occurred between Week 10 and Week 154 through study with maximum of 94 weeks.

Period 1

Period 1 title	Induction Phase (Week 0 to Week 14)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Induction Phase: Cohort 1, Placebo

Arm description:

Vedolizumab placebo-matching, intravenous (IV) infusion, once at Weeks 0, 2 and 6 in the induction phase.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab-matching placebo on Weeks 2, 4 and 6.

Arm title	Induction Phase: Cohort 1, Vedolizumab 300 mg

Arm description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2, and 6 in the induction phase.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab 300 mg IV infusion on Weeks 2, 4 and 6

Arm title	Induction Phase: Cohort 2, Vedolizumab 300 mg

Arm description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 in the induction phase.

Arm type	Experimental

Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab 300 mg IV infusion on Weeks 2, 4 and 6

Number of subjects in period 1	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg
Started	82	164	46
Completed	78	155	36
Not completed	4	9	10
Pretreatment Event/Adverse Event	2	8	7
Major Protocol Deviation	1	-	-
Lack of efficacy	1	1	3

Period 2

Period 2 title	Intermediate Induction Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Induction Phase: Cohort 1, Placebo

Arm description:

Vedolizumab placebo-matching, intravenous (IV) infusion, once at Weeks 0, 2 and 6 in the induction phase.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Induction Phase: Cohort 1, Vedolizumab 300 mg

Arm description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2, and 6 in the induction phase.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Induction Phase: Cohort 2, Vedolizumab 300 mg

Arm description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 in the induction phase.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg
Started	78	155	36
Completed	42	41	26
Not completed	36	114	10
Did not achieve clinical response	36	114	10

Period 3

Period 3 title	Maintenance Phase (Week 14 to Week 60)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Maintenance Phase: Placebo

Arm description:

Vedolizumab placebo-matching, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab in induction phase and achieved clinical response at Week 10 and were randomized to receive placebo in maintenance phase.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Matching placebo on Week 2, 4 and 6.

Arm title	Maintenance Phase: Vedolizumab 300 mg

Arm description:

Vedolizumab 300 mg, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab in induction phase and achieved clinical response at Week 10 and were randomized to receive vedolizumab in maintenance phase.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab 300 mg IV infusion on Weeks 2, 4 and 6

Arm title	Maintenance Phase: Placebo continuation

Arm description:

Vedolizumab placebo-matching, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab placebo-matching in induction phase and achieved clinical response at Week 10 received placebo in maintenance phase without randomization.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Matching placebo on Week 2, 4 and 6.

Number of subjects in period 3	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg	Maintenance Phase: Placebo continuation
Started	42	41	26
Completed	18	30	12
Not completed	24	11	14
Pretreatment Event/Adverse Event	6	1	1
Voluntary Withdrawal	3	2	1
Pregnancy	2	-	-
Lack of efficacy	13	8	12

Baseline characteristics

Reporting groups	
Reporting group title	Induction Phase: Cohort 1, Placebo
Reporting group description:	
Vedolizumab placebo-matching, intravenous (IV) infusion, once at Weeks 0, 2 and 6 in the induction phase.	
Reporting group title	Induction Phase: Cohort 1, Vedolizumab 300 mg
Reporting group description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2, and 6 in the induction phase.	
Reporting group title	Induction Phase: Cohort 2, Vedolizumab 300 mg
Reporting group description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 in the induction phase.	

Reporting group values	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg
Number of subjects	82	164	46
Age categorical			
Units: Subjects			
Age Continuous			
Units: years			
arithmetic mean	44.0	42.3	42.4
standard deviation	± 15.97	± 14.42	± 15.60
Sex: Female, Male			
Units: Subjects			
Female	27	65	20
Male	55	99	26
Smoking Classification			
Units: Subjects			
Never smoked	44	85	23
Current smoker	3	9	5
Ex-smoker	35	70	18
Disease Localization			
Units: Subjects			
Total Colitis	51	101	32
Left-sided Colitis	31	63	14
Extraintestinal Manifestations			
Units: Subjects			
Had No Extraintestinal Manifestations	66	111	32
Had Extraintestinal Manifestations	16	53	14
Region of Enrollment			
Units: Subjects			
Japan	82	164	46
Weight			
99999: Data was not analyzed for the subject analysis set.			
Units: kg			

arithmetic mean	60.36	58.58	57.74
standard deviation	± 12.411	± 11.640	± 10.559
Body Mass Index (BMI)			
Body Mass Index = weight(kg)/[height(m)^2]. 99999: Data was not analyzed for the subject analysis set.			
Units: kg/m^2			
arithmetic mean	21.76	21.72	21.12
standard deviation	± 3.660	± 3.411	± 2.714
Duration of Ulcerative Colitis (UC)			
Mean duration between the first diagnosis of ulcerative colitis and the start of the study was reported. 99999: Data was not analyzed for the subject analysis set.			
Units: years			
arithmetic mean	8.57	7.23	9.19
standard deviation	± 7.973	± 6.230	± 7.725
Complete Mayo Score			
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). 99999: Data was not analyzed for the subject analysis set.			
Units: score on a scale			
arithmetic mean	8.1	8.3	8.3
standard deviation	± 1.50	± 1.54	± 1.66

