ID: C13006 | Study of Vedolizumab (MLN0002) in Patients With Moderate to Severe Ulcerative Colitis | NCT00783718

Results Preview

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Participant Flow

Recruitment Details: Participants took part in the study at 211 investigative sites worldwide. The Induction Phase contained 2 cohorts. The eligibility criteria for both cohorts were identical. The purpose of Cohort 2 was to provide enough responders to power the Maintenance Phase primary efficacy analysis.

Pre-Assignment Details: In Cohort 1, eligible patients who met entry criteria were randomized to treatment with double-blind vedolizumab 300 mg or placebo in a 3:2 ratio. All Cohort 2 patients were treated with open-label vedolizumab. In the Maintenance Phase participants were assigned to treatment groups based on their Induction Phase treatment and response to therapy.

Arm/Group Title	Placebo	Induction Phase: DB Vedolizumab	Induction Phase: OL Vedolizumab	Maintenance Phase: Placebo	Maintenance Phase: Vedolizumab Q8W	Maintenance Phase: Vedolizumab Q4W	Maintenance Phase: Non-responders	Total (Not public)
Arm/Group Description	In the Induction Phase participants in Cohort 1 were randomized to receive double-blind placebo intravenous infusions at Week 0 and Week 2. Participants continued to receive placebo every 4 weeks from Week 6 through Week 50 during the Maintenance Phase, regardless of treatment response during induction.	In the Induction Phase participants in Cohort 1 were randomized to receive double-blind (DB) vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2.	In the Induction Phase participants in Cohort 2 received open-label (OL) vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were then randomized to receive double-blind treatment with placebo every 4 weeks up to Week 50 during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were then randomized to receive double-blind treatment with vedolizumab 300 mg every 8 weeks (Q8W) at Weeks 6, 14, 22, 30, 38, and 46, and, to maintain blinding, placebo infusions at Weeks 10, 18, 26, 34, 42, and 50.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were then randomized to receive double-blind treatment with vedolizumab 300 mg every 4 weeks (Q4W) from Week 6 to Week 50.	Participants who received vedolizumab during the Induction Phase who did not demonstrate a clinical response at Week 6 received open-label treatment with vedolizumab 300 mg every 4 weeks from Week 6 to Week 50.	
Period Title: Induction Phase								
Started	149	225	521	0	0	0	0	895
Completed	135	218	485	0	0	0	0	838
Not Completed	14	7	36	0	0	0	0	57
Reason Not Completed								
Adverse Event	4	0	7	0	0	0	0	11
Protocol Violation	1	1	6	0	0	0	0	8
Lack of Efficacy	5	2	14	0	0	0	0	21
Withdrawal by Subject	3	4	8	0	0	0	0	15
Lost to Follow-up	1	0	1	0	0	0	0	2
(Not Public)	Not Completed = 14 Total from all reasons = 14	Not Completed = 7 Total from all reasons = 7	Not Completed = 36 Total from all reasons = 36	Not Completed = 0 Total from all reasons = 0	Not Completed = 0 Total from all reasons = 0	Not Completed = 0 Total from all reasons = 0	Not Completed = 0 Total from all reasons = 0	
Period Title: Maintenance Phase								
Started	135	0 NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	0 NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	126 NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	122 NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	125 NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	330 NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	838
Completed	30	0	0	48	77	84	135	374
Not Completed	105	0	0	78	45	41	195	464
Reason Not Completed								
Adverse Event	12	0	0	15	7	6	16	56
Protocol Violation	1	0	0	0	0	0	2	3
Lack of Efficacy	83	0	0	61	31	33	155	363
Withdrawal by Subject	6	0	0	2	5	2	20	35
Lost to Follow-up	3	0	0	0	2	0	2	7
(Not Public)	Not Completed = 105 Total from all reasons = 105	Not Completed = 0 Total from all reasons = 0	Not Completed = 0 Total from all reasons = 0	Not Completed = 78 Total from all reasons = 78	Not Completed = 45 Total from all reasons = 45	Not Completed = 41 Total from all reasons = 41	Not Completed = 195 Total from all reasons = 195	

