Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tralokinumab (Adtralza®)

LEO Pharma GmbH

Anhang 4-G zu Modul 4 B

Behandlung von mittelschwerer bis schwerer atopischer Dermatitis bei Jugendlichen ab 12 Jahren, die für eine kontinuierliche systemische Therapie in Frage kommen.

Stand: 10.11.2022

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LEO Pharma A/S

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Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	36 (37.1)	17.3 (5.18;29.39)	1.9 (1.17; 2.99)	2.6 (1.29; 5.08)	0.0075	0.6402
Placebo	94	19 (20.2)					
Moderate [IGA=3]							
Tralokinumab 300 Q2W	49	19 (38.8)	15.2 (-2.69;33.05)	1.6 (0.90; 3.04)	2.1 (0.86; 4.95)	0.1070	
Placebo	51	12 (23.5)					
Severe [IGA=4]							
Tralokinumab 300 Q2W	48	17 (35.4)	19.6 (3.53;35.67)	2.2 (1.07; 4.64)	3.6 (1.15;11.03)	0.0254	
Placebo	43	7 (16.3)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.7.206.12.1: Total, Disease severity (IGA), EASI 90, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	22 (22.7)	15.4 (5.48;25.24)	3.1 (1.38; 7.04)	3.7 (1.49; 9.20)	0.0035	0.7190
Placebo	94	7 (7.4)					
Moderate [IGA=3]							
Tralokinumab 300 Q2W	49	13 (26.5)	16.6 (1.79;31.39)	2.7 (1.03; 7.11)	3.3 (1.08;10.23)	0.0338	
Placebo	51	5 (9.8)					
Severe [IGA=4]							
Tralokinumab 300 Q2W	48	9 (18.8)	14.0 (1.13;26.90)	4.0 (0.89;18.34)	4.5 (0.94;21.14)	0.0430	
Placebo	43	2 (4.7)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.7.209.12.1: Total, Disease severity (IGA), SCORAD 75, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	15 (15.5)	13.5 (5.63;21.29)	7.3 (1.72;31.34)	8.2 (1.87;36.25)	0.0012	0.9959
Placebo	94	2 (2.1)					
Moderate [IGA=3]							
Tralokinumab 300 Q2W	49	7 (14.3)	12.6 (2.01;23.29)	7.4 (0.96;57.30)	8.4 (1.02;69.14)	0.0207	
Placebo	51	1 (2.0)					
Severe [IGA=4]							
Tralokinumab 300 Q2W	48	8 (16.7)	14.4 (2.81;25.89)	7.2 (0.92;56.99)	8.1 (1.01;64.86)	0.0236	
Placebo	43	1 (2.3)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.7.213.12.1: Total, Disease severity (IGA), POEM improvement of >= 4, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	94	70 (74.5)	27.0 (13.17;40.84)	1.6 (1.22; 2.03)	3.2 (1.70; 5.92)	0.0002	0.7594
Placebo	87	41 (47.1)					
Moderate [IGA=3]							
Tralokinumab 300 Q2W	46	32 (69.6)	26.0 (5.98;45.96)	1.6 (1.08; 2.37)	2.8 (1.22; 6.53)	0.0142	
Placebo	46	20 (43.5)					
Severe [IGA=4]							
Tralokinumab 300 Q2W	48	38 (79.2)	28.1 (8.98;47.17)	1.6 (1.11; 2.17)	3.7 (1.44; 9.35)	0.0060	
Placebo	41	21 (51.2)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Including subjects with a baseline of at least 4. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
EASI Score								
Total								
Baseline	94	94	31.2 (14.47)		97	97	31.8 (13.91)	
Week 2		94	24.9 (15.33)			97	22.4 (12.46)	
Week 2 chg		94	-6.3 (10.06)	-6.41 (1.15)		97	-9.4 (9.84)	-9.32 (1.13)
LS Means (T - P) p-value								-2.91 (1.62) (-6.09, 0.27)
					0.072			
[SMD T - P]								[-0.29 (-0.58, -0.01)]
Week 4		90	23.6 (15.77)			96	18.4 (13.04)	
Week 4 chg		90	-7.9 (12.13)	-7.94 (1.17)		96	-13.5 (11.34)	-13.35 (1.14)
LS Means (T - P) p-value								-5.42 (1.63) (-8.62, -2.21)
					<.001			
[SMD T - P]								[-0.46 (-0.75, -0.17)]
Week 6		91	21.6 (14.67)			94	16.1 (13.84)	
Week 6 chg		91	-9.9 (11.90)	-10.06 (1.16)		94	-15.7 (13.62)	-15.62 (1.14)
LS Means (T - P) p-value								-5.56 (1.63) (-8.77, -2.35)
					<.001			
[SMD T - P]								[-0.43 (-0.73, -0.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		88	20.5 (15.07)				95	13.6 (12.57)		
Week 8 chg		88	-10.8 (12.19)	-10.89	(1.17)		95	-18.2 (12.35)	-18.12	(1.14)
LS Means (T - P) p-value									-7.23	(1.64) (-10.4, -4.01)
						<.001				
[SMD T - P]									[-0.59 (-0.89, -0.29)]	
Week 10		86	20.2 (15.71)				93	13.4 (12.32)		
Week 10 chg		86	-11.1 (12.85)	-11.31	(1.18)		93	-18.8 (12.82)	-18.63	(1.15)
LS Means (T - P) p-value									-7.33	(1.65) (-10.6, -4.09)
						<.001				
[SMD T - P]									[-0.57 (-0.87, -0.27)]	
Week 12		90	19.2 (14.92)				93	12.6 (11.83)		
Week 12 chg		90	-11.8 (14.49)	-12.20	(1.17)		93	-19.0 (14.14)	-18.64	(1.15)
LS Means (T - P) p-value									-6.44	(1.64) (-9.66, -3.22)
						<.001				
[SMD T - P]									[-0.45 (-0.74, -0.16)]	
Week 14		83	18.7 (15.04)				95	12.7 (13.33)		
Week 14 chg		83	-12.5 (14.00)	-12.71	(1.19)		95	-19.2 (13.78)	-19.01	(1.14)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-6.31 (1.65)	(-9.55, -3.06)
									<.001	
[SMD T - P]									[-0.45	(-0.75, -0.16)]
Week 16		87	19.5 (15.17)				95	13.2 (13.81)		
Week 16 chg		87	-11.7 (12.88)	-11.54	(1.18)		95	-18.7 (13.43)	-18.52	(1.14)
LS Means (T - P) p-value									-6.97 (1.64)	(-10.2, -3.75)
									<.001	
[SMD T - P]									[-0.53	(-0.83, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Moderate [IGA=3]										
Baseline	51	51	23.0 (6.34)			49	49	24.6 (8.74)		
Week 2		51	18.3 (9.39)				49	16.6 (8.56)		
Week 2 chg		51	-4.7 (7.04)	-5.00	(1.31)		49	-8.0 (8.29)	-7.77	(1.34)
LS Means (T - P) p-value									-2.78	(1.88) (-6.48, 0.92)
									0.141	
[SMD T - P]									[-0.36 (-0.76, 0.03)]	
Week 4		48	18.1 (11.54)				48	13.7 (9.51)		
Week 4 chg		48	-5.0 (9.59)	-5.12	(1.34)		48	-11.0 (9.21)	-10.67	(1.35)
LS Means (T - P) p-value									-5.55	(1.90) (-9.30, -1.80)
									0.004	
[SMD T - P]									[-0.59 (-1.00, -0.18)]	
Week 6		49	15.4 (11.40)				47	12.3 (10.13)		
Week 6 chg		49	-7.7 (10.31)	-8.08	(1.33)		47	-12.4 (9.72)	-12.06	(1.35)
LS Means (T - P) p-value									-3.98	(1.90) (-7.73, -0.23)
									0.038	
[SMD T - P]									[-0.40 (-0.80, 0.01)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		48	14.2 (9.75)				48	10.4 (10.09)		
Week 8 chg		48	-9.1 (8.87)	-9.34	(1.33)		48	-14.3 (9.89)	-13.88	(1.35)
LS Means (T - P) p-value									-4.54	(1.90) (-8.28, -0.79)
						0.018				
[SMD T - P]									[-0.48 (-0.89, -0.08)]	
Week 10		47	14.3 (10.83)				45	10.9 (10.02)		
Week 10 chg		47	-9.1 (9.54)	-9.33	(1.34)		45	-13.9 (9.74)	-13.79	(1.37)
LS Means (T - P) p-value									-4.46	(1.92) (-8.24, -0.67)
						0.021				
[SMD T - P]									[-0.46 (-0.88, -0.05)]	
Week 12		49	14.0 (12.09)				46	10.8 (10.91)		
Week 12 chg		49	-9.2 (11.44)	-9.56	(1.33)		46	-13.9 (10.10)	-13.65	(1.36)
LS Means (T - P) p-value									-4.10	(1.91) (-7.86, -0.34)
						0.033				
[SMD T - P]									[-0.38 (-0.78, 0.03)]	
Week 14		45	12.9 (10.71)				47	10.6 (11.74)		
Week 14 chg		45	-10.1 (9.51)	-9.90	(1.36)		47	-14.2 (9.48)	-13.96	(1.35)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-4.06 (1.92)	(-7.84, -0.27)
						0.036				
[SMD T - P]						[-0.43			(-0.84, -0.01)]	
Week 16		47	14.3 (10.95)				47	10.9 (12.87)		
Week 16 chg		47	-8.5 (9.21)	-8.12	(1.34)		47	-13.8 (10.08)	-13.68	(1.35)
LS Means (T - P) p-value									-5.56 (1.91)	(-9.33, -1.78)
						0.004				
[SMD T - P]						[-0.58			(-0.99, -0.16)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Severe [IGA=4]										
Baseline	43	43	40.9 (15.40)			48	48	39.0 (14.51)		
Week 2		43	32.8 (17.31)				48	28.3 (13.13)		
Week 2 chg		43	-8.2 (12.59)	-7.72	(1.92)		48	-10.8 (11.12)	-11.15	(1.81)
LS Means (T - P) p-value									-3.43	(2.64) (-8.64, 1.78)
						0.195				
[SMD T - P]									[-0.29 (-0.70, 0.12)]	
Week 4		42	29.9 (17.64)				48	23.0 (14.46)		
Week 4 chg		42	-11.2 (13.88)	-10.81	(1.93)		48	-16.0 (12.73)	-16.40	(1.81)
LS Means (T - P) p-value									-5.59	(2.65) (-10.8, -0.36)
						0.036				
[SMD T - P]									[-0.42 (-0.84, -0.00)]	
Week 6		42	28.7 (14.91)				47	20.0 (15.94)		
Week 6 chg		42	-12.4 (13.21)	-11.83	(1.93)		47	-19.0 (16.09)	-19.63	(1.82)
LS Means (T - P) p-value									-7.80	(2.66) (-13.0, -2.55)
						0.004				
[SMD T - P]									[-0.53 (-0.95, -0.10)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		40	28.1 (16.86)				47	16.8 (14.06)		
Week 8 chg		40	-12.9 (15.12)	-12.21	(1.95)		47	-22.1 (13.41)	-22.75	(1.82)
LS Means (T - P) p-value								-10.55	(2.67)	(-15.8, -5.27)
						<.001				
[SMD T - P]						[-0.74		(-1.18, -0.31)]		
Week 10		39	27.4 (17.72)				48	15.7 (13.86)		
Week 10 chg		39	-13.4 (15.77)	-13.08	(1.96)		48	-23.4 (13.74)	-23.86	(1.81)
LS Means (T - P) p-value								-10.77	(2.68)	(-16.1, -5.50)
						<.001				
[SMD T - P]						[-0.73		(-1.17, -0.30)]		
Week 12		41	25.5 (15.66)				47	14.4 (12.52)		
Week 12 chg		41	-14.9 (17.08)	-14.55	(1.94)		47	-24.0 (15.77)	-24.31	(1.82)
LS Means (T - P) p-value								-9.77	(2.67)	(-15.0, -4.51)
						<.001				
[SMD T - P]						[-0.60		(-1.02, -0.17)]		
Week 14		38	25.6 (16.61)				48	14.8 (14.54)		
Week 14 chg		38	-15.4 (17.64)	-15.03	(1.98)		48	-24.2 (15.51)	-24.83	(1.81)