Reporting group values	Total		
Number of subjects	292		
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: Subjects			
Female	112		
Male	180		
Smoking Classification			
Units: Subjects			
Never smoked	152		
Current smoker	17		
Ex-smoker	123		
Disease Localization			
Units: Subjects			
Total Colitis	184		
Left-sided Colitis	108		
Extraintestinal Manifestations			
Units: Subjects			
Had No Extraintestinal Manifestations	209		
Had Extraintestinal Manifestations	83		
Region of Enrollment			
Units: Subjects			

Japan	292		

Weight			
99999: Data was not analyzed for the subject analysis set.			
Units: kg arithmetic mean standard deviation	- -		
Body Mass Index (BMI)			
Body Mass Index = weight(kg)/[height(m)^2]. 99999: Data was not analyzed for the subject analysis set.			
Units: kg/m^2 arithmetic mean standard deviation	- -		
Duration of Ulcerative Colitis (UC)			
Mean duration between the first diagnosis of ulcerative colitis and the start of the study was reported. 99999: Data was not analyzed for the subject analysis set.			
Units: years arithmetic mean standard deviation	- -		
Complete Mayo Score			
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). 99999: Data was not analyzed for the subject analysis set.			
Units: score on a scale arithmetic mean standard deviation	- -		

Subject analysis sets

Subject analysis set title	Open-Label Cohort: Vedolizumab 300 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 and then every 8 weeks thereafter up to Week 94 in open-label cohort.

Reporting group values	Open-Label Cohort: Vedolizumab 300 mg		
Number of subjects	259		
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	 ±		
Sex: Female, Male Units: Subjects			
Female Male			

Smoking Classification Units: Subjects			
Never smoked Current smoker Ex-smoker			
Disease Localization Units: Subjects			
Total Colitis Left-sided Colitis			
Extraintestinal Manifestations Units: Subjects			
Had No Extraintestinal Manifestations Had Extraintestinal Manifestations			
Region of Enrollment Units: Subjects			
Japan			
Weight			
99999: Data was not analyzed for the subject analysis set.			
Units: kg arithmetic mean standard deviation	 99999 ± 99999		
Body Mass Index (BMI)			
Body Mass Index = weight(kg)/[height(m)^2]. 99999: Data was not analyzed for the subject analysis set.			
Units: kg/m^2 arithmetic mean standard deviation	 99999 ± 99999		
Duration of Ulcerative Colitis (UC)			
Mean duration between the first diagnosis of ulcerative colitis and the start of the study was reported. 99999: Data was not analyzed for the subject analysis set.			
Units: years arithmetic mean standard deviation	 99999 ± 99999		
Complete Mayo Score			
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). 99999: Data was not analyzed for the subject analysis set.			
Units: score on a scale arithmetic mean standard deviation	 99999 ± 99999		

End points

End points reporting groups

Reporting group title	Induction Phase: Cohort 1, Placebo
Reporting group description:	
Vedolizumab placebo-matching, intravenous (IV) infusion, once at Weeks 0, 2 and 6 in the induction phase.	
Reporting group title	Induction Phase: Cohort 1, Vedolizumab 300 mg
Reporting group description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2, and 6 in the induction phase.	
Reporting group title	Induction Phase: Cohort 2, Vedolizumab 300 mg
Reporting group description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 in the induction phase.	
Reporting group title	Induction Phase: Cohort 1, Placebo
Reporting group description:	
Vedolizumab placebo-matching, intravenous (IV) infusion, once at Weeks 0, 2 and 6 in the induction phase.	
Reporting group title	Induction Phase: Cohort 1, Vedolizumab 300 mg
Reporting group description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2, and 6 in the induction phase.	
Reporting group title	Induction Phase: Cohort 2, Vedolizumab 300 mg
Reporting group description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 in the induction phase.	
Reporting group title	Maintenance Phase: Placebo
Reporting group description:	
Vedolizumab placebo-matching, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab in induction phase and achieved clinical response at Week 10 and were randomized to receive placebo in maintenance phase.	
Reporting group title	Maintenance Phase: Vedolizumab 300 mg
Reporting group description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab in induction phase and achieved clinical response at Week 10 and were randomized to receive vedolizumab in maintenance phase.	
Reporting group title	Maintenance Phase: Placebo continuation
Reporting group description:	
Vedolizumab placebo-matching, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab placebo-matching in induction phase and achieved clinical response at Week 10 received placebo in maintenance phase without randomization.	
Subject analysis set title	Open-Label Cohort: Vedolizumab 300 mg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 and then every 8 weeks thereafter up to Week 94 in open-label cohort.	