Baseline Characteristics

Arm/Group Title	Placebo	Induction Phase: DB Vedolizumab	Induction Phase: OL Vedolizumab	Total
Arm/Group Description	In the Induction Phase participants in Cohort 1 were randomized to receive double-blind placebo intravenous infusions at Week 0 and Week 2. Participants continued to receive placebo every 4 weeks from Week 6 through Week 50 during the Maintenance Phase, regardless of treatment response during induction.	In the Induction Phase participants in Cohort 1 were randomized to receive double-blind vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2.	In the Induction Phase participants in Cohort 2 received open-label vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2.	
Overall Number of Baseline Participants	149	225	521	**895**
Baseline Analysis Population Description	Baseline characteristics are provided for the Induction Phase Safety Population, defined as all participants, in both Cohort 1 and Cohort 2, who received any amount of study drug in the Induction Phase (Weeks 0-6), according to the actual study drug received.			

Age, Continuous **Mean (Standard Deviation)** **Units: years**	41.2 (12.50)	40.1 (13.11)	40.1 (13.27)	40.3 (13.09)
Age, Customized **Measure Type: Number** **Units: participants**				
< 35	53	86	214	353
≥ 35	96	139	307	542
Age, Customized **Measure Type: Number** **Units: participants**				
< 65	142	217	503	862
≥ 65	7	8	18	33
Gender, Male/Female **Measure Type: Number** **Units: participants**				
Female	57	93	220	370
Male	92	132	301	525
Race/Ethnicity, Customized **Measure Type: Number** **Units: participants**				
White	115	183	436	734
Black	2	5	5	12
Asian	32	36	67	135
Other	0	1	13	14
Race/Ethnicity, Customized **Measure Type: Number** **Units: participants**				
Hispanic or Latino	5	10	31	46
Not Hispanic or Latino	140	211	481	832
Not reported	4	4	9	17
Region of Enrollment **Measure Type: Number** **Units: participants**				
Australia	7	17	29	53
	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	
Austria	4	3	12	19
Belgium	7	14	35	56
Bulgaria	2	1	3	6
Canada	16	14	62	92
Czech Republic	7	12	19	38
Denmark	2	7	5	14
Estonia	1	4	5	10
France	1	3	13	17
Germany	0	1	16	17
Greece	0	1	4	5
Hong Kong	0	0	1	1
Hungary	2	6	8	16
Iceland	0	1	2	3
India	18	16	24	58
Ireland	0	0	1	1
Israel	0	1	1	2
Italy	1	9	11	21
Korea, Republic of	5	10	26	41
Latvia	1	2	0	3
Malaysia	5	2	2	9
Netherlands	1	0	2	3
New Zealand	0	5	6	11
Norway	2	1	6	9
Poland	2	6	52	60
Russian Federation	9	15	25	49
Singapore	0	0	1	1
South Africa	4	5	10	19
Spain	0	0	2	2
Switzerland	2	1	3	6
Turkey	0	3	3	6
United Kingdom	2	0	4	6
United States	47	64	127	238
Body Weight [1] **Mean (Standard Deviation)** **Units: kg**	72.4 (17.65)	72.4 (17.11)	74.2 (19.32)	73.4 (18.51)
	[1] Body weight data only available for 148 participants in the placebo arm.			
Body Mass Index (BMI) [1] **Mean (Standard Deviation)** **Units: kg/m^2**	24.6 (5.11)	24.9 (4.85)	25.3 (6.05)	25.1 (5.62)
	[1] BMI data only available for 148 participants in the placebo arm.			
Duration of Ulcerative Colitis [1] **Mean (Standard Deviation)**				

Units: years	7.1 (7.25)	6.1 (5.08)	7.2 (6.61)	6.9 (6.39)

[1] Duration of ulcerative colitis data only available for 519 participants in the Induction Phase: OL Vedolizumab arm.

Categorical Duration of Ulcerative Colitis				
Measure Type: Number				
Units: participants				
< 1 year	13	13	38	64
≥1 - < 3 years	44	63	121	228
≥ 3 - < 7 years	39	77	163	279
≥ 7 years	53	72	197	322
Missing	0	0	2	2
Baseline Mayo Score [1]				
Mean (Standard Deviation)				
Units: units on a scale	8.6 (1.68)	8.5 (1.78)	8.6 (1.76)	8.6 (1.75)

[1] The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).