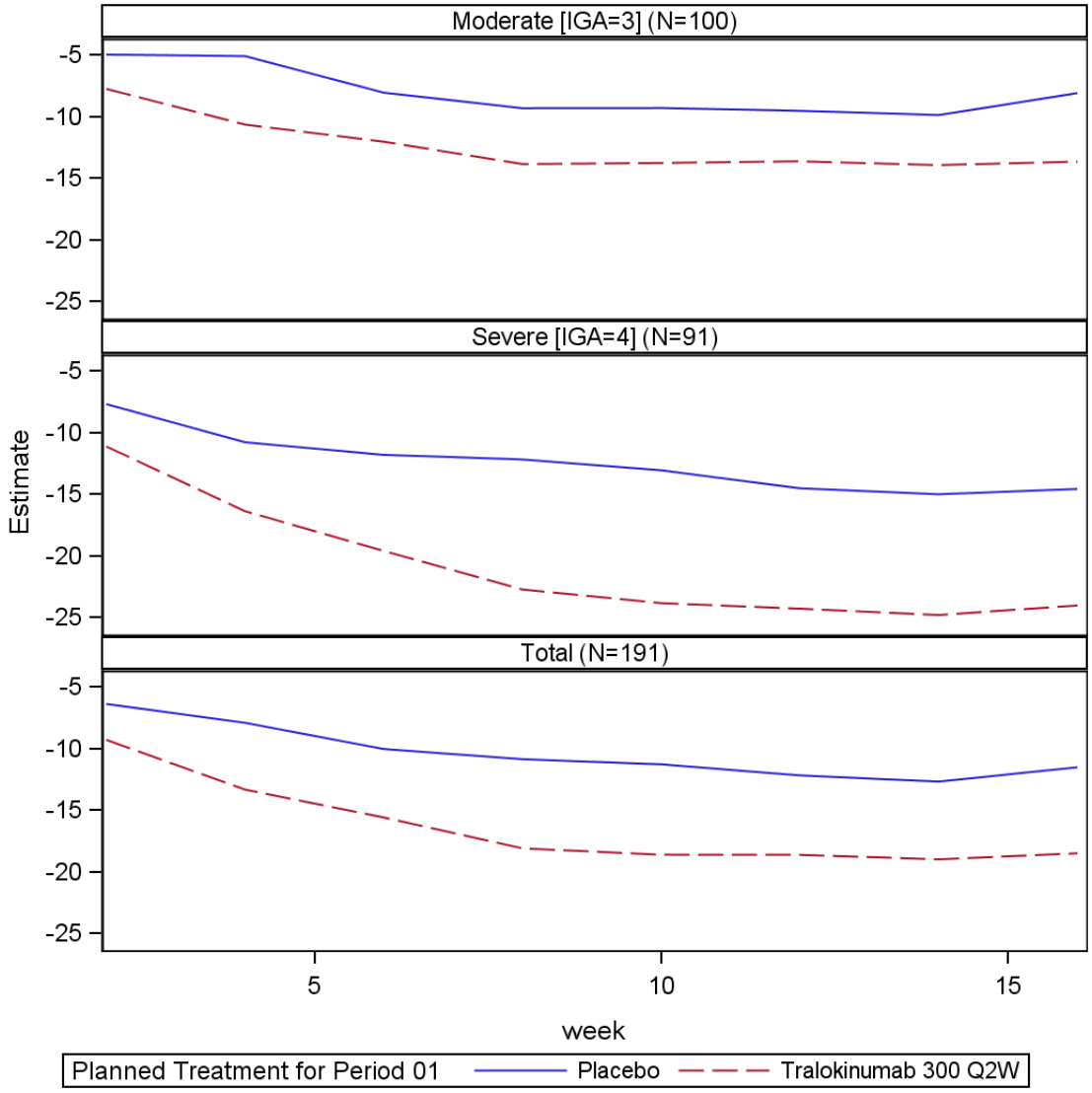
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.291.12.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-9.80 (2.69)	(-15.1, -4.50)
									<.001	
[SMD T - P]									[-0.59	(-1.03, -0.16)]
Week 16		40	25.7 (17.14)				48	15.5 (14.46)		
Week 16 chg		40	-15.4 (15.48)	-14.60	(1.95)		48	-23.6 (14.59)	-24.05	(1.81)
LS Means (T - P) p-value									-9.45 (2.67)	(-14.7, -4.19)
									<.001	
[SMD T - P]									[-0.63	(-1.06, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1166
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.7.291.12.2: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Interference With Sleep (eDiary)										
Total										
Baseline	94	92	6.8 (2.06)			97	96	6.8 (2.12)		
Week 1		91	6.4 (2.21)				94	6.1 (2.23)		
Week 1 chg		91	-0.4 (1.34)	-0.40	(0.23)		94	-0.7 (1.60)	-0.77	(0.23)
LS Means (T - P) p-value									-0.37	(0.32) (-1.00, 0.27)
						0.258				
[SMD T - P]						[-0.25 (-0.54, 0.04)]				
Week 2		90	6.0 (2.35)				94	5.8 (2.29)		
Week 2 chg		90	-0.8 (1.85)	-0.76	(0.23)		94	-1.1 (1.97)	-1.06	(0.23)
LS Means (T - P) p-value									-0.30	(0.32) (-0.94, 0.33)
						0.350				
[SMD T - P]						[-0.16 (-0.45, 0.13)]				
Week 3		89	5.7 (2.31)				94	5.3 (2.40)		
Week 3 chg		89	-1.1 (2.12)	-1.09	(0.23)		94	-1.5 (2.09)	-1.50	(0.23)
LS Means (T - P) p-value									-0.41	(0.32) (-1.05, 0.23)
						0.205				
[SMD T - P]						[-0.20 (-0.49, 0.09)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		89	5.5 (2.29)				91	5.2 (2.48)		
Week 4 chg		89	-1.3 (2.18)	-1.25	(0.23)		91	-1.5 (2.19)	-1.61	(0.23)
LS Means (T - P) p-value									-0.36	(0.33) (-1.00, 0.28)
						0.268				
[SMD T - P]						[-0.17 (-0.46, 0.13)]				
Week 5		85	5.1 (2.41)				94	4.9 (2.57)		
Week 5 chg		85	-1.7 (2.47)	-1.68	(0.23)		94	-1.9 (2.48)	-1.99	(0.23)
LS Means (T - P) p-value									-0.30	(0.33) (-0.95, 0.34)
						0.353				
[SMD T - P]						[-0.12 (-0.42, 0.17)]				
Week 6		86	4.9 (2.56)				92	4.9 (2.64)		
Week 6 chg		86	-1.9 (2.54)	-1.87	(0.23)		92	-1.9 (2.46)	-1.99	(0.23)
LS Means (T - P) p-value									-0.12	(0.33) (-0.76, 0.52)
						0.711				
[SMD T - P]						[-0.05 (-0.34, 0.25)]				
Week 7		82	4.8 (2.47)				91	4.7 (2.51)		
Week 7 chg		82	-2.1 (2.42)	-1.98	(0.24)		91	-2.1 (2.49)	-2.22	(0.23)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
LS Means (T - P) p-value						-0.24 (0.33) (-0.88, 0.41)
[SMD T - P]						0.466 [-0.10 (-0.40, 0.20)]
Week 8	85	4.6 (2.46)		91	4.6 (2.52)	
Week 8 chg	85	-2.2 (2.49)	-2.17 (0.23)	91	-2.3 (2.55)	-2.36 (0.23)
LS Means (T - P) p-value						-0.18 (0.33) (-0.83, 0.46)
[SMD T - P]						0.573 [-0.07 (-0.37, 0.22)]
Week 9	81	4.6 (2.26)		92	4.3 (2.55)	
Week 9 chg	81	-2.3 (2.30)	-2.17 (0.24)	92	-2.5 (2.55)	-2.59 (0.23)
LS Means (T - P) p-value						-0.42 (0.33) (-1.07, 0.22)
[SMD T - P]						0.199 [-0.17 (-0.47, 0.13)]
Week 10	83	4.4 (2.50)		89	4.2 (2.66)	
Week 10 chg	83	-2.5 (2.44)	-2.28 (0.24)	89	-2.6 (2.77)	-2.64 (0.23)
LS Means (T - P) p-value						-0.35 (0.33) (-1.00, 0.29)
[SMD T - P]						0.281 [-0.14 (-0.44, 0.16)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		79	4.4 (2.41)				88	4.2 (2.62)		
Week 11 chg		79	-2.4 (2.45)	-2.26	(0.24)		88	-2.5 (2.61)	-2.71	(0.23)
LS Means (T - P) p-value									-0.46	(0.33) (-1.10, 0.19)
						0.169				
[SMD T - P]									[-0.18 (-0.48, 0.12)]	
Week 12		85	4.5 (2.40)				88	4.3 (2.65)		
Week 12 chg		85	-2.3 (2.64)	-2.23	(0.23)		88	-2.5 (2.55)	-2.66	(0.23)
LS Means (T - P) p-value									-0.43	(0.33) (-1.07, 0.22)
						0.191				
[SMD T - P]									[-0.17 (-0.46, 0.13)]	
Week 13		81	4.3 (2.44)				90	4.1 (2.57)		
Week 13 chg		81	-2.4 (2.57)	-2.31	(0.24)		90	-2.8 (2.62)	-2.83	(0.23)
LS Means (T - P) p-value									-0.52	(0.33) (-1.17, 0.12)
						0.112				
[SMD T - P]									[-0.20 (-0.50, 0.10)]	
Week 14		79	4.3 (2.60)				86	3.9 (2.63)		
Week 14 chg		79	-2.7 (2.69)	-2.36	(0.24)		86	-2.8 (2.66)	-2.90	(0.23)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.54 (0.33)	(-1.19, 0.11)
						0.105				
[SMD T - P]						[-0.20			(-0.51, 0.10)]	
Week 15	77	77	4.3 (2.43)			84	84	3.8 (2.53)		
Week 15 chg	77	77	-2.7 (2.57)	-2.39	(0.24)	84	84	-3.0 (2.64)	-3.06	(0.23)
LS Means (T - P) p-value									-0.67 (0.33)	(-1.32, -0.02)
						0.044				
[SMD T - P]						[-0.26			(-0.57, 0.05)]	
Week 16	78	78	4.6 (2.48)			88	88	3.8 (2.56)		
Week 16 chg	78	78	-2.4 (2.58)	-2.17	(0.24)	88	88	-3.0 (2.69)	-3.00	(0.23)
LS Means (T - P) p-value									-0.83 (0.33)	(-1.48, -0.18)
						0.013				
[SMD T - P]						[-0.31			(-0.62, -0.01)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Moderate [IGA=3]										
Baseline	51	50	6.5 (1.87)			49	49	6.3 (2.23)		
Week 1		49	6.1 (2.00)				48	5.6 (2.32)		
Week 1 chg		49	-0.3 (1.19)	-0.30	(0.31)		48	-0.7 (1.77)	-0.77	(0.31)
LS Means (T - P) p-value									-0.48	(0.44) (-1.34, 0.38)
						0.277				
[SMD T - P]									[-0.32 (-0.72, 0.09)]	
Week 2		48	5.9 (2.26)				47	5.4 (2.33)		
Week 2 chg		48	-0.6 (1.77)	-0.56	(0.31)		47	-1.0 (2.13)	-0.97	(0.31)
LS Means (T - P) p-value									-0.41	(0.44) (-1.27, 0.45)
						0.351				
[SMD T - P]									[-0.21 (-0.61, 0.19)]	
Week 3		49	5.7 (2.23)				48	5.1 (2.36)		
Week 3 chg		49	-0.8 (1.98)	-0.79	(0.31)		48	-1.3 (2.08)	-1.31	(0.31)
LS Means (T - P) p-value									-0.52	(0.44) (-1.38, 0.34)
						0.238				
[SMD T - P]									[-0.25 (-0.65, 0.15)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		48	5.4 (2.12)				46	5.0 (2.54)		
Week 4 chg		48	-1.1 (1.96)	-0.99	(0.31)		46	-1.2 (2.30)	-1.37	(0.31)
LS Means (T - P) p-value									-0.38	(0.44) (-1.25, 0.49)
						0.389				
[SMD T - P]									[-0.18 (-0.58, 0.23)]	
Week 5		45	5.0 (2.27)				48	4.6 (2.45)		
Week 5 chg		45	-1.5 (2.26)	-1.45	(0.31)		48	-1.7 (2.40)	-1.86	(0.31)
LS Means (T - P) p-value									-0.40	(0.44) (-1.27, 0.47)
						0.361				
[SMD T - P]									[-0.17 (-0.58, 0.23)]	
Week 6		47	4.6 (2.49)				46	4.5 (2.47)		
Week 6 chg		47	-1.9 (2.56)	-1.78	(0.31)		46	-1.9 (2.45)	-2.06	(0.31)
LS Means (T - P) p-value									-0.29	(0.44) (-1.16, 0.58)
						0.514				
[SMD T - P]									[-0.11 (-0.52, 0.29)]	
Week 7		43	4.4 (2.41)				45	4.4 (2.51)		
Week 7 chg		43	-2.3 (2.43)	-2.03	(0.31)		45	-1.9 (2.64)	-2.11	(0.31)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.08 (0.44)	(-0.95, 0.80)
[SMD T - P]									0.865 [-0.03	(-0.45, 0.39)]
Week 8		45	4.3 (2.47)				45	4.3 (2.51)		
Week 8 chg		45	-2.2 (2.56)	-2.09	(0.31)		45	-2.0 (2.71)	-2.22	(0.31)
LS Means (T - P) p-value									-0.12 (0.44)	(-0.99, 0.75)
[SMD T - P]									0.783 [-0.05	(-0.46, 0.37)]
Week 9		42	4.4 (2.25)				46	3.9 (2.37)		
Week 9 chg		42	-2.2 (2.22)	-2.05	(0.32)		46	-2.3 (2.72)	-2.58	(0.31)
LS Means (T - P) p-value									-0.53 (0.44)	(-1.40, 0.35)
[SMD T - P]									0.236 [-0.21	(-0.63, 0.21)]
Week 10		44	4.2 (2.64)				45	4.1 (2.50)		
Week 10 chg		44	-2.4 (2.44)	-2.14	(0.31)		45	-2.3 (2.79)	-2.47	(0.31)
LS Means (T - P) p-value									-0.33 (0.44)	(-1.21, 0.54)
[SMD T - P]									0.457 [-0.13	(-0.54, 0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		41	4.1 (2.43)				46	4.1 (2.47)		
Week 11 chg		41	-2.5 (2.35)	-2.19	(0.32)		46	-2.1 (2.46)	-2.45	(0.31)
LS Means (T - P) p-value									-0.26	(0.45) (-1.14, 0.62)
						0.564				
[SMD T - P]									[-0.11 (-0.53, 0.31)]	
Week 12		45	4.2 (2.51)				45	4.2 (2.56)		
Week 12 chg		45	-2.1 (2.71)	-2.08	(0.31)		45	-2.1 (2.57)	-2.48	(0.31)
LS Means (T - P) p-value									-0.40	(0.44) (-1.27, 0.47)
						0.363				
[SMD T - P]									[-0.15 (-0.57, 0.26)]	
Week 13		44	3.9 (2.39)				45	3.9 (2.50)		
Week 13 chg		44	-2.5 (2.46)	-2.29	(0.31)		45	-2.4 (2.71)	-2.64	(0.31)
LS Means (T - P) p-value									-0.35	(0.44) (-1.23, 0.52)
						0.428				
[SMD T - P]									[-0.14 (-0.55, 0.28)]	
Week 14		44	4.1 (2.50)				43	3.9 (2.49)		
Week 14 chg		44	-2.4 (2.49)	-2.14	(0.31)		43	-2.4 (2.64)	-2.68	(0.32)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.54 (0.44)	(-1.41, 0.34)
						0.230				
[SMD T - P]						[-0.21 (-0.63, 0.21)]				
Week 15	40	40	3.9 (2.42)			42	42	3.7 (2.49)		
Week 15 chg	40	40	-2.7 (2.45)	-2.37	(0.32)	42	42	-2.6 (2.67)	-2.85	(0.32)
LS Means (T - P) p-value									-0.47 (0.45)	(-1.36, 0.41)
						0.294				
[SMD T - P]						[-0.18 (-0.62, 0.25)]				
Week 16	41	41	4.2 (2.46)			44	44	3.6 (2.44)		
Week 16 chg	41	41	-2.5 (2.45)	-2.18	(0.32)	44	44	-2.7 (2.75)	-2.90	(0.31)
LS Means (T - P) p-value									-0.72 (0.45)	(-1.60, 0.16)
						0.110				
[SMD T - P]						[-0.28 (-0.70, 0.15)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Severe [IGA=4]										
Baseline	43	42	7.1 (2.24)			48	47	7.3 (1.89)		
Week 1		42	6.6 (2.44)				46	6.5 (2.05)		
Week 1 chg		42	-0.5 (1.50)	-0.48	(0.35)		46	-0.8 (1.41)	-0.80	(0.33)
LS Means (T - P) p-value									-0.32	(0.49) (-1.28, 0.64)
						0.515				
[SMD T - P]									[-0.22 (-0.64, 0.20)]	
Week 2		42	6.2 (2.46)				47	6.1 (2.23)		
Week 2 chg		42	-0.9 (1.94)	-0.95	(0.35)		47	-1.2 (1.82)	-1.20	(0.33)
LS Means (T - P) p-value									-0.25	(0.49) (-1.21, 0.71)
						0.605				
[SMD T - P]									[-0.13 (-0.55, 0.28)]	
Week 3		40	5.7 (2.44)				46	5.6 (2.45)		
Week 3 chg		40	-1.5 (2.25)	-1.40	(0.36)		46	-1.8 (2.11)	-1.74	(0.33)
LS Means (T - P) p-value									-0.33	(0.49) (-1.30, 0.63)
						0.497				
[SMD T - P]									[-0.15 (-0.58, 0.27)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		41	5.6 (2.50)				45	5.5 (2.43)		
Week 4 chg		41	-1.6 (2.42)	-1.50	(0.35)		45	-1.8 (2.05)	-1.89	(0.33)
LS Means (T - P) p-value									-0.38	(0.49) (-1.35, 0.58)
						0.434				
[SMD T - P]						[-0.17 (-0.60, 0.25)]				
Week 5		40	5.2 (2.59)				46	5.2 (2.68)		
Week 5 chg		40	-1.9 (2.70)	-1.91	(0.36)		46	-2.1 (2.56)	-2.15	(0.33)
LS Means (T - P) p-value									-0.24	(0.49) (-1.20, 0.73)
						0.628				
[SMD T - P]						[-0.09 (-0.51, 0.33)]				
Week 6		39	5.3 (2.64)				46	5.4 (2.75)		
Week 6 chg		39	-2.0 (2.55)	-1.92	(0.36)		46	-1.9 (2.50)	-1.96	(0.33)
LS Means (T - P) p-value									-0.04	(0.49) (-1.01, 0.92)
						0.928				
[SMD T - P]						[-0.02 (-0.44, 0.41)]				
Week 7		39	5.4 (2.46)				46	5.0 (2.50)		
Week 7 chg		39	-1.9 (2.43)	-1.88	(0.36)		46	-2.4 (2.35)	-2.39	(0.33)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.51 (0.49)	(-1.47, 0.46)
						0.303				
[SMD T - P]						[-0.21			(-0.64, 0.22)]	
Week 8	40	40	4.9 (2.44)			46	46	4.8 (2.55)		
Week 8 chg	40	40	-2.3 (2.46)	-2.21	(0.36)	46	46	-2.5 (2.38)	-2.55	(0.33)
LS Means (T - P) p-value									-0.34 (0.49)	(-1.30, 0.63)
						0.489				
[SMD T - P]						[-0.14			(-0.56, 0.28)]	
Week 9	39	39	4.8 (2.29)			46	46	4.7 (2.69)		
Week 9 chg	39	39	-2.4 (2.40)	-2.24	(0.36)	46	46	-2.7 (2.39)	-2.67	(0.33)
LS Means (T - P) p-value									-0.43 (0.49)	(-1.39, 0.54)
						0.385				
[SMD T - P]						[-0.18			(-0.61, 0.25)]	
Week 10	39	39	4.7 (2.35)			44	44	4.4 (2.84)		
Week 10 chg	39	39	-2.6 (2.46)	-2.39	(0.36)	44	44	-2.9 (2.74)	-2.85	(0.34)
LS Means (T - P) p-value									-0.46 (0.49)	(-1.43, 0.51)
						0.353				
[SMD T - P]						[-0.18			(-0.61, 0.26)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		38	4.8 (2.36)				42	4.3 (2.79)		
Week 11 chg		38	-2.4 (2.59)	-2.28	(0.36)		42	-3.0 (2.71)	-3.02	(0.34)
LS Means (T - P) p-value								-0.74 (0.49) (-1.71, 0.24)		
						0.136				
[SMD T - P]						[-0.28 (-0.72, 0.16)]				
Week 12		40	4.7 (2.28)				43	4.4 (2.77)		
Week 12 chg		40	-2.5 (2.58)	-2.35	(0.36)		43	-2.9 (2.48)	-2.89	(0.34)
LS Means (T - P) p-value								-0.54 (0.49) (-1.51, 0.43)		
						0.274				
[SMD T - P]						[-0.21 (-0.64, 0.22)]				
Week 13		37	4.8 (2.45)				45	4.2 (2.65)		
Week 13 chg		37	-2.4 (2.73)	-2.28	(0.36)		45	-3.1 (2.53)	-3.08	(0.34)
LS Means (T - P) p-value								-0.80 (0.49) (-1.77, 0.17)		
						0.106				
[SMD T - P]						[-0.30 (-0.74, 0.13)]				
Week 14		35	4.6 (2.72)				43	3.9 (2.80)		
Week 14 chg		35	-3.0 (2.92)	-2.58	(0.36)		43	-3.2 (2.64)	-3.17	(0.34)