Primary: Percentage of Participants with a Clinical Response at Week 10 in Induction Phase

End point title	Percentage of Participants with a Clinical Response at Week 10 in Induction Phase[1]
End point description:	
Clinical response is defined as a reduction in complete Mayo score of ≥3 points and ≥30% from Baseline with an accompanying decrease in rectal bleeding subscore of ≥1 point or absolute rectal bleeding subscore of ≤1 point. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores (rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment), a global assessment by the physician, and an endoscopic subscore. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score	

ranges from 0 to 12 (higher scores indicate greater disease activity). Full analysis set (FAS) included participants who were randomized and received at least one dose of the study drug in the induction phase. The FAS in the induction phase does not include participants allocated in the Cohort 2 in the induction phase.

End point type	Primary

End point timeframe:

Week 10

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was performed only in the Induction Phase.

End point values	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	164		
Units: percentage of participants				
number (confidence interval 95%)	32.9 (22.942 to 44.186)	39.6 (32.093 to 47.557)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Phase: Cohort 1, Vedolizumab 300 mg v Induction Phase: Cohort 1, Placebo
Number of subjects included in analysis	246
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2722 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	1.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.779
upper limit	2.399

Notes:

[2] - Cochran-Mantel-Haenszel (CMH) test was used for analysis. Prior tumor necrosis factor alpha (TNFα) antagonist use (yes/no) was used as stratification factor.

Primary: Percentage of Participants with Clinical Remission at Week 60 in Maintenance Phase

End point title	Percentage of Participants with Clinical Remission at Week 60 in Maintenance Phase

End point description:

Clinical Remission is defined as a complete Mayo score of ≤2 points and no individual subscore >1 point. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). FAS included participants who were randomized and received at least one dose of the study drug in the maintenance phase. The FAS in the maintenance phase does not include participants who received placebo in the induction phase

and were enrolled into the maintenance phase.

End point type	Primary

End point timeframe:

Week 60

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: percentage of participants				
number (confidence interval 95%)	31.0 (17.622 to 47.086)	56.1 (39.750 to 71.531)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase: Placebo v Maintenance Phase: Vedolizumab 300 mg
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.021 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	2.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.168
upper limit	7.108

Notes:

[3] - CMH test was used for analysis. Prior TNFα antagonist use (yes/no) was used as stratification factor.

Primary: Number of Participants Who Experienced at Least One or More Treatment-Emergent Adverse Events (TEAEs)

End point title	Number of Participants Who Experienced at Least One or More Treatment-Emergent Adverse Events (TEAEs)[4]

End point description:

An Adverse Event (AE) is defined as any untoward medical occurrence in a clinical investigation participant administered a drug; it does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (e.g., a clinically significant abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, whether or not it is considered related to the drug. A treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset that occurs after receiving study drug. Safety analysis set included participants who received at least one dose of the study drug in either the induction phase, the maintenance phase or the open-label cohort.

End point type	Primary

End point timeframe:

From Baseline to 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

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: Statistical analyses were not planned for this endpoint.

End point values	Induction Phase: Cohort 1, Placebo	Maintenance Phase: Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Maintenance Phase: Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	42	164	41
Units: participants	43	33	82	36

End point values	Induction Phase: Cohort 2, Vedolizumab 300 mg	Maintenance Phase: Placebo continuation	Open-Label Cohort: Vedolizumab 300 mg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	46	26	259	
Units: participants	33	18	241	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with TEAE Related to Body Weight

End point title	Number of Participants with TEAE Related to Body Weight[5]

End point description:

Safety analysis set included participants who received at least one dose of the study drug in either the induction phase, the maintenance phase or the open-label cohort.

End point type	Primary

End point timeframe:

From Baseline to 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

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: Statistical analyses were not planned for this endpoint.

End point values	Induction Phase: Cohort 1, Placebo	Maintenance Phase: Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Maintenance Phase: Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	42	164	41
Units: participants	0	0	0	0

End point values	Induction Phase: Cohort 2, Vedolizumab 300 mg	Maintenance Phase: Placebo continuation	Open-Label Cohort: Vedolizumab 300 mg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	46	26	259	
Units: participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with TEAE Related to Vital Signs

End point title	Number of Participants with TEAE Related to Vital Signs[6]

End point description:

Vital signs included body temperature (axilla), sitting blood pressure (after the participant has rested for at least 5 minutes), and pulse (bpm). Safety analysis set included participants who received at least one dose of the study drug in either the induction phase, the maintenance phase or the open-label cohort.

End point type	Primary

End point timeframe:

From Baseline to 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

Notes:

[6] - 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: Statistical analyses were not planned for this endpoint.