Baseline Disease Activity				
Measure Type: Number				
Units: participants				
Complete Mayo score < 6	5	6	14	25
Complete Mayo score of 6 to 8 (inclusive)	70	105	249	424
Complete Mayo score of 9 to 12 (inclusive)	74	114	258	446
Baseline Fecal Calprotectin [1]				
Mean (Standard Deviation)				
Units: µg/g	2369.9 (3258.82)	2552.2 (3800.36)	1442.7 (1855.61)	1868.8 (2753.28)

[1] Number of participants for whom baseline fecal calprotectin data were available were 139, 213, and 505, respectively.

Categorical Baseline Fecal Calprotectin				
Measure Type: Number				
Units: participants				
≤ 250 µg/g	27	37	94	158
> 250 to ≤ 500 µg/g	20	20	82	122
> 500 µg/g	92	156	329	577
Missing	10	12	16	38
Disease Localization				
Measure Type: Number				
Units: participants				
Proctosigmoiditis	22	25	69	116
Left-sided colitis	59	92	188	339
Extensive colitis	18	25	66	109
Pancolitis	50	83	198	331
Smoking Status				
Measure Type: Number				
Units: participants				
Current smoker	11	12	32	55
Nonsmoker	88	145	322	555
Former smoker	50	68	167	285
History of Extraintestinal Manifestations				
Measure Type: Number				
Units: participants				
Yes	44	74	180	298
No	105	151	341	597

Outcome Measures

1. Primary Outcome

Title: Induction Phase: Percentage of Participants With a Clinical Response at Week 6

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. The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity). All participants who prematurely discontinued for any reason were considered as not achieving clinical response.

Time Frame: Baseline and Week 6

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Induction Study Intent-to-treat (ITT) population which consisted of all randomized patients in Cohort 1 who received any amount of blinded study drug.

Arm/Group Title	**Placebo**	**DB Vedolizumab**
Arm/Group Description:	Participants in Cohort 1 received double-blind placebo intravenous infusions at Week 0 and Week 2 in the Induction Phase.	Participants in Cohort 1 received double-blind vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2 in the Induction Phase.
Number of Participants Analyzed	149	225
Number (95% Confidence Interval)	25.5 (18.5 to 32.5)	47.1 (40.6 to 53.6)
Units: percentage of participants		

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, DB Vedolizumab
	Comments	The primary comparison of the Induction Phase was tested using the Cochran-Mantel-Haenszel (CMH) chi-square test at a 5% significance level, with stratification according to the stratification factors (concomitant use of oral corticosteroids and previous exposure to tumor necrosis factor alpha (TNFα) antagonists or concomitant immunomodulator [6-mercaptopurine or azathioprine] use).
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	21.7
	Confidence Interval	(2-Sided) 95% 11.6 to 31.7
	Estimation Comments	[Not specified]

2. Primary Outcome

Title: Maintenance Phase: Percentage of Participants in Clinical Remission at Week 52

Description: Clinical Remission is defined as a complete Mayo score of ≤ 2 points and no individual subscore > 1 point.
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).
All participants who prematurely discontinued for any reason were considered as not achieving clinical remission.

Time Frame: Week 52

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Maintenance Study ITT Population, defined as all randomized participants who received vedolizumab during the Induction Phase and met the protocol definition of clinical response at Week 6, as assessed by the investigator, were randomized, and received any amount of double-blind study drug in the Maintenance Phase.

Arm/Group Title	**Placebo**	**Vedolizumab Q8W**	**Vedolizumab Q4W**
Arm/Group Description:	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with placebo every 4 weeks up to Week 50 during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 8 weeks (Q8W) from Week 6 to Week 50.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 4 weeks (Q4W) from Week 6 to Week 50.
Number of Participants Analyzed	126	122	125
Number (95% Confidence Interval) Units: percentage of participants	15.9 (9.5 to 22.3)	41.8 (33.1 to 50.6)	44.8 (36.1 to 53.5)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q8W
	Comments	The Hochberg method was applied to control the overall Type I error rate at a 5% significance level. If both P-values were ≤ 0.05, both dose regimens were to be declared significant. If 1 of the P-values for the 2 dose comparisons was > 0.05, the other P-value was to be tested at the 0.025 level and declared significant only if the P-value was ≤ 0.025. If neither dose was declared significant for the primary endpoint, no further testing was to be conducted.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	26.1
	Confidence Interval	(2-Sided) 95% 14.9 to 37.2
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q4W
	Comments	The Hochberg method was applied to control the overall Type I error rate at a 5% significance level. If both P-values were ≤ 0.05, both dose regimens were to be declared significant. If 1 of the P-values for the 2 dose comparisons was > 0.05, the other P-value was to be tested at the 0.025 level and declared significant only if the P-value was ≤ 0.025. If neither dose was declared significant for the primary endpoint, no further testing was to be conducted.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	29.1
	Confidence Interval	(2-Sided) 95% 17.9 to 40.4
	Estimation Comments	[Not specified]