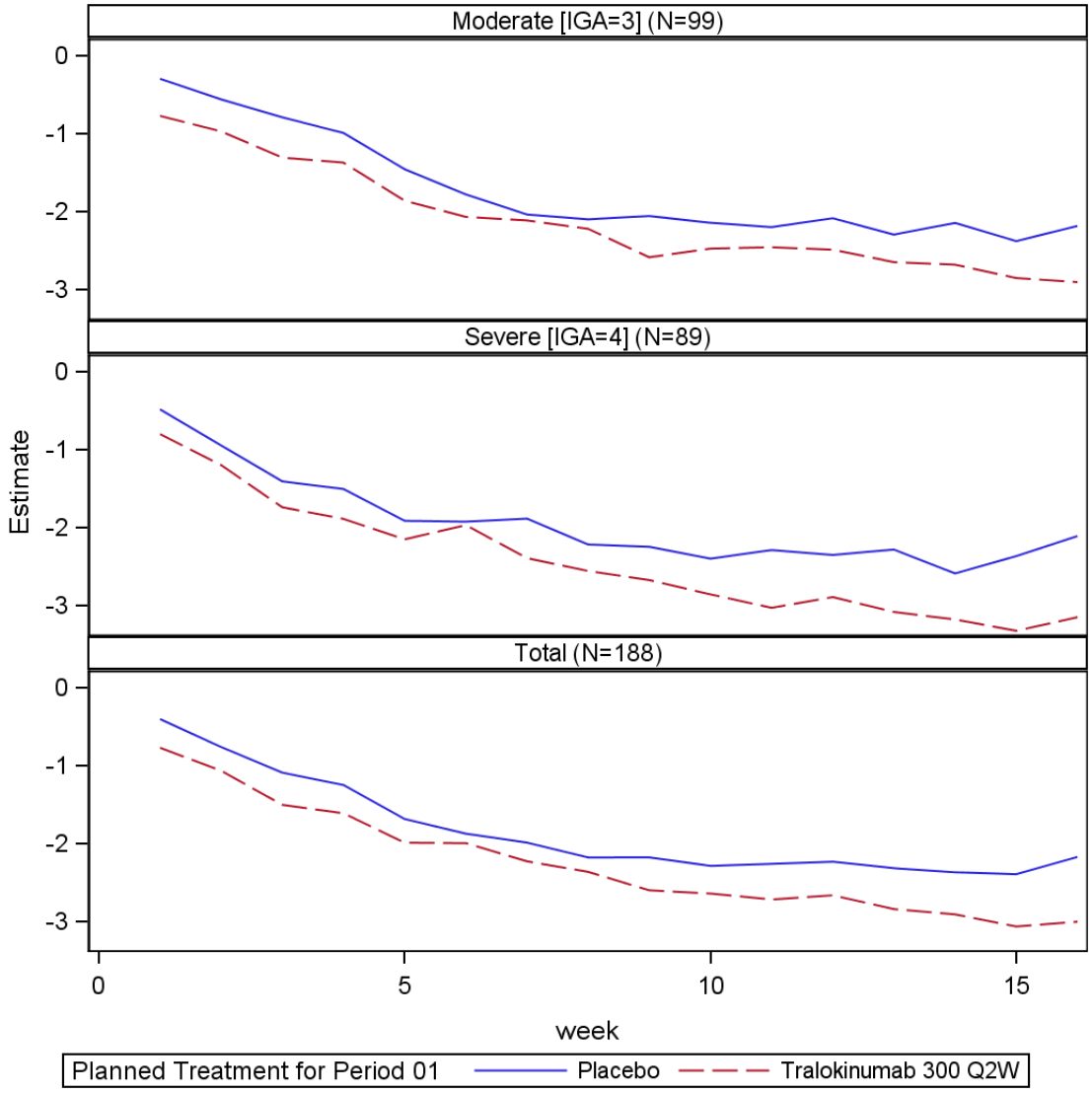
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.295.12.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.59 (0.50)	(-1.57, 0.39)
									0.238	
[SMD T - P]									[-0.21	(-0.66, 0.23)]
Week 15		37	4.7 (2.41)				42	3.8 (2.58)		
Week 15 chg		37	-2.6 (2.72)	-2.36	(0.36)		42	-3.4 (2.58)	-3.32	(0.34)
LS Means (T - P) p-value									-0.96 (0.49)	(-1.93, 0.02)
									0.055	
[SMD T - P]									[-0.36	(-0.81, 0.08)]
Week 16		37	5.0 (2.47)				44	4.1 (2.68)		
Week 16 chg		37	-2.4 (2.75)	-2.10	(0.36)		44	-3.2 (2.64)	-3.14	(0.34)
LS Means (T - P) p-value									-1.04 (0.49)	(-2.01, -0.06)
									0.037	
[SMD T - P]									[-0.39	(-0.83, 0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8053
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.7.295.12.2: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
SCORAD Score										
Total										
Baseline	94	94	67.4 (14.91)			97	97	68.3 (13.71)		
Week 2		94	59.2 (18.89)				97	55.4 (15.59)		
Week 2 chg		94	-8.2 (14.01)	-8.28	(1.79)		97	-12.9 (12.97)	-12.78	(1.76)
LS Means (T - P) p-value									-4.50	(2.51) (-9.43, 0.43)
						0.073				
[SMD T - P]									[-0.33 (-0.62, -0.05)]	
Week 4		90	54.7 (20.17)				96	49.3 (16.99)		
Week 4 chg		90	-12.6 (16.38)	-12.88	(1.81)		96	-19.2 (16.02)	-18.86	(1.76)
LS Means (T - P) p-value									-5.98	(2.53) (-11.0, -1.02)
						0.018				
[SMD T - P]									[-0.37 (-0.66, -0.08)]	
Week 6		91	52.1 (20.65)				94	43.6 (19.42)		
Week 6 chg		91	-15.3 (17.61)	-15.57	(1.80)		94	-24.7 (18.93)	-24.40	(1.77)
LS Means (T - P) p-value									-8.84	(2.53) (-13.8, -3.87)
						<.001				
[SMD T - P]									[-0.48 (-0.78, -0.19)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		88	49.6 (20.33)				95	40.9 (18.23)		
Week 8 chg		88	-17.4 (17.17)	-17.65	(1.82)		95	-27.4 (17.97)	-27.17	(1.77)
LS Means (T - P) p-value									-9.52	(2.54) (-14.5, -4.54)
						<.001				
[SMD T - P]						[-0.54 (-0.84, -0.25)]				
Week 10		86	49.3 (20.83)				93	39.0 (19.16)		
Week 10 chg		86	-17.8 (19.00)	-17.91	(1.83)		93	-29.8 (18.96)	-29.52	(1.78)
LS Means (T - P) p-value									-11.62	(2.55) (-16.6, -6.60)
						<.001				
[SMD T - P]						[-0.61 (-0.91, -0.31)]				
Week 12		90	48.6 (20.94)				93	39.5 (19.84)		
Week 12 chg		90	-18.5 (18.90)	-18.67	(1.81)		93	-28.6 (20.28)	-28.16	(1.78)
LS Means (T - P) p-value									-9.50	(2.54) (-14.5, -4.51)
						<.001				
[SMD T - P]						[-0.48 (-0.78, -0.19)]				
Week 14		83	46.0 (20.48)				95	37.9 (20.73)		
Week 14 chg		83	-20.6 (18.53)	-20.64	(1.84)		95	-30.5 (20.04)	-30.11	(1.77)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-9.47 (2.56)	(-14.5, -4.45)
						<.001				
[SMD T - P]						[-0.49			(-0.79, -0.19)]	
Week 16		87	50.1 (20.98)				95	38.3 (20.94)		
Week 16 chg		87	-16.5 (18.56)	-16.36	(1.82)		95	-30.2 (21.40)	-29.74	(1.77)
LS Means (T - P) p-value									-13.37 (2.54)	(-18.4, -8.38)
						<.001				
[SMD T - P]						[-0.67			(-0.96, -0.37)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Moderate [IGA=3]										
Baseline	51	51	58.9 (11.57)			49	49	60.2 (10.97)		
Week 2		51	52.0 (16.51)				49	48.6 (13.44)		
Week 2 chg		51	-6.9 (11.04)	-6.86	(2.28)		49	-11.6 (12.03)	-11.58	(2.33)
LS Means (T - P) p-value									-4.72	(3.27) (-11.2, 1.72)
						0.150				
[SMD T - P]								[-0.41 (-0.81, -0.01)]		
Week 4		48	48.9 (19.42)				48	43.8 (15.85)		
Week 4 chg		48	-9.5 (15.32)	-9.65	(2.32)		48	-16.5 (16.11)	-16.23	(2.35)
LS Means (T - P) p-value									-6.57	(3.31) (-13.1, -0.05)
						0.048				
[SMD T - P]								[-0.42 (-0.82, -0.01)]		
Week 6		49	45.5 (18.93)				47	38.9 (16.94)		
Week 6 chg		49	-13.1 (16.37)	-13.38	(2.31)		47	-21.2 (17.22)	-20.74	(2.36)
LS Means (T - P) p-value									-7.36	(3.31) (-13.9, -0.83)
						0.027				
[SMD T - P]								[-0.44 (-0.84, -0.03)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		48	42.6 (18.09)				48	37.2 (17.50)		
Week 8 chg		48	-15.8 (15.19)	-15.88	(2.32)		48	-23.1 (17.72)	-22.73	(2.35)
LS Means (T - P) p-value									-6.86	(3.31) (-13.4, -0.33)
									0.040	
[SMD T - P]									[-0.42 (-0.82, -0.01)]	
Week 10		47	42.8 (19.40)				45	35.0 (16.60)		
Week 10 chg		47	-15.8 (17.71)	-15.98	(2.33)		45	-25.3 (17.78)	-25.31	(2.38)
LS Means (T - P) p-value									-9.33	(3.34) (-15.9, -2.74)
									0.006	
[SMD T - P]									[-0.53 (-0.94, -0.11)]	
Week 12		49	42.2 (19.98)				46	35.3 (16.66)		
Week 12 chg		49	-16.5 (18.21)	-16.79	(2.31)		46	-24.6 (17.80)	-24.52	(2.37)
LS Means (T - P) p-value									-7.73	(3.32) (-14.3, -1.19)
									0.021	
[SMD T - P]									[-0.43 (-0.84, -0.02)]	
Week 14		45	39.6 (18.75)				47	34.0 (19.10)		
Week 14 chg		45	-18.3 (16.09)	-17.91	(2.36)		47	-26.2 (18.20)	-25.81	(2.36)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-7.90 (3.35)	(-14.5, -1.30)
						0.019				
[SMD T - P]						[-0.46 (-0.87, -0.05)]				
Week 16		47	44.1 (18.52)				47	35.1 (19.70)		
Week 16 chg		47	-13.9 (16.02)	-13.59 (2.34)			47	-25.0 (20.13)	-24.57 (2.36)	
LS Means (T - P) p-value									-10.97 (3.33)	(-17.5, -4.41)
						0.001				
[SMD T - P]						[-0.60 (-1.02, -0.19)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Severe [IGA=4]										
Baseline	43	43	77.4 (11.92)			48	48	76.6 (11.00)		
Week 2		43	67.7 (18.10)				48	62.4 (14.62)		
Week 2 chg		43	-9.7 (16.90)	-9.29	(2.77)		48	-14.3 (13.86)	-14.53	(2.62)
LS Means (T - P) p-value									-5.24	(3.81) (-12.8, 2.28)
						0.171				
[SMD T - P]									[-0.34 (-0.76, 0.07)]	
Week 4		42	61.4 (19.12)				48	54.8 (16.45)		
Week 4 chg		42	-16.3 (16.97)	-16.02	(2.78)		48	-21.8 (15.64)	-22.06	(2.62)
LS Means (T - P) p-value									-6.04	(3.82) (-13.6, 1.50)
						0.116				
[SMD T - P]									[-0.37 (-0.79, 0.05)]	
Week 6		42	59.8 (20.09)				47	48.3 (20.75)		
Week 6 chg		42	-17.8 (18.83)	-17.54	(2.78)		47	-28.2 (20.07)	-28.60	(2.63)
LS Means (T - P) p-value									-11.06	(3.83) (-18.6, -3.50)
						0.004				
[SMD T - P]									[-0.57 (-0.99, -0.14)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		40	58.0 (19.90)				47	44.7 (18.36)		
Week 8 chg		40	-19.4 (19.31)	-19.05	(2.82)		47	-31.8 (17.34)	-32.19	(2.63)
LS Means (T - P) p-value								-13.13	(3.85)	(-20.7, -5.53)
						<.001				
[SMD T - P]						[-0.72		(-1.15, -0.28)]		
Week 10		39	57.1 (19.99)				48	42.7 (20.76)		
Week 10 chg		39	-20.3 (20.41)	-19.58	(2.83)		48	-33.9 (19.26)	-34.20	(2.62)
LS Means (T - P) p-value								-14.62	(3.86)	(-22.2, -7.01)
						<.001				
[SMD T - P]						[-0.74		(-1.18, -0.30)]		
Week 12		41	56.2 (19.65)				47	43.5 (21.95)		
Week 12 chg		41	-20.9 (19.66)	-20.28	(2.80)		47	-32.6 (21.91)	-32.32	(2.63)
LS Means (T - P) p-value								-12.03	(3.84)	(-19.6, -4.45)
						0.002				
[SMD T - P]						[-0.58		(-1.00, -0.15)]		
Week 14		38	53.6 (20.06)				48	41.8 (21.70)		
Week 14 chg		38	-23.4 (20.96)	-22.95	(2.85)		48	-34.8 (21.01)	-35.09	(2.62)