End point values	Induction Phase: Cohort 1, Placebo	Maintenance Phase: Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Maintenance Phase: Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	42	164	41
Units: participants	2	2	5	2

End point values	Induction Phase: Cohort 2, Vedolizumab 300 mg	Maintenance Phase: Placebo continuation	Open-Label Cohort: Vedolizumab 300 mg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	46	26	259	
Units: participants	3	0	24	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with TEAE Related to Electrocardiogram (ECG)

End point title	Number of Participants with TEAE Related to Electrocardiogram

	(ECG)[7]

End point description:

Safety analysis set included participants who received at least one dose of the study drug in either the induction phase, the maintenance phase or the open-label cohort.

End point type	Primary

End point timeframe:

From Baseline to 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

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: Statistical analyses were not planned for this endpoint.

End point values	Induction Phase: Cohort 1, Placebo	Maintenance Phase: Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Maintenance Phase: Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	42	164	41
Units: participants	1	0	1	0

End point values	Induction Phase: Cohort 2, Vedolizumab 300 mg	Maintenance Phase: Placebo continuation	Open-Label Cohort: Vedolizumab 300 mg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	46	26	259	
Units: participants	0	1	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Markedly Abnormal Laboratory Parameters Values

End point title	Number of Participants with Markedly Abnormal Laboratory Parameters Values[8]

End point description:

The laboratory values outside the range (Hemoglobin <=7 g/dL, Lymphocytes <500 /µL, WBC <2000 /µL, Platelets <7.5 10^4/µL, Neutrophils <1000 /µL, alanine aminotransferase (ALT) >3.0 U/L x upper limit of normal (ULN), aspartate aminotransferase AST >3.0 U/L x ULN, Total Bilirubin >2.0 mg/dL x ULN, Amylase >2.0 (U/L) x ULN were considered markedly abnormal. Safety analysis set included participants who received at least one dose of the study drug in either the induction phase, the maintenance phase or the open-label cohort.

End point type	Primary

End point timeframe:

From Baseline to 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

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: Statistical analyses were not planned for this endpoint.

End point values	Induction Phase: Cohort 1, Placebo	Maintenance Phase: Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Maintenance Phase: Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	42	164	41
Units: participants				
Hemoglobin (g/dL) <=7	1	0	4	0
Lymphocytes (/µL) <500	6	1	2	0
White Blood Cell (WBC) (/µL) <2000	0	0	0	0
Neutrophils (/µL) <1000	1	1	1	0
Alanine Aminotransferase (ALT) (U/L) >3.0 x ULN	1	1	0	0
Aspartate Aminotransferase (AST) (U/L) >3.0 x ULN	1	1	0	0
Total Bilirubin (mg/dL) >2.0 x ULN	0	0	2	0
Amylase (U/L) >2.0 x ULN	1	0	2	0

End point values	Induction Phase: Cohort 2, Vedolizumab 300 mg	Maintenance Phase: Placebo continuation	Open-Label Cohort: Vedolizumab 300 mg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	46	26	259	
Units: participants				
Hemoglobin (g/dL) <=7	1	0	6	
Lymphocytes (/µL) <500	2	1	20	
White Blood Cell (WBC) (/µL) <2000	1	0	0	
Neutrophils (/µL) <1000	1	0	4	
Alanine Aminotransferase (ALT) (U/L) >3.0 x ULN	0	0	4	
Aspartate Aminotransferase (AST) (U/L) >3.0 x ULN	0	0	2	
Total Bilirubin (mg/dL) >2.0 x ULN	0	0	1	
Amylase (U/L) >2.0 x ULN	1	0	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Clinical Remission at Week 10 in Induction Phase

End point title	Percentage of Participants with Clinical Remission at Week 10 in Induction Phase[9]

End point description:

Clinical Remission is defined as a complete Mayo score of ≤2 points and no individual subscore >1 point. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). FAS included participants who were randomized and received at least one dose of the study drug in the induction phase. The FAS in the induction phase does not include participants allocated in the Cohort 2 in the induction phase.

End point type	Secondary

End point timeframe:

Week 10

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was performed only in the Induction Phase.

End point values	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	164		
Units: percentage of participants				
number (confidence interval 95%)	12.2 (6.006 to 21.286)	18.3 (12.695 to 25.072)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Phase: Cohort 1, Placebo v Induction Phase: Cohort 1, Vedolizumab 300 mg
Number of subjects included in analysis	246
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.198 [10]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	1.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.762
upper limit	3.596

Notes:

[10] - CMH test was used for analysis. Prior TNFα antagonist use (yes/no) was used as stratification factor.