3. Secondary Outcome

Title: Induction Phase: Percentage of Participants in Clinical Remission at Week 6

Description: Clinical Remission is defined as a complete Mayo score of ≤ 2 points and no individual subscore > 1 point.
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).
All participants who prematurely discontinued for any reason were considered as not achieving clinical remission.

Time Frame: Week 6

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Induction Study ITT Population

Arm/Group Title	**Placebo**	**DB Vedolizumab**
Arm/Group Description:	Participants in Cohort 1 received double-blind placebo intravenous infusions at Week 0 and Week 2 in the Induction Phase.	Participants in Cohort 1 received double-blind vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2 in the Induction Phase.
Number of Participants Analyzed	149	225
Number (95% Confidence Interval) Units: percentage of participants	5.4 (1.7 to 9.0)	16.9 (12.0 to 21.8)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, DB Vedolizumab
	Comments	To maintain the overall Type I error rate at 5%, the key secondary assessments were performed sequentially (closed sequential method). The first secondary endpoint was to be tested only if the primary comparison was significant and the second key secondary endpoint was to be tested only if the first secondary endpoint was significant for vedolizumab.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.0009
	Comments	P-value is based on the CMH chi-square test, with stratification according to: 1) concomitant use of oral corticosteroids (yes/no); and 2) previous exposure to TNFα antagonists or concomitant immunomodulator use (yes/no).
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	11.5
	Confidence Interval	(2-Sided) 95% 4.7 to 18.3
	Estimation Comments	[Not specified]

4. Secondary Outcome

Title: Induction Phase: Percentage of Participants With Mucosal Healing at Week 6

Description: Mucosal healing is defined as a Mayo endoscopic subscore of ≤ 1 point.
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. 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).
All participants who prematurely discontinued for any reason were considered as not achieving mucosal healing.

Time Frame: Week 6

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Induction Study ITT Population

Arm/Group Title	Placebo	DB Vedolizumab
Arm/Group Description:	Participants in Cohort 1 received double-blind placebo intravenous infusions at Week 0 and Week 2 in the Induction Phase.	Participants in Cohort 1 received double-blind vedolizumab 300 mg, administered by intravenous infusion at Week 0 and Week 2 in the Induction Phase.
Number of Participants Analyzed	149	225
Number (95% Confidence Interval) Units: percentage of participants	24.8 (17.9 to 31.8)	40.9 (34.5 to 47.3)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, DB Vedolizumab
	Comments	To maintain the overall Type I error rate at 5%, the key secondary assessments were performed sequentially (closed sequential method). The first secondary endpoint was to be tested only if the primary comparison was significant and the second key secondary endpoint was to be tested only if the first secondary endpoint was significant for vedolizumab.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.0012
	Comments	P-value is based on the CMH chi-square test, with stratification according to: 1) concomitant use of oral corticosteroids (yes/no); and 2) previous exposure to TNFα antagonists or concomitant immunomodulator use (yes/no).
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	16.1
	Confidence Interval	(2-Sided) 95% 6.4 to 25.9
	Estimation Comments	[Not specified]

5. Secondary Outcome

Title: Maintenance Phase: Percentage of Participants With Durable Clinical Response

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 6 and 52. The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).
All participants who prematurely discontinued for any reason were considered as not achieving durable clinical response.