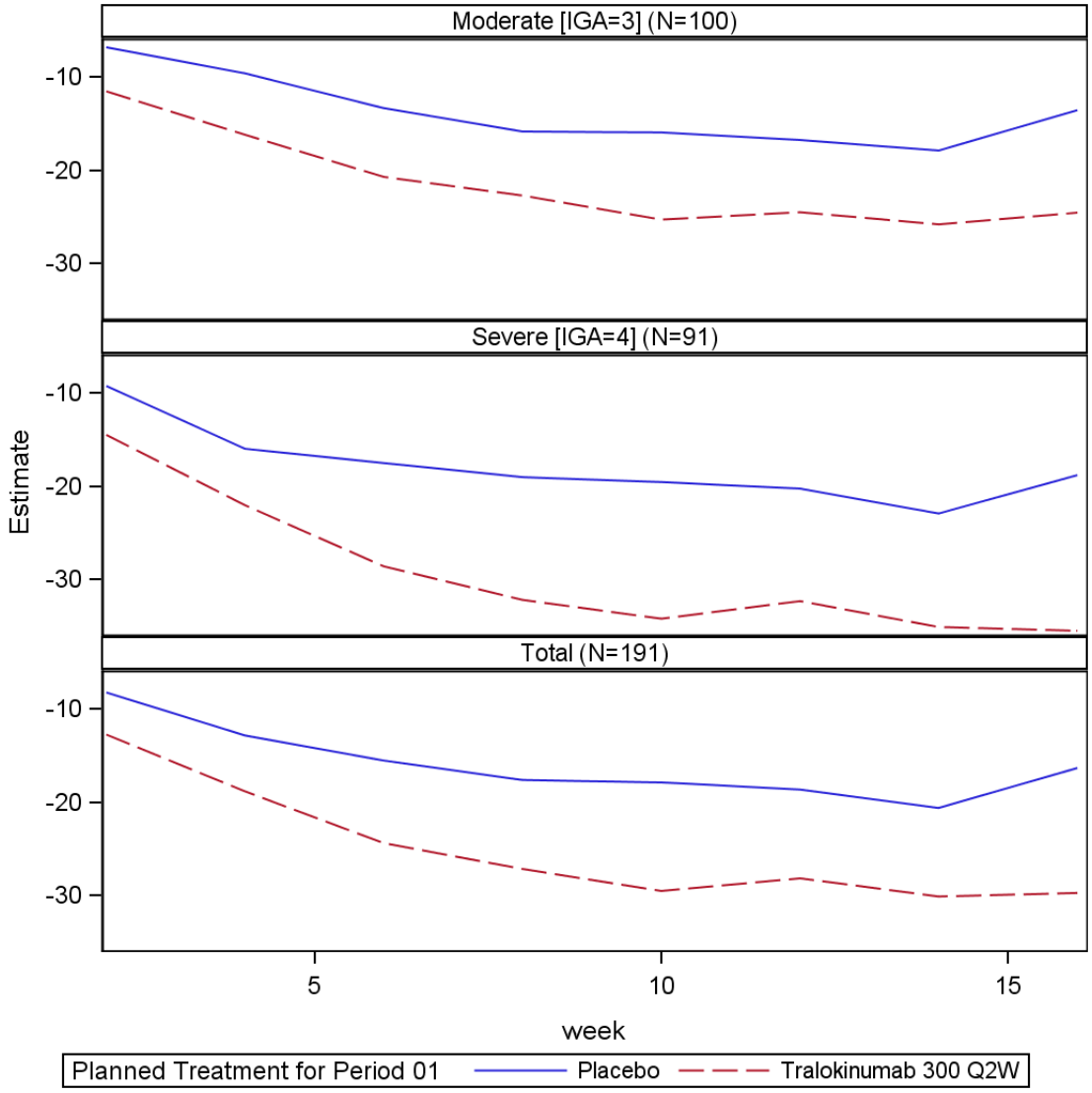
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.297.12.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-12.15 (3.87)	(-19.8, -4.51)
									0.002	
[SMD T - P]									[-0.58	(-1.01, -0.14)]
Week 16		40	57.2 (21.68)				48	41.4 (21.84)		
Week 16 chg		40	-19.7 (20.93)	-18.83	(2.81)		48	-35.2 (21.61)	-35.50	(2.62)
LS Means (T - P) p-value									-16.66 (3.84)	(-24.2, -9.08)
									<.001	
[SMD T - P]									[-0.78	(-1.22, -0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9032
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.7.297.12.2: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.300.12.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
POEM Total										
Total										
Baseline	94	87	20.8 (5.59)			97	94	20.1 (5.83)		
Week 2		86	18.1 (6.90)				93	15.7 (6.02)		
Week 2 chg		86	-2.6 (6.14)	-2.47	(0.68)		93	-4.4 (5.26)	-4.56	(0.65)
LS Means (T - P) p-value									-2.09	(0.94) (-3.95, -0.23)
						0.027				
[SMD T - P]									[-0.37 (-0.66, -0.07)]	
Week 4		82	16.4 (6.70)				91	13.8 (6.32)		
Week 4 chg		82	-4.1 (6.82)	-4.21	(0.69)		91	-6.3 (6.66)	-6.45	(0.66)
LS Means (T - P) p-value									-2.24	(0.95) (-4.11, -0.36)
						0.019				
[SMD T - P]									[-0.33 (-0.63, -0.03)]	
Week 6		82	16.1 (7.75)				91	12.8 (6.65)		
Week 6 chg		82	-4.7 (7.86)	-4.56	(0.69)		91	-7.3 (6.81)	-7.44	(0.66)
LS Means (T - P) p-value									-2.88	(0.95) (-4.76, -1.00)
						0.003				
[SMD T - P]									[-0.39 (-0.69, -0.09)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4866
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.300.12.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		82	14.9 (7.61)				91	11.7 (6.15)		
Week 8 chg		82	-5.8 (7.71)	-5.62	(0.69)		91	-8.4 (6.83)	-8.63	(0.66)
LS Means (T - P) p-value									-3.00	(0.95) (-4.88, -1.13)
									0.002	
[SMD T - P]									[-0.41	(-0.72, -0.11)]
Week 12		83	15.8 (7.32)				88	11.8 (6.80)		
Week 12 chg		83	-4.8 (7.40)	-4.68	(0.69)		88	-8.3 (7.29)	-8.34	(0.66)
LS Means (T - P) p-value									-3.67	(0.96) (-5.55, -1.79)
									<.001	
[SMD T - P]									[-0.50	(-0.80, -0.20)]
Week 16		83	16.1 (7.33)				92	11.4 (6.80)		
Week 16 chg		83	-4.6 (8.00)	-4.34	(0.69)		92	-8.7 (7.18)	-8.78	(0.66)
LS Means (T - P) p-value									-4.44	(0.95) (-6.31, -2.57)
									<.001	
[SMD T - P]									[-0.59	(-0.89, -0.28)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4866
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.300.12.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Moderate [IGA=3]										
Baseline	51	46	19.5 (5.26)			49	46	18.7 (5.50)		
Week 2		45	16.5 (6.71)				46	15.5 (5.64)		
Week 2 chg		45	-2.8 (5.70)	-2.70	(0.86)		46	-3.2 (4.45)	-3.30	(0.85)
LS Means (T - P) p-value									-0.61	(1.21) (-2.99, 1.78)
						0.618				
[SMD T - P]									[-0.12 (-0.53, 0.29)]	
Week 4		43	15.6 (6.55)				44	13.2 (5.45)		
Week 4 chg		43	-3.4 (6.37)	-3.38	(0.87)		44	-5.5 (6.24)	-5.63	(0.86)
LS Means (T - P) p-value									-2.25	(1.23) (-4.68, 0.17)
						0.068				
[SMD T - P]									[-0.36 (-0.78, 0.07)]	
Week 6		42	14.7 (7.55)				44	11.4 (5.56)		
Week 6 chg		42	-4.8 (6.99)	-4.53	(0.88)		44	-7.1 (5.74)	-7.20	(0.87)
LS Means (T - P) p-value									-2.67	(1.24) (-5.11, -0.23)
						0.032				
[SMD T - P]									[-0.42 (-0.85, 0.01)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4866
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.300.12.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		43	14.3 (7.67)				45	10.6 (5.63)		
Week 8 chg		43	-5.0 (7.39)	-4.69	(0.87)		45	-8.0 (6.31)	-8.12	(0.86)
LS Means (T - P) p-value									-3.43	(1.23) (-5.85, -1.01)
									0.006	
[SMD T - P]									[-0.50	(-0.92, -0.08)]
Week 12		43	15.1 (6.96)				42	10.5 (5.91)		
Week 12 chg		43	-4.0 (6.34)	-3.87	(0.87)		42	-7.8 (6.26)	-8.00	(0.88)
LS Means (T - P) p-value									-4.13	(1.24) (-6.57, -1.69)
									0.001	
[SMD T - P]									[-0.66	(-1.09, -0.22)]
Week 16		43	15.3 (6.64)				44	11.2 (5.82)		
Week 16 chg		43	-3.9 (6.89)	-3.59	(0.87)		44	-7.4 (6.18)	-7.52	(0.87)
LS Means (T - P) p-value									-3.93	(1.23) (-6.36, -1.51)
									0.002	
[SMD T - P]									[-0.60	(-1.03, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4866
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.300.12.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Severe [IGA=4]										
Baseline	43	41	22.2 (5.66)			48	48	21.5 (5.85)		
Week 2		41	19.9 (6.74)				47	15.9 (6.43)		
Week 2 chg		41	-2.3 (6.65)	-2.16	(1.07)		47	-5.6 (5.76)	-5.83	(0.99)
LS Means (T - P) p-value									-3.67	(1.46) (-6.55, -0.78)
						0.013				
[SMD T - P]									[-0.59	(-1.02, -0.16)]
Week 4		39	17.3 (6.85)				47	14.5 (7.03)		
Week 4 chg		39	-4.9 (7.28)	-5.07	(1.08)		47	-7.0 (7.02)	-7.30	(0.99)
LS Means (T - P) p-value									-2.23	(1.47) (-5.13, 0.68)
						0.132				
[SMD T - P]									[-0.31	(-0.74, 0.12)]
Week 6		40	17.5 (7.79)				47	14.1 (7.36)		
Week 6 chg		40	-4.7 (8.76)	-4.54	(1.08)		47	-7.5 (7.74)	-7.76	(0.99)
LS Means (T - P) p-value									-3.22	(1.47) (-6.12, -0.32)
						0.030				
[SMD T - P]									[-0.39	(-0.82, 0.03)]