Secondary: Percentage of Participants with Mucosal Healing at Week 10 in Induction Phase

End point title	Percentage of Participants with Mucosal Healing at Week 10 in Induction Phase[11]

End point description:

Mucosal healing is defined as a Mayo endoscopic subscore of ≤1 point. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Endoscopic findings were scored on a scale from 0 to 3 as follows: 0=Normal or inactive disease; 1=Mild disease (erythema, decreased vascular pattern, mild friability); 2=Moderate disease (marked erythema, lack of vascular pattern, friability, erosions); 3=Severe disease (spontaneous bleeding, ulceration). FAS included participants who were randomized and received at least one dose of the study drug in the induction phase. The FAS in the induction phase does not include participants allocated in the Cohort 2 in the induction phase.

End point type	Secondary

End point timeframe:

Week 10

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was performed only in the Induction Phase.

End point values	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	164		
Units: percentage of participants				
number (confidence interval 95%)	30.5 (20.796 to 41.638)	36.6 (29.213 to 44.452)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Phase: Cohort 1, Placebo v Induction Phase: Cohort 1, Vedolizumab 300 mg
Number of subjects included in analysis	246
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3168 [12]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.755
upper limit	2.356

Notes:

[12] - CMH test was used for analysis. Prior TNFα antagonist use (yes/no) was used as stratification factor.

Secondary: Percentage of Participants with Durable Clinical Response in Maintenance Phase

End point title	Percentage of Participants with Durable Clinical Response in Maintenance Phase

End point description:

Durable clinical response is defined as reduction in complete Mayo score of ≥3 points and ≥30% from Baseline (Week 0) with an accompanying decrease in rectal bleeding subscore of ≥1 point or absolute rectal bleeding subscore of ≤1 point at both Weeks 10 and 60. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). FAS included participants who were randomized and received at least one dose of the study drug in the maintenance phase. The FAS in the maintenance phase does not include participants who received placebo in the induction phase and were enrolled into the maintenance phase.

End point type	Secondary

End point timeframe:

Weeks 10 and 60

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: percentage of participants				
number (confidence interval 95%)	35.7 (21.551 to 51.974)	65.9 (49.405 to 79.917)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase: Placebo v Maintenance Phase: Vedolizumab 300 mg
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0067 [13]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	3.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.407
upper limit	8.626

Notes:

[13] - CMH test was used for analysis. Prior TNFα antagonist use (yes/no) was used as stratification factor.

Secondary: Percentage of Participants with Mucosal Healing at Week 60 in Maintenance Phase

End point title	Percentage of Participants with Mucosal Healing at Week 60 in Maintenance Phase

End point description:

Mucosal healing is defined as a Mayo endoscopic subscore of ≤1 point. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Endoscopic findings were scored on a scale from 0 to 3 as follows: 0=Normal or inactive disease; 1=Mild disease (erythema, decreased vascular pattern, mild friability); 2=Moderate disease (marked erythema, lack of vascular pattern, friability, erosions); 3=Severe disease (spontaneous bleeding, ulceration). FAS included participants who were randomized and received at least one dose of the study drug in the maintenance phase. The FAS in the maintenance phase does not include participants who received placebo in the induction phase and were enrolled into the maintenance phase.

End point type	Secondary

End point timeframe:

Week 60

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: percentage of participants				
number (confidence interval 95%)	33.3 (19.567 to 49.549)	63.4 (46.936 to 77.877)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase: Placebo v Maintenance Phase: Vedolizumab 300 mg
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0066
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	3.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.409
upper limit	8.642

Secondary: Percentage of Participants with Durable Remission in Maintenance Phase

End point title	Percentage of Participants with Durable Remission in Maintenance Phase

End point description:

Durable clinical remission is defined as complete Mayo score of ≤2 points and no individual subscore >1 point at both Weeks 10 and 60. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). FAS included participants who were randomized and received at least one dose of the study drug in the maintenance phase. The FAS in the maintenance phase does not include participants who received placebo in the induction phase and were enrolled into the maintenance phase.

End point type	Secondary

End point timeframe:

Weeks 10 and 60

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: percentage of participants				
number (confidence interval 95%)	16.7 (6.974 to 31.364)	26.8 (14.221 to 42.944)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase: Placebo v Maintenance Phase: Vedolizumab 300 mg
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.209 [14]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	2.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.677
upper limit	6.033

Notes:

[14] - CMH test was used for analysis. Prior TNFα antagonist use (yes/no) was used as stratification factor.

Secondary: Percentage of Participants with Corticosteroid-Free Remission at Week 60 in Maintenance Phase

End point title	Percentage of Participants with Corticosteroid-Free Remission at Week 60 in Maintenance Phase

End point description:

Clinical Remission is defined as a complete Mayo score of ≤2 points and no individual subscore >1 point. Corticosteroid-free clinical remission is defined as participants using oral corticosteroids at baseline (Week 0) who discontinued corticosteroids and were in clinical remission at Week 60. Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 subscores: rectal bleeding, stool frequency, findings on endoscopy, and physician's global assessment. Each subscore is scored on a scale from 0 to 3 and the complete Mayo score ranges from 0 to 12 (higher scores indicate greater disease activity). Participants from FAS included participants who were randomized and received at least one dose of the study drug in the maintenance phase and administered oral corticosteroids concomitantly at Week 0, were analyzed at the given timepoint.