Time Frame: Baseline, Week 6 and Week 52

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Maintenance Study ITT Population

Arm/Group Title	Placebo	Vedolizumab Q8W	Vedolizumab Q4W
Arm/Group Description:	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with placebo every 4 weeks up to Week 50 during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 8 weeks (Q8W) from Week 6 to Week 50.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 4 weeks (Q4W) from Week 6 to Week 50.
Number of Participants Analyzed	126	122	125
Number (95% Confidence Interval) Units: percentage of participants	23.8 (16.4 to 31.2)	56.6 (47.8 to 65.4)	52.0 (43.2 to 60.8)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q8W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	32.8
	Confidence Interval	(2-Sided) 95% 20.8 to 44.7
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q4W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	28.5
	Confidence Interval	(2-Sided) 95% 16.7 to 40.3
	Estimation Comments	[Not specified]

6. Secondary Outcome

Title: Maintenance Phase: Percentage of Participants With Mucosal Healing at Week 52

Description: Mucosal healing is defined as a Mayo endoscopic subscore of ≤ 1 point.
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. 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).
All participants who prematurely discontinued for any reason were considered as not achieving mucosal healing.

Time Frame: Week 52

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Maintenance Study ITT Population

Arm/Group Title	**Placebo**	**Vedolizumab Q8W**	**Vedolizumab Q4W**
Arm/Group Description:	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with placebo every 4 weeks up to Week 50 during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 8 weeks (Q8W) from Week 6 to Week 50.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 4 weeks (Q4W) from Week 6 to Week 50.
Number of Participants Analyzed	126	122	125
Number (95% Confidence Interval)	19.8 (12.9 to 26.8)	51.6 (42.8 to 60.5)	56.0 (47.3 to 64.7)

Units: percentage of participants

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q8W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	32.0
	Confidence Interval	(2-Sided) 95% 20.3 to 43.8
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q4W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	36.3

	Confidence Interval	(2-Sided) 95% 24.4 to 48.3
	Estimation Comments	[Not specified]

7. Secondary Outcome

Title: Maintenance Phase: Percentage of Participants With Durable Clinical Remission

Description: Durable clinical remission is defined as complete Mayo score of ≤ 2 points and no individual subscore > 1 point at both Weeks 6 and 52. The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).
All participants who prematurely discontinued for any reason were considered as not achieving durable clinical remission.

Time Frame: Week 6 and Week 52

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Maintenance Study ITT Population

Arm/Group Title	**Placebo**	**Vedolizumab Q8W**	**Vedolizumab Q4W**
Arm/Group Description:	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with placebo every 4 weeks up to Week 50 during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 8 weeks (Q8W) from Week 6 to Week 50.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 4 weeks (Q4W) from Week 6 to Week 50.
Number of Participants Analyzed	126	122	125
Number (95% Confidence Interval) **Units: percentage of participants**	8.7 (3.8 to 13.7)	20.5 (13.3 to 27.7)	24.0 (16.5 to 31.5)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q8W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.0079
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	11.8
	Confidence Interval	(2-Sided) 95% 3.1 to 20.5
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q4W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.0009
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of	**Estimation Parameter**	Risk Difference (RD)

Estimation	**Estimated Value**	15.3
	Confidence Interval	(2-Sided) 95% 6.2 to 24.4
	Estimation Comments	[Not specified]

8. Secondary Outcome

Title: Maintenance Phase: Percentage of Participants With Corticosteroid-free Remission at Week 52

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 52.
The Mayo Score is a standard assessment tool to measure ulcerative colitis disease activity in clinical trials. The index consists of 4 components: two that are patient reported (rectal bleeding and stool frequency), a global assessment by the physician, and an endoscopic subscore. Each component is scored on a scale from 0 to 3 and the complete score ranges from 1 to 12 (higher scores indicate greater disease activity).
All participants who prematurely discontinued for any reason were considered as not achieving corticosteroid-free remission.

Time Frame: Week 52

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Maintenance Study ITT Population, participants who were on corticosteroids at Baseline.