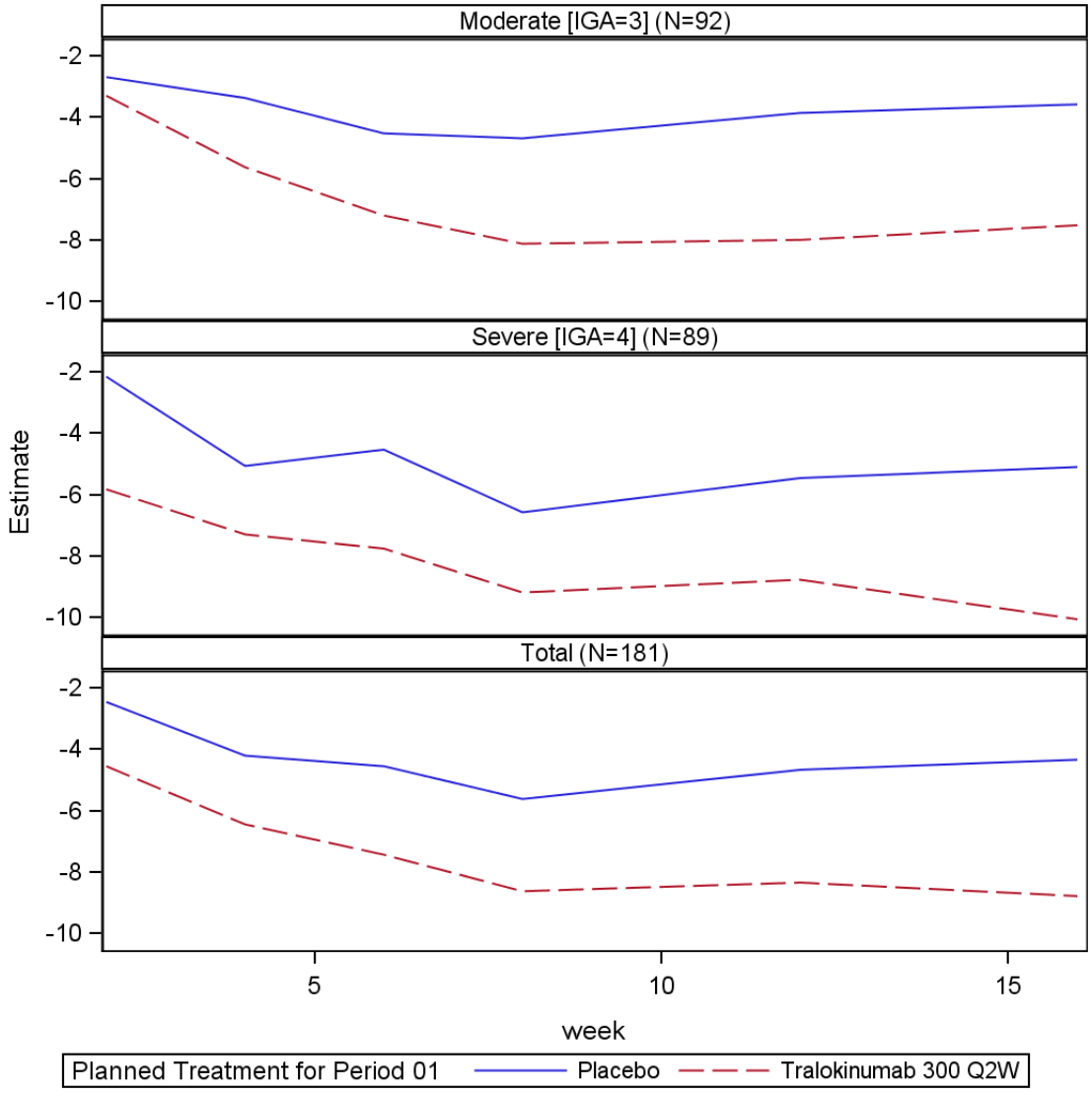
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4866
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.300.12.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		39	15.6 (7.59)				46	12.8 (6.50)		
Week 8 chg		39	-6.7 (8.04)	-6.58	(1.08)		46	-8.8 (7.34)	-9.19	(1.00)
LS Means (T - P) p-value									-2.61	(1.48) (-5.52, 0.30)
						0.079				
[SMD T - P]						[-0.34 (-0.77, 0.09)]				
Week 12		40	16.6 (7.70)				46	12.9 (7.40)		
Week 12 chg		40	-5.7 (8.38)	-5.46	(1.08)		46	-8.7 (8.16)	-8.77	(1.00)
LS Means (T - P) p-value									-3.31	(1.47) (-6.21, -0.40)
						0.026				
[SMD T - P]						[-0.40 (-0.83, 0.03)]				
Week 16		40	17.0 (8.00)				48	11.7 (7.63)		
Week 16 chg		40	-5.3 (9.08)	-5.10	(1.08)		48	-9.9 (7.87)	-10.06	(0.99)
LS Means (T - P) p-value									-4.95	(1.46) (-7.84, -2.06)
						<.001				
[SMD T - P]						[-0.59 (-1.02, -0.16)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4866
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.7.300.12.2: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.480.12.1: Total, Disease severity (IGA), CDLQI 0/1, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	14 (14.4)	7.4 (-1.41;16.24)	2.0 (0.85; 4.81)	2.2 (0.84; 5.70)	0.1060	0.6345
Placebo	94	7 (7.4)					
Moderate [IGA=3]							
Tralokinumab 300 Q2W	49	8 (16.3)	6.8 (-6.50;20.04)	1.7 (0.60; 4.79)	1.8 (0.56; 5.99)	0.3197	
Placebo	51	5 (9.8)					
Severe [IGA=4]							
Tralokinumab 300 Q2W	48	6 (12.5)	8.1 (-3.29;19.54)	2.8 (0.57;13.68)	3.0 (0.56;15.68)	0.1805	
Placebo	43	2 (4.7)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. Setting missing data in dataset to non-responders. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.7.482.12.1: Total, Disease severity (IGA), change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
CDLQI Score										
Total										
Baseline	94	89	13.3 (6.04)			97	94	13.4 (7.26)		
Week 2		88	9.9 (5.59)				93	9.1 (5.75)		
Week 2 chg		88	-3.4 (5.37)	-3.41	(0.50)		93	-4.2 (5.37)	-4.29	(0.49)
LS Means (T - P) p-value									-0.88 (0.70) (-2.25, 0.49)	
						0.206				
[SMD T - P]									[-0.16 (-0.46, 0.13)]	
Week 4		84	9.3 (5.98)				91	7.6 (5.56)		
Week 4 chg		84	-3.9 (6.29)	-3.97	(0.51)		91	-5.7 (6.06)	-5.75	(0.49)
LS Means (T - P) p-value									-1.78 (0.70) (-3.17, -0.40)	
						0.012				
[SMD T - P]									[-0.29 (-0.59, 0.01)]	
Week 6		84	8.7 (5.91)				91	7.2 (5.56)		
Week 6 chg		84	-4.9 (6.38)	-4.69	(0.51)		91	-6.1 (6.16)	-6.07	(0.49)
LS Means (T - P) p-value									-1.39 (0.70) (-2.77, -0.00)	
						0.050				
[SMD T - P]									[-0.22 (-0.52, 0.08)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0997
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.482.12.1: Total, Disease severity (IGA), change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		84	7.1 (5.06)				92	6.6 (5.01)		
Week 8 chg		84	-6.4 (5.85)	-6.24	(0.51)		92	-6.7 (6.09)	-6.69	(0.49)
LS Means (T - P) p-value								-0.45 (0.70)	(-1.83, 0.94)	
						0.525				
[SMD T - P]								[-0.07 (-0.37, 0.22)]		
Week 12		85	7.9 (5.33)				87	6.4 (5.42)		
Week 12 chg		85	-5.3 (6.44)	-5.36	(0.50)		87	-6.9 (6.56)	-6.84	(0.49)
LS Means (T - P) p-value								-1.48 (0.71)	(-2.87, -0.09)	
						0.037				
[SMD T - P]								[-0.23 (-0.53, 0.07)]		
Week 16		84	8.3 (5.27)				92	6.1 (5.47)		
Week 16 chg		84	-5.0 (6.57)	-4.98	(0.51)		92	-7.2 (6.90)	-7.19	(0.49)
LS Means (T - P) p-value								-2.21 (0.70)	(-3.59, -0.83)	
						0.002				
[SMD T - P]								[-0.33 (-0.63, -0.03)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0997
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.482.12.1: Total, Disease severity (IGA), change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
Moderate [IGA=3]								
Baseline	51	47	12.1 (5.33)		49	46	11.8 (7.36)	
Week 2		46	9.4 (5.41)			46	9.1 (5.77)	
Week 2 chg		46	-2.6 (4.77)	-2.37 (0.64)		46	-2.7 (5.04)	-2.71 (0.65)
LS Means (T - P) p-value							-0.34 (0.91) (-2.14, 1.47)	
					0.714			
[SMD T - P]							[-0.07 (-0.48, 0.34)]	
Week 4		44	9.4 (6.03)			44	7.1 (5.21)	
Week 4 chg		44	-2.5 (5.88)	-2.32 (0.65)		44	-4.4 (5.64)	-4.63 (0.66)
LS Means (T - P) p-value							-2.31 (0.93) (-4.14, -0.48)	
					0.014			
[SMD T - P]							[-0.40 (-0.82, 0.02)]	
Week 6		43	7.7 (5.53)			44	6.5 (5.34)	
Week 6 chg		43	-4.5 (5.91)	-4.07 (0.66)		44	-5.1 (5.63)	-5.23 (0.66)
LS Means (T - P) p-value							-1.16 (0.93) (-2.99, 0.68)	
					0.216			
[SMD T - P]							[-0.20 (-0.62, 0.22)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0997
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.482.12.1: Total, Disease severity (IGA), change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		44	6.4 (4.90)				45	6.2 (4.55)		
Week 8 chg		44	-5.6 (5.99)	-5.26	(0.65)		45	-5.4 (6.05)	-5.51	(0.65)
LS Means (T - P) p-value								-0.25 (0.92) (-2.08, 1.57)		
						0.785				
[SMD T - P]								[-0.04 (-0.46, 0.37)]		
Week 12		44	7.7 (5.61)				42	5.2 (4.48)		
Week 12 chg		44	-4.1 (5.91)	-4.00	(0.65)		42	-6.2 (5.74)	-6.42	(0.67)
LS Means (T - P) p-value								-2.42 (0.93) (-4.26, -0.58)		
						0.010				
[SMD T - P]								[-0.42 (-0.84, 0.01)]		
Week 16		44	7.6 (5.07)				44	5.7 (5.23)		
Week 16 chg		44	-4.3 (6.15)	-4.02	(0.65)		44	-5.9 (6.76)	-6.00	(0.66)
LS Means (T - P) p-value								-1.98 (0.93) (-3.81, -0.15)		
						0.034				
[SMD T - P]								[-0.31 (-0.73, 0.11)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0997
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.482.12.1: Total, Disease severity (IGA), change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
Severe [IGA=4]								
Baseline	43	42	14.8 (6.52)		48	48	15.0 (6.88)	
Week 2		42	10.4 (5.80)			47	9.0 (5.80)	
Week 2 chg		42	-4.4 (5.86)	-4.39 (0.76)		47	-5.8 (5.28)	-5.93 (0.72)
LS Means (T - P) p-value								-1.54 (1.05) (-3.60, 0.52)
								0.142
[SMD T - P]								[-0.28 (-0.70, 0.14)]
Week 4		40	9.3 (6.01)			47	8.0 (5.90)	
Week 4 chg		40	-5.5 (6.41)	-5.63 (0.77)		47	-6.9 (6.25)	-6.97 (0.72)
LS Means (T - P) p-value								-1.34 (1.05) (-3.42, 0.74)
								0.205
[SMD T - P]								[-0.21 (-0.63, 0.21)]
Week 6		41	9.6 (6.20)			47	7.9 (5.73)	
Week 6 chg		41	-5.2 (6.88)	-5.24 (0.77)		47	-7.0 (6.56)	-7.02 (0.72)
LS Means (T - P) p-value								-1.79 (1.05) (-3.86, 0.28)
								0.090
[SMD T - P]								[-0.27 (-0.69, 0.15)]