End point type	Secondary

End point timeframe:

Week 60

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	13		
Units: percentage of participants				
number (confidence interval 95%)	20.0 (4.331 to 48.089)	46.2 (19.223 to 74.865)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase: Placebo v Maintenance Phase: Vedolizumab 300 mg
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1571 [15]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted Odds Ratio
Point estimate	3.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.636
upper limit	17.981

Notes:

[15] - CMH test was used for analysis. Prior TNFα antagonist use (yes/no) was used as stratification factor.

Secondary: Serum Vedolizumab Concentration in Induction Phase

End point title	Serum Vedolizumab Concentration in Induction Phase[16]

End point description:

Participants from FAS, who received at least one dose of study drug in induction phase for whom sample was available for pharmacokinetic (PK) analysis. n=number of participants with evaluable data at the given time-point.

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 2, 6, 10 and 14

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was performed only in the Induction Phase.

End point values	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	46		
Units: µg/mL				
arithmetic mean (standard deviation)				
Week 2 (n=104, 31)	31.93 (± 9.0617)	33.96 (± 7.7002)		
Week 6 (n=96, 28)	29.58 (± 12.965)	31.53 (± 12.937)		
Week 10 (n=110, 29)	31.42 (± 14.462)	36.63 (± 16.058)		
Week 14 (n=45, 12)	16.09 (± 7.3624)	19.04 (± 6.6528)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Vedolizumab Concentration in Maintenance Phase

End point title	Serum Vedolizumab Concentration in Maintenance Phase

End point description:

Participants from FAS, who were randomized and received at least one dose of the study drug in the maintenance phase for whom sample was available for PK analysis. n=number of participants with evaluable data at the given time-point.

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 2, 6, 10, 14, 22, 30 and 60

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: µg/mL				
arithmetic mean (standard deviation)				
Week 2 (n=31, 30)	32.87 (± 9.8729)	34.92 (± 7.3732)		
Week 6 (n=29, 27)	32.80 (± 12.953)	35.87 (± 11.983)		
Week 10 (n=32, 32)	39.21 (± 15.076)	41.02 (± 11.955)		
Week 14 (n=27, 30)	16.05 (± 7.4224)	17.31 (± 7.1914)		
Week 22 (n=25, 26)	2.913 (± 2.3243)	14.45 (± 6.0327)		
Week 30 (n=25, 25)	0.2200 (± 0.48146)	13.77 (± 6.3692)		

Week 60 (n=14, 25)	0.000 (± 0.0000)	21.16 (± 8.9078)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-vedolizumab Antibodies (AVA) in Induction Phase

End point title	Number of Participants with Anti-vedolizumab Antibodies (AVA) in Induction Phase[17]

End point description:

Blood samples were collected and tested for serum concentration of anti-vedolizumab antibodies in a laboratory by means of electrochemoluminescent (ECL) assay. Participants who underwent proper AVA test out of "the FAS in the induction phase" and, "the participants who received at least one dose of study drug in the Cohort 2" were analyzed at the given timepoint. n=number of participants with evaluable data at the given time-point.

End point type	Secondary

End point timeframe:

Weeks 0, 10 and 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was performed only in the Induction Phase.

End point values	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	46		
Units: participants				
Week 0 (n=116, 36)	0	0		
Week 10 (n=116, 36)	1	0		
16 Weeks After Last Administration (n=7, 7)	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-vedolizumab Antibodies (AVA) in Maintenance Phase

End point title	Number of Participants with Anti-vedolizumab Antibodies (AVA) in Maintenance Phase

End point description:

Blood samples were collected and tested for serum concentration of anti-vedolizumab antibodies in a laboratory by means of ECL assay. Participants who underwent proper AVA test out of the FAS, the participants who received at least one dose of study drug in the maintenance phase were analyzed at

the given timepoint. n=number of participants with evaluable data at the given time-point.

End point type	Secondary

End point timeframe:

Weeks 0, 10, 30, 60 and 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: participants				
Week 0 (n=32, 33)	0	0		
Week 10 (n=32, 33)	0	0		
Week 30 (n=31, 33)	4	0		
Week 60 (n=17, 25)	1	0		
16 Weeks After Last Administration (n=4, 2)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Neutralizing Anti-vedolizumab Antibodies (AVA) in Induction Phase

End point title	Number of Participants with Neutralizing Anti-vedolizumab Antibodies (AVA) in Induction Phase[18]

End point description:

Blood samples were collected, and serum neutralizing AVA was determined only for the AVA-positive samples in a laboratory by means of ECL assay. Participants who underwent proper AVA test out of "the FAS in the induction phase" and, "the participants who received at least one dose of study drug in the Cohort 2 were analyzed at the given timepoint. n=number of participants with evaluable data at the given time-point.