Arm/Group Title	**Placebo**	**Vedolizumab Q8W**	**Vedolizumab Q4W**
Arm/Group Description:	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with placebo every 4 weeks up to Week 50 during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 8 weeks (Q8W) from Week 6 to Week 50.	Participants who received vedolizumab during the Induction Phase and demonstrated a clinical response at Week 6 were randomized to receive double-blind treatment with vedolizumab 300 mg every 4 weeks (Q4W) from Week 6 to Week 50.
Number of Participants Analyzed	72	70	73
Number (95% Confidence Interval) **Units: percentage of participants**	13.9 (5.9 to 21.9)	31.4 (20.6 to 42.3)	45.2 (33.8 to 56.6)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q8W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.0120
	Comments	P-value based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	17.6
	Confidence Interval	(2-Sided) 95% 3.9 to 31.3
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vedolizumab Q4W
	Comments	To maintain the overall Type I error rate at 5% for the 2 dose regimen comparisons for each key secondary endpoint, the Hochberg method was used as described for the primary outcome measure. To further maintain the overall Type I error rate at 5%, the key secondary endpoints were also performed sequentially. The first was tested only if 1 or both of the primary comparisons were significant and the next endpoint was tested only if the previous endpoint was significant for at least 1 dose.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.0001
	Comments	P-value is based on the CMH chi-square test, with 3 stratification factors: concomitant use of oral corticosteroids; previous exposure to TNFα antagonists or concomitant immunomodulator use; enrollment in Cohort 1 or 2 in the Induction Phase.
	Method	Cochran-Mantel-Haenszel

	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Risk Difference (RD)
	Estimated Value	31.4
	Confidence Interval	(2-Sided) 95% 16.6 to 46.2
	Estimation Comments	[Not specified]

Adverse Events

Time Frame	From the start of the Induction Phase until a final on-study safety assessment at Week 66 (or Final Safety visit 16 weeks after the last dose).
Additional Description	
Source Vocabulary Name	MedDRA (14.0)
Assessment Type	Systematic Assessment

Arm/Group Title	Placebo	Vedolizumab Then Placebo	Vedolizumab
Arm/Group Description	Participants who received double-blind placebo intravenous infusions in the Induction Phase and continued to receive placebo during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and were then randomized to receive placebo during the Maintenance Phase.	Participants who received vedolizumab during the Induction Phase and continued to receive vedolizumab during the Maintenance Phase. This includes participants who had a clinical response at Week 6 and were randomized to vedolizumab every 4 weeks or every 8 weeks in the Maintenance Phase, participants who did not achieve a clinical response at Week 6 and continued to receive vedolizumab every 4 weeks for the duration of the study, and participants who withdrew during the Induction phase.

Serious Adverse Events

	Placebo Affected / at Risk (%)	**Vedolizumab Then Placebo** Affected / at Risk (%)	**Vedolizumab** Affected / at Risk (%)
Total	17/149 (11.41%)	20/126 (15.87%)	77/620 (12.42%)
Blood and lymphatic system disorders			
Anaemia † A	1/149 (0.67%)	1/126 (0.79%)	1/620 (0.16%)
Cardiac disorders			
Aortic valve stenosis † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Arteriosclerosis coronary artery † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Atrial fibrillation † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Ear and labyrinth disorders			
Vertigo positional † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Gastrointestinal disorders			
Abdominal pain † A	1/149 (0.67%)	0/126 (0%)	2/620 (0.32%)
Abdominal pain upper † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Colitis ulcerative † A	10/149 (6.71%)	7/126 (5.56%)	47/620 (7.58%)
Colon dysplasia † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Ileus † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Nausea † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Pancreatitis acute † A	1/149 (0.67%)	0/126 (0%)	0/620 (0%)
Peritoneal haemorrhage † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Rectal haemorrhage † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Small intestinal obstruction † A	1/149 (0.67%)	0/126 (0%)	1/620 (0.16%)
Subileus † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Upper gastrointestinal haemorrhage † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
General disorders			
Fatigue † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Multi-organ failure † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Pyrexia † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Hepatobiliary disorders			
Bile duct stone † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Cholangitis sclerosing † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Hepatitis acute † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Immune system disorders			
Sarcoidosis † A	1/149 (0.67%)	0/126 (0%)	0/620 (0%)
Infections and infestations			
Anal abscess † A	0/149 (0%)	0/126 (0%)	2/620 (0.32%)
Appendicitis † A	0/149 (0%)	2/126 (1.59%)	0/620 (0%)
Bronchitis † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Cellulitis † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Cholangitis suppurative † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Infection † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Klebsiella infection † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Lower respiratory tract infection † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Pelvic abscess † A	1/149 (0.67%)	0/126 (0%)	0/620 (0%)
Pericoronitis † A	1/149 (0.67%)	0/126 (0%)	0/620 (0%)
Perirectal abscess † A	1/149 (0.67%)	0/126 (0%)	1/620 (0.16%)