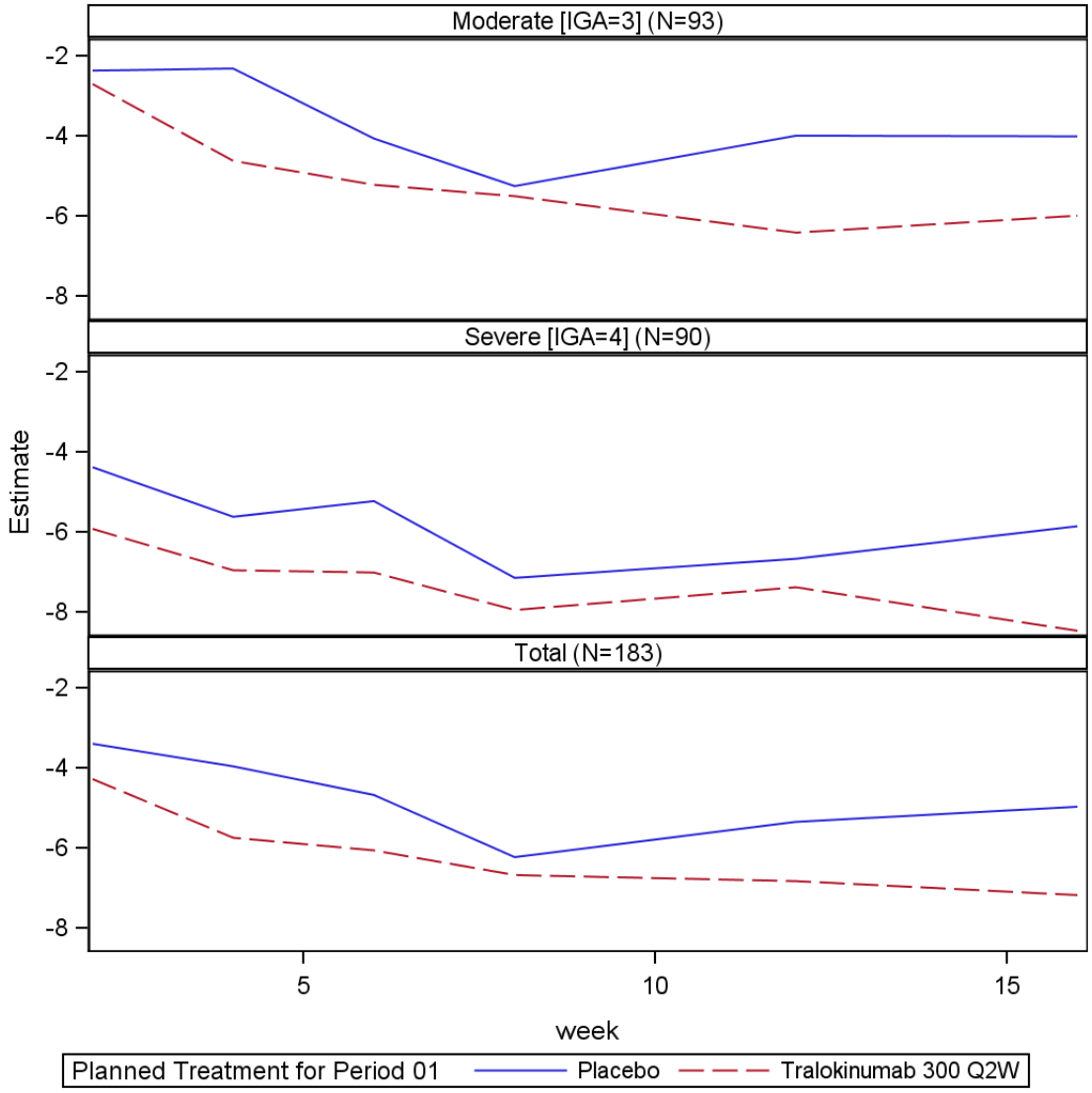
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0997
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.482.12.1: Total, Disease severity (IGA), change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		40	7.9 (5.19)				47	7.0 (5.43)		
Week 8 chg		40	-7.3 (5.61)	-7.16	(0.77)		47	-7.9 (5.94)	-7.96	(0.72)
LS Means (T - P) p-value									-0.80	(1.05) (-2.88, 1.28)
									0.448	
[SMD T - P]									[-0.14	(-0.56, 0.28)]
Week 12		41	8.2 (5.08)				45	7.4 (6.03)		
Week 12 chg		41	-6.7 (6.77)	-6.68	(0.77)		45	-7.5 (7.26)	-7.39	(0.72)
LS Means (T - P) p-value									-0.71	(1.05) (-2.79, 1.37)
									0.500	
[SMD T - P]									[-0.10	(-0.52, 0.32)]
Week 16		40	9.1 (5.44)				48	6.5 (5.71)		
Week 16 chg		40	-5.9 (6.98)	-5.87	(0.77)		48	-8.5 (6.86)	-8.48	(0.71)
LS Means (T - P) p-value									-2.61	(1.05) (-4.69, -0.54)
									0.014	
[SMD T - P]									[-0.38	(-0.80, 0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0997
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.7.482.12.2: Total, Disease severity (IGA), change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.483.12.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	96	32 (33.3)	15.7 (3.43;27.88)	1.9 (1.11; 3.21)	2.4 (1.17; 4.76)	0.0141	0.5762
Placebo	90	16 (17.8)					
Moderate [IGA=3]							
Tralokinumab 300 Q2W	49	14 (28.6)	17.2 (1.38;32.94)	2.4 (1.01; 5.78)	3.0 (1.04; 8.42)	0.0366	
Placebo	49	6 (12.2)					
Severe [IGA=4]							
Tralokinumab 300 Q2W	47	18 (38.3)	14.0 (-4.98;32.92)	1.6 (0.81; 3.11)	2.0 (0.76; 5.05)	0.1585	
Placebo	41	10 (24.4)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Including subjects with a baseline of at least 4. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.7.484.12.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	96	38 (39.6)	9.0 (-4.61;22.61)	1.3 (0.87; 1.93)	1.5 (0.81; 2.74)	0.2017	0.9431
Placebo	91	28 (30.8)					
Moderate [IGA=3]							
Tralokinumab 300 Q2W	49	18 (36.7)	9.7 (-8.34;27.78)	1.4 (0.77; 2.38)	1.6 (0.67; 3.77)	0.3022	
Placebo	50	14 (28.0)					
Severe [IGA=4]							
Tralokinumab 300 Q2W	47	20 (42.6)	8.2 (-12.4;28.76)	1.2 (0.71; 2.18)	1.4 (0.59; 3.31)	0.4397	
Placebo	41	14 (34.1)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Including subjects with a baseline of at least 3. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA. Including subjects with a baseline score of at least 3.