End point type	Secondary

End point timeframe:

Weeks 0, 10 and 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analyses were not planned for this endpoint.

End point values	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	46		
Units: participants				
Week 0 (n=116, 36)	0	0		
Week 10 (n=116, 36)	1	0		

16 Weeks After Last Administration (n=7, 7)	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Neutralizing Anti-vedolizumab Antibodies (AVA) in Maintenance Phase

End point title	Number of Participants with Neutralizing Anti-vedolizumab Antibodies (AVA) in Maintenance Phase

End point description:

Blood samples were collected, and serum neutralizing AVA was determined only for the AVA-positive samples in a laboratory by means of ECL assay. Participants who underwent proper AVA test out of the FAS, the participants who received at least one dose of study drug in the maintenance phase were analyzed at the given timepoint. n=number of participants with evaluable data at the given time-point.

End point type	Secondary

End point timeframe:

Weeks 0, 10, 30, 60 and 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

End point values	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: participants				
Week 0 (n=32, 33)	0	0		
Week 10 (n=32, 33)	0	0		
Week 30 (n=31, 32)	3	0		
Week 60 (n=17, 25)	0	0		
16 Weeks After Last Administration (n=4, 2)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline to 16 weeks after the last dose of study drug (Up to approximately 170 weeks)

Adverse event reporting additional description:

At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Induction Phase: Cohort 1, Placebo

Reporting group description:

Vedolizumab placebo-matching, intravenous (IV) infusion, once at Weeks 0, 2 and 6 in the induction phase.

Reporting group title	Induction Phase: Cohort 1, Vedolizumab 300 mg

Reporting group description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2, and 6 in the induction phase.

Reporting group title	Induction Phase: Cohort 2, Vedolizumab 300 mg

Reporting group description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 in the induction phase.

Reporting group title	Maintenance Phase: Placebo

Reporting group description:

Vedolizumab placebo-matching, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab in induction phase and achieved clinical response at Week 10 and were randomized to receive placebo in maintenance phase.

Reporting group title	Maintenance Phase: Vedolizumab 300 mg

Reporting group description:

Vedolizumab 300 mg, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab in induction phase and achieved clinical response at Week 10 and were randomized to receive vedolizumab in maintenance phase.

Reporting group title	Maintenance Phase: Placebo continuation

Reporting group description:

Vedolizumab placebo-matching, IV infusion, once at Weeks 14, 22, 30, 38, 46 and 54 in maintenance phase. Participants received vedolizumab placebo-matching in induction phase and achieved clinical response at Week 10 received placebo in maintenance phase without randomization.

Reporting group title	Open-Label Cohort: Vedolizumab 300 mg

Reporting group description:

Vedolizumab 300 mg, IV infusion, once at Weeks 0, 2 and 6 and then every 8 weeks thereafter up to Week 94 in open-label cohort.

Serious adverse events	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 82 (4.88%)	10 / 164 (6.10%)	6 / 46 (13.04%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 82 (0.00%)	1 / 164 (0.61%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 82 (0.00%)	1 / 164 (0.61%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug intolerance			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Cervical dysplasia			
subjects affected / exposed	0 / 82 (0.00%)	1 / 164 (0.61%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
White blood cell count decreased			
subjects affected / exposed	0 / 82 (0.00%)	1 / 164 (0.61%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest X-ray abnormal			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal compression fracture			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Facial paralysis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis cranial			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 82 (0.00%)	1 / 164 (0.61%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	2 / 82 (2.44%)	6 / 164 (3.66%)	4 / 46 (8.70%)
occurrences causally related to treatment / all	0 / 2	1 / 6	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal stenosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal hernia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema nodosum			
subjects affected / exposed	0 / 82 (0.00%)	1 / 164 (0.61%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Henoch-Schonlein purpura			

subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granulomatous dermatitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 82 (0.00%)	1 / 164 (0.61%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 82 (1.22%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 82 (1.22%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis bacterial			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis viral			

subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg	Maintenance Phase: Placebo continuation
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 42 (7.14%)	4 / 41 (9.76%)	1 / 26 (3.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			

subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug intolerance			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			

subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
White blood cell count decreased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest X-ray abnormal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Facial paralysis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis cranial			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	2 / 42 (4.76%)	2 / 41 (4.88%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal stenosis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal hernia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema nodosum			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granulomatous dermatitis			

subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal abscess			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis bacterial			
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis viral			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Open-Label Cohort: Vedolizumab 300 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	48 / 259 (18.53%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon adenoma			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			

subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug intolerance			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometriosis			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
White blood cell count decreased			

subjects affected / exposed	0 / 259 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest X-ray abnormal				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Eosinophil count increased				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Foreign body				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Angina pectoris				
subjects affected / exposed	2 / 259 (0.77%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Nervous system disorders			
Facial paralysis			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neuritis cranial			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	2 / 259 (0.77%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	25 / 259 (9.65%)		
occurrences causally related to treatment / all	3 / 26		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Anal stenosis			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenitis			

subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis erosive			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Internal hernia			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal perforation			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Erythema nodosum			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Granulomatous dermatitis			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			