Pneumonia † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Pulpitis dental † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Sepsis † A	1/149 (0.67%)	0/126 (0%)	1/620 (0.16%)
Tonsillitis † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Urinary tract infection † A	1/149 (0.67%)	0/126 (0%)	1/620 (0.16%)
Wound infection † A	0/149 (0%)	0/126 (0%)	2/620 (0.32%)
Injury, poisoning and procedural complications			
Accidental poisoning † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Concussion † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Fall † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Fibula fracture † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Gastrointestinal stoma complication † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Pubis fracture † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Wrist fracture † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Investigations			
Haemoglobin decrease † A	0/149 (0%)	1/126 (0.79%)	1/620 (0.16%)
Lipase increased † A	1/149 (0.67%)	0/126 (0%)	0/620 (0%)
Weight decreased † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Metabolism and nutrition disorders			
Dehydration † A	1/149 (0.67%)	0/126 (0%)	2/620 (0.32%)
Musculoskeletal and connective tissue disorders			
Osteoporosis † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer † A	0/149 (0%)	1/126 (0.79%)	1/620 (0.16%)
Transitional cell carcinoma † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Nervous system disorders			
Syncope † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Renal and urinary disorders			
Renal failure † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Tubulointerstitial nephritis † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Reproductive system and breast disorders			
Benign prostatic hyperplasia † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Menorrhagia † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Respiratory, thoracic and mediastinal disorders			
Pleural effusion † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)
Pneumothorax † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Pulmonary embolism † A	1/149 (0.67%)	0/126 (0%)	2/620 (0.32%)
Skin and subcutaneous tissue disorders			
Pemphigoid † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Rash † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Vascular disorders			
Arteriosclerosis obliterans † A	1/149 (0.67%)	0/126 (0%)	0/620 (0%)
Deep vein thrombosis † A	0/149 (0%)	0/126 (0%)	1/620 (0.16%)
Venous thrombosis † A	0/149 (0%)	1/126 (0.79%)	0/620 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (14.0)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events: 5%

	Placebo Affected / at Risk (%)	**Vedolizumab Then Placebo** Affected / at Risk (%)	**Vedolizumab** Affected / at Risk (%)
Total	67/149 (44.97%)	69/126 (54.76%)	321/620 (51.77%)
Blood and lymphatic system disorders			
Anaemia † A	10/149 (6.71%)	4/126 (3.17%)	35/620 (5.65%)
Gastrointestinal disorders			
Abdominal pain † A	7/149 (4.7%)	2/126 (1.59%)	34/620 (5.48%)
Colitis ulcerative † A	20/149 (13.42%)	22/126 (17.46%)	57/620 (9.19%)
Nausea † A	11/149 (7.38%)	8/126 (6.35%)	38/620 (6.13%)
General disorders			
Fatigue † A	5/149 (3.36%)	5/126 (3.97%)	32/620 (5.16%)
Infections and infestations			
Bronchitis † A	5/149 (3.36%)	7/126 (5.56%)	23/620 (3.71%)
Nasopharyngitis † A	11/149 (7.38%)	15/126 (11.9%)	80/620 (12.9%)
Upper respiratory tract infection † A	8/149 (5.37%)	13/126 (10.32%)	52/620 (8.39%)
Musculoskeletal and connective tissue disorders			
Arthralgia † A	10/149 (6.71%)	15/126 (11.9%)	56/620 (9.03%)
Nervous system disorders			
Headache † A	13/149 (8.72%)	15/126 (11.9%)	80/620 (12.9%)
Respiratory, thoracic and mediastinal disorders			
Cough † A	7/149 (4.7%)	6/126 (4.76%)	36/620 (5.81%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The first study related publication will be a multi-center publication submitted within 24 months after conclusion or termination of a study at all sites. After such multi site publication, all proposed site publications and presentations will be submitted to sponsor for review 60 days in advance of publication. Site will remove Sponsor confidential information unrelated to study results. Sponsor can delay a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact

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