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Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Adolescent Pruritus NRS (eDiary)										
Total										
Baseline	94	92	7.5 (1.65)			97	96	7.8 (1.53)		
Week 1		90	7.0 (1.77)				94	7.2 (1.70)		
Week 1 chg		90	-0.5 (1.08)	-0.51	(0.22)		94	-0.7 (1.65)	-0.66	(0.21)
LS Means (T - P) p-value									-0.15	(0.30) (-0.75, 0.44)
						0.612				
[SMD T - P]									[-0.11 (-0.40, 0.18)]	
Week 2		91	6.8 (1.89)				94	6.7 (1.97)		
Week 2 chg		91	-0.7 (1.52)	-0.71	(0.22)		94	-1.1 (1.84)	-1.11	(0.21)
LS Means (T - P) p-value									-0.40	(0.30) (-1.00, 0.19)
						0.184				
[SMD T - P]									[-0.24 (-0.53, 0.05)]	
Week 3		89	6.5 (1.89)				94	6.2 (2.18)		
Week 3 chg		89	-1.0 (1.74)	-1.06	(0.22)		94	-1.6 (2.02)	-1.51	(0.21)
LS Means (T - P) p-value									-0.45	(0.30) (-1.05, 0.15)
						0.138				
[SMD T - P]									[-0.24 (-0.53, 0.05)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		89	6.3 (1.97)				91	6.1 (2.24)		
Week 4 chg		89	-1.2 (1.96)	-1.22	(0.22)		91	-1.7 (1.95)	-1.70	(0.21)
LS Means (T - P) p-value									-0.48	(0.30) (-1.08, 0.11)
						0.112				
[SMD T - P]									[-0.25 (-0.54, 0.05)]	
Week 5		85	6.0 (1.99)				94	5.8 (2.26)		
Week 5 chg		85	-1.5 (1.98)	-1.63	(0.22)		94	-2.1 (2.14)	-2.05	(0.21)
LS Means (T - P) p-value									-0.43	(0.30) (-1.03, 0.17)
						0.163				
[SMD T - P]									[-0.21 (-0.50, 0.09)]	
Week 6		86	5.8 (2.23)				92	5.8 (2.30)		
Week 6 chg		86	-1.7 (2.26)	-1.77	(0.22)		92	-2.0 (2.19)	-2.05	(0.21)
LS Means (T - P) p-value									-0.27	(0.30) (-0.87, 0.33)
						0.371				
[SMD T - P]									[-0.12 (-0.42, 0.17)]	
Week 7		82	5.8 (1.97)				91	5.5 (2.21)		
Week 7 chg		82	-1.8 (2.02)	-1.84	(0.22)		91	-2.2 (2.09)	-2.30	(0.21)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.45 (0.31)	(-1.06, 0.15)
						0.139				
[SMD T - P]						[-0.22			(-0.52, 0.08)]	
Week 8		85	5.5 (2.20)				91	5.4 (2.31)		
Week 8 chg		85	-2.0 (2.20)	-2.04	(0.22)		91	-2.5 (2.26)	-2.45	(0.21)
LS Means (T - P) p-value									-0.41 (0.31)	(-1.01, 0.19)
						0.178				
[SMD T - P]						[-0.19			(-0.48, 0.11)]	
Week 9		81	5.6 (2.08)				92	5.1 (2.37)		
Week 9 chg		81	-2.0 (1.98)	-1.99	(0.22)		92	-2.7 (2.42)	-2.73	(0.21)
LS Means (T - P) p-value									-0.75 (0.31)	(-1.35, -0.14)
						0.015				
[SMD T - P]						[-0.34			(-0.64, -0.04)]	
Week 10		83	5.4 (2.33)				89	5.0 (2.47)		
Week 10 chg		83	-2.1 (2.29)	-2.08	(0.22)		89	-2.9 (2.55)	-2.77	(0.21)
LS Means (T - P) p-value									-0.70 (0.31)	(-1.30, -0.09)
						0.024				
[SMD T - P]						[-0.29			(-0.59, 0.01)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		79	5.4 (2.30)				88	5.0 (2.33)		
Week 11 chg		79	-2.1 (2.31)	-2.13	(0.22)		88	-2.7 (2.29)	-2.79	(0.21)
LS Means (T - P) p-value									-0.65	(0.31) (-1.26, -0.05)
						0.034				
[SMD T - P]						[-0.29 (-0.59, 0.02)]				
Week 12		85	5.4 (2.34)				88	5.0 (2.33)		
Week 12 chg		85	-2.0 (2.39)	-2.12	(0.22)		88	-2.7 (2.38)	-2.78	(0.21)
LS Means (T - P) p-value									-0.65	(0.31) (-1.25, -0.05)
						0.034				
[SMD T - P]						[-0.27 (-0.57, 0.03)]				
Week 13		81	5.3 (2.37)				90	5.0 (2.35)		
Week 13 chg		81	-2.2 (2.47)	-2.20	(0.22)		90	-2.8 (2.34)	-2.83	(0.21)
LS Means (T - P) p-value									-0.63	(0.31) (-1.23, -0.02)
						0.043				
[SMD T - P]						[-0.26 (-0.56, 0.04)]				
Week 14		79	5.2 (2.44)				86	4.8 (2.42)		
Week 14 chg		79	-2.4 (2.55)	-2.29	(0.22)		86	-3.0 (2.42)	-2.95	(0.21)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.66 (0.31)	(-1.27, -0.05)
						0.033				
[SMD T - P]						[-0.27			(-0.57, 0.04)]	
Week 15	77	77	5.2 (2.26)			84	84	4.8 (2.43)		
Week 15 chg	77	77	-2.4 (2.41)	-2.32	(0.22)	84	84	-2.9 (2.43)	-2.97	(0.22)
LS Means (T - P) p-value									-0.65 (0.31)	(-1.26, -0.04)
						0.038				
[SMD T - P]						[-0.27			(-0.58, 0.04)]	
Week 16	78	78	5.5 (2.26)			88	88	4.8 (2.48)		
Week 16 chg	78	78	-2.2 (2.35)	-2.09	(0.22)	88	88	-2.9 (2.46)	-2.96	(0.21)
LS Means (T - P) p-value									-0.87 (0.31)	(-1.48, -0.27)
						0.005				
[SMD T - P]						[-0.36			(-0.67, -0.05)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Moderate [IGA=3]										
Baseline	51	50	7.2 (1.57)			49	49	7.6 (1.51)		
Week 1		48	6.8 (1.67)				48	7.0 (1.64)		
Week 1 chg		48	-0.4 (1.06)	-0.43	(0.28)		48	-0.6 (1.64)	-0.59	(0.28)
LS Means (T - P) p-value									-0.15	(0.40) (-0.95, 0.64)
									0.708	
[SMD T - P]									[-0.11	(-0.51, 0.29)]
Week 2		49	6.8 (1.88)				47	6.5 (1.88)		
Week 2 chg		49	-0.5 (1.50)	-0.51	(0.28)		47	-1.0 (1.86)	-0.98	(0.29)
LS Means (T - P) p-value									-0.47	(0.40) (-1.27, 0.32)
									0.240	
[SMD T - P]									[-0.28	(-0.68, 0.12)]
Week 3		49	6.5 (1.82)				48	6.1 (2.09)		
Week 3 chg		49	-0.7 (1.69)	-0.74	(0.28)		48	-1.5 (1.94)	-1.37	(0.28)
LS Means (T - P) p-value									-0.63	(0.40) (-1.42, 0.17)
									0.122	
[SMD T - P]									[-0.34	(-0.74, 0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		48	6.4 (1.89)				46	6.0 (2.22)		
Week 4 chg		48	-0.9 (1.78)	-0.89	(0.28)		46	-1.6 (1.85)	-1.65	(0.29)
LS Means (T - P) p-value									-0.76	(0.41) (-1.56, 0.04)
									0.062	
[SMD T - P]									[-0.42 (-0.83, -0.01)]	
Week 5		45	5.9 (1.79)				48	5.5 (2.02)		
Week 5 chg		45	-1.4 (1.71)	-1.43	(0.29)		48	-2.0 (1.94)	-2.05	(0.28)
LS Means (T - P) p-value									-0.62	(0.41) (-1.42, 0.18)
									0.127	
[SMD T - P]									[-0.34 (-0.75, 0.07)]	
Week 6		47	5.6 (2.28)				46	5.6 (2.07)		
Week 6 chg		47	-1.6 (2.28)	-1.66	(0.28)		46	-1.9 (1.86)	-2.08	(0.29)
LS Means (T - P) p-value									-0.42	(0.41) (-1.22, 0.38)
									0.298	
[SMD T - P]									[-0.20 (-0.61, 0.20)]	
Week 7		43	5.4 (1.89)				45	5.5 (2.10)		
Week 7 chg		43	-1.9 (1.92)	-1.84	(0.29)		45	-2.1 (1.97)	-2.19	(0.29)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.36 (0.41) (-1.16, 0.45)	
[SMD T - P]						0.387			[-0.18 (-0.60, 0.24)]	
Week 8	45	45	5.2 (2.32)			45	45	5.3 (2.23)		
Week 8 chg	45	45	-2.0 (2.19)	-2.02	(0.29)	45	45	-2.3 (2.10)	-2.30	(0.29)
LS Means (T - P) p-value									-0.28 (0.41) (-1.08, 0.53)	
[SMD T - P]						0.500			[-0.13 (-0.54, 0.28)]	
Week 9	42	42	5.5 (2.20)			46	46	4.8 (2.19)		
Week 9 chg	42	42	-1.8 (1.80)	-1.85	(0.29)	46	46	-2.8 (2.27)	-2.86	(0.29)
LS Means (T - P) p-value									-1.01 (0.41) (-1.82, -0.20)	
[SMD T - P]						0.015			[-0.49 (-0.92, -0.07)]	
Week 10	44	44	5.2 (2.58)			45	45	4.9 (2.25)		
Week 10 chg	44	44	-2.1 (2.27)	-1.94	(0.29)	45	45	-2.7 (2.24)	-2.68	(0.29)
LS Means (T - P) p-value									-0.74 (0.41) (-1.55, 0.07)	
[SMD T - P]						0.073			[-0.33 (-0.75, 0.09)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		41	5.1 (2.45)				46	5.0 (2.19)		
Week 11 chg		41	-2.1 (2.11)	-2.02	(0.29)		46	-2.5 (2.27)	-2.66	(0.29)
LS Means (T - P) p-value									-0.64	(0.41) (-1.46, 0.17)
						0.119				
[SMD T - P]									[-0.29 (-0.72, 0.13)]	
Week 12		45	5.3 (2.54)				45	5.0 (2.17)		
Week 12 chg		45	-1.8 (2.30)	-1.91	(0.29)		45	-2.5 (2.34)	-2.71	(0.29)
LS Means (T - P) p-value									-0.80	(0.41) (-1.60, 0.01)
						0.053				
[SMD T - P]									[-0.34 (-0.76, 0.07)]	
Week 13		44	4.9 (2.42)				45	4.8 (2.33)		
Week 13 chg		44	-2.2 (2.39)	-2.23	(0.29)		45	-2.7 (2.24)	-2.83	(0.29)
LS Means (T - P) p-value									-0.60	(0.41) (-1.41, 0.21)
						0.145				
[SMD T - P]									[-0.26 (-0.68, 0.16)]	
Week 14		44	4.8 (2.44)				43	4.9 (2.19)		
Week 14 chg		44	-2.3 (2.50)	-2.31	(0.29)		43	-2.6 (2.08)	-2.75	(0.29)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.44 (0.41)	(-1.25, 0.38)
									0.292	
[SMD T - P]									[-0.19	(-0.61, 0.23)]
Week 15	40		4.8 (2.29)			42		4.9 (2.30)		
Week 15 chg	40		-2.4 (2.26)	-2.36	(0.30)	42		-2.6 (2.16)	-2.75	(0.29)
LS Means (T - P) p-value									-0.39 (0.42)	(-1.21, 0.43)
									0.349	
[SMD T - P]									[-0.18	(-0.61, 0.26)]
Week 16	41		5.2 (2.25)			44		4.7 (2.33)		
Week 16 chg	41		-2.1 (2.17)	-2.08	(0.29)	44		-2.8 (2.32)	-2.90	(0.29)
LS Means (T - P) p-value									-0.82 (0.41)	(-1.63, -0.00)
									0.050	
[SMD T - P]									[-0.36	(-0.79, 0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Severe [IGA=4]										
Baseline	43	42	7.8 (1.72)			48	47	8.1 (1.53)		
Week 1		42	7.3 (1.87)				46	7.4 (1.75)		
Week 1 chg		42	-0.5 (1.11)	-0.57	(0.33)		46	-0.8 (1.68)	-0.76	(0.31)
LS Means (T - P) p-value									-0.18	(0.46) (-1.08, 0.72)
						0.692				
[SMD T - P]									[-0.13 (-0.55, 0.29)]	
Week 2		42	6.9 (1.92)				47	6.8 (2.06)		
Week 2 chg		42	-0.9 (1.54)	-0.93	(0.33)		47	-1.3 (1.83)	-1.27	(0.31)
LS Means (T - P) p-value									-0.34	(0.46) (-1.24, 0.56)
						0.453				
[SMD T - P]									[-0.20 (-0.62, 0.22)]	
Week 3		40	6.4 (2.00)				46	6.4 (2.29)		
Week 3 chg		40	-1.4 (1.73)	-1.42	(0.33)		46	-1.7 (2.11)	-1.68	(0.31)
LS Means (T - P) p-value									-0.26	(0.46) (-1.17, 0.64)
						0.568				
[SMD T - P]									[-0.14 (-0.56, 0.29)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		41	6.3 (2.08)				45	6.3 (2.27)		
Week 4 chg		41	-1.5 (2.10)	-1.58	(0.33)		45	-1.8 (2.07)	-1.79	(0.31)
LS Means (T - P) p-value									-0.21	(0.46) (-1.11, 0.70)
						0.655				
[SMD T - P]						[-0.10 (-0.52, 0.32)]				
Week 5		40	6.0 (2.21)				46	6.0 (2.48)		
Week 5 chg		40	-1.8 (2.25)	-1.83	(0.33)		46	-2.1 (2.35)	-2.07	(0.31)
LS Means (T - P) p-value									-0.24	(0.46) (-1.15, 0.67)
						0.601				
[SMD T - P]						[-0.10 (-0.53, 0.32)]				
Week 6		39	6.1 (2.16)				46	6.1 (2.50)		
Week 6 chg		39	-1.8 (2.26)	-1.89	(0.34)		46	-2.1 (2.49)	-2.03	(0.31)
LS Means (T - P) p-value									-0.15	(0.46) (-1.05, 0.76)
						0.753				
[SMD T - P]						[-0.06 (-0.49, 0.37)]				
Week 7		39	6.1 (2.01)				46	5.6 (2.33)		
Week 7 chg		39	-1.7 (2.15)	-1.84	(0.34)		46	-2.4 (2.20)	-2.42	(0.31)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.58 (0.46)	(-1.49, 0.33)
						0.207				
[SMD T - P]						[-0.27			(-0.70, 0.16)]	
Week 8	40	5.9 (2.04)				46	5.4 (2.41)			
Week 8 chg	40	-2.0 (2.23)	-2.03 (0.33)			46	-2.7 (2.42)	-2.62 (0.31)		
LS Means (T - P) p-value									-0.59 (0.46)	(-1.50, 0.32)
						0.200				
[SMD T - P]						[-0.25			(-0.68, 0.17)]	
Week 9	39	5.6 (1.96)				46	5.4 (2.53)			
Week 9 chg	39	-2.1 (2.17)	-2.13 (0.34)			46	-2.7 (2.58)	-2.63 (0.31)		
LS Means (T - P) p-value									-0.50 (0.46)	(-1.41, 0.41)
						0.281				
[SMD T - P]						[-0.21			(-0.64, 0.22)]	
Week 10	39	5.6 (2.04)				44	5.1 (2.69)			
Week 10 chg	39	-2.2 (2.33)	-2.22 (0.34)			44	-3.0 (2.85)	-2.90 (0.32)		
LS Means (T - P) p-value									-0.69 (0.46)	(-1.60, 0.23)
						0.139				
[SMD T - P]						[-0.26			(-0.70, 0.17)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		38	5.7 (2.12)				42	5.1 (2.50)		
Week 11 chg		38	-2.2 (2.53)	-2.25	(0.34)		42	-2.9 (2.31)	-2.94	(0.32)
LS Means (T - P) p-value									-0.70	(0.46) (-1.61, 0.22)
						0.136				
[SMD T - P]						[-0.29 (-0.73, 0.15)]				
Week 12		40	5.5 (2.11)				43	5.1 (2.52)		
Week 12 chg		40	-2.3 (2.47)	-2.34	(0.33)		43	-2.9 (2.42)	-2.87	(0.32)
LS Means (T - P) p-value									-0.52	(0.46) (-1.44, 0.39)
						0.258				
[SMD T - P]						[-0.21 (-0.65, 0.22)]				
Week 13		37	5.8 (2.24)				45	5.1 (2.38)		
Week 13 chg		37	-2.1 (2.60)	-2.13	(0.34)		45	-2.9 (2.46)	-2.84	(0.31)
LS Means (T - P) p-value									-0.71	(0.46) (-1.63, 0.20)
						0.127				
[SMD T - P]						[-0.28 (-0.72, 0.16)]				
Week 14		35	5.7 (2.37)				43	4.7 (2.66)		
Week 14 chg		35	-2.4 (2.65)	-2.24	(0.34)		43	-3.3 (2.69)	-3.18	(0.32)