Acute prerenal failure				
subjects affected / exposed	0 / 259 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 259 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	0 / 259 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vertebral foraminal stenosis				
subjects affected / exposed	1 / 259 (0.39%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Pneumonia				
subjects affected / exposed	0 / 259 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	0 / 259 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Clostridium difficile infection			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis bacterial			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	2 / 259 (0.77%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	2 / 259 (0.77%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Enteritis infectious			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Enterocolitis viral			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	1 / 259 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Induction Phase: Cohort 1, Placebo	Induction Phase: Cohort 1, Vedolizumab 300 mg	Induction Phase: Cohort 2, Vedolizumab 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 82 (12.20%)	28 / 164 (17.07%)	15 / 46 (32.61%)
Investigations			
White blood cell count decreased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 82 (2.44%)	6 / 164 (3.66%)	3 / 46 (6.52%)
occurrences (all)	2	9	5
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 82 (0.00%)	2 / 164 (1.22%)	3 / 46 (6.52%)
occurrences (all)	0	2	3
Colitis ulcerative			

subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	8 / 82 (9.76%)	23 / 164 (14.02%)	12 / 46 (26.09%)
occurrences (all)	10	25	17

Gastroenteritis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Upper respiratory tract infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 164 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab 300 mg	Maintenance Phase: Placebo continuation
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 42 (40.48%)	27 / 41 (65.85%)	13 / 26 (50.00%)
Investigations			
White blood cell count decreased			
subjects affected / exposed	2 / 42 (4.76%)	2 / 41 (4.88%)	2 / 26 (7.69%)
occurrences (all)	3	2	2
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 42 (2.38%)	2 / 41 (4.88%)	2 / 26 (7.69%)
occurrences (all)	1	5	2
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	4 / 42 (9.52%)	0 / 41 (0.00%)	1 / 26 (3.85%)
occurrences (all)	4	0	1
Vomiting			

subjects affected / exposed	1 / 42 (2.38%)	3 / 41 (7.32%)	1 / 26 (3.85%)
occurrences (all)	3	3	1
Dental caries			
subjects affected / exposed	0 / 42 (0.00%)	4 / 41 (9.76%)	0 / 26 (0.00%)
occurrences (all)	0	4	0
Haemorrhoids			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Stomatitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 42 (0.00%)	3 / 41 (7.32%)	1 / 26 (3.85%)
occurrences (all)	0	3	1
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 42 (0.00%)	3 / 41 (7.32%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	3 / 42 (7.14%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 42 (0.00%)	3 / 41 (7.32%)	1 / 26 (3.85%)
occurrences (all)	0	3	1
Back pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	9 / 42 (21.43%)	18 / 41 (43.90%)	8 / 26 (30.77%)
occurrences (all)	22	27	11
Gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	9	3
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Open-Label Cohort: Vedolizumab 300 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	191 / 259 (73.75%)		
Investigations			
White blood cell count decreased			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	23 / 259 (8.88%)		
occurrences (all)	27		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	17 / 259 (6.56%)		
occurrences (all)	26		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences (all)	0		
Colitis ulcerative			
subjects affected / exposed	18 / 259 (6.95%)		
occurrences (all)	20		
Vomiting			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences (all)	0		
Dental caries			

subjects affected / exposed	0 / 259 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	14 / 259 (5.41%)		
occurrences (all)	15		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 259 (0.00%)		
occurrences (all)	0		
Upper respiratory tract inflammation			
subjects affected / exposed	14 / 259 (5.41%)		
occurrences (all)	22		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	13 / 259 (5.02%)		
occurrences (all)	17		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	14 / 259 (5.41%)		
occurrences (all)	14		
Back pain			
subjects affected / exposed	22 / 259 (8.49%)		
occurrences (all)	25		
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	130 / 259 (50.19%)		
occurrences (all)	281		
Gastroenteritis			
subjects affected / exposed	13 / 259 (5.02%)		
occurrences (all)	16		
Upper respiratory tract infection			
subjects affected / exposed	19 / 259 (7.34%)		
occurrences (all)	33		

Influenza subjects affected / exposed occurrences (all)	24 / 259 (9.27%) 24		
Pharyngitis subjects affected / exposed occurrences (all)	16 / 259 (6.18%) 24		

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