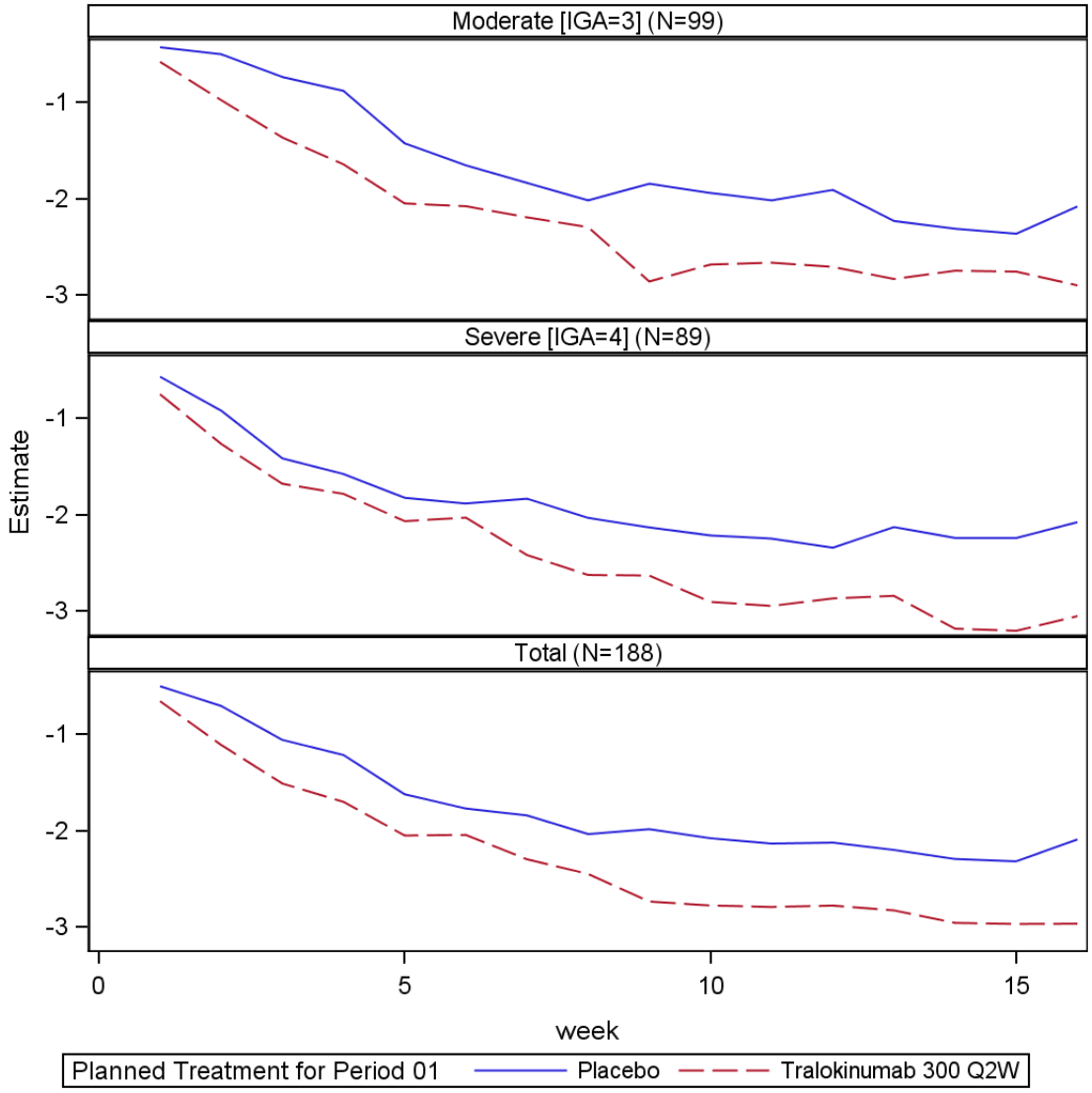
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.7.485.12.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.94 (0.47)	(-1.86, -0.02)
						0.046				
[SMD T - P]						[-0.35 (-0.80, 0.10)]				
Week 15	37		5.6 (2.19)			42		4.7 (2.58)		
Week 15 chg	37		-2.4 (2.59)	-2.24	(0.34)	42		-3.3 (2.64)	-3.20	(0.32)
LS Means (T - P) p-value									-0.96 (0.47)	(-1.88, -0.04)
						0.041				
[SMD T - P]						[-0.37 (-0.81, 0.08)]				
Week 16	37		5.8 (2.27)			44		4.9 (2.64)		
Week 16 chg	37		-2.2 (2.57)	-2.08	(0.34)	44		-3.1 (2.61)	-3.05	(0.32)
LS Means (T - P) p-value									-0.97 (0.46)	(-1.89, -0.06)
						0.038				
[SMD T - P]						[-0.37 (-0.82, 0.07)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6963
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.7.485.12.2: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Tralokinumab

Subgruppenanalysen der Wirksamkeitsendpunkte: Region

LEO Pharma A/S

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Statistical appendix

Table 1.19.205.12.1: Total, Region, EASI 75, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	36 (37.1)	17.3 (5.18;29.39)	1.9 (1.17; 2.99)	2.6 (1.29; 5.08)	0.0075	0.8624
Placebo	94	19 (20.2)					
Asia							
Tralokinumab 300 Q2W	11	6 (54.5)	18.2 (-18.2;54.57)	1.5 (0.64; 3.52)	2.6 (0.36;18.44)	0.3607	
Placebo	11	4 (36.4)					
Australia							
Tralokinumab 300 Q2W	5	1 (20.0)	15.4 (-17.5;48.31)			0.4795	
Placebo	4	0 (0.0)					
Europe							
Tralokinumab 300 Q2W	33	11 (33.3)	18.2 (-2.22;38.52)	2.2 (0.84; 5.73)	2.8 (0.83; 9.39)	0.0952	
Placebo	32	5 (15.6)					
North America							
Tralokinumab 300 Q2W	48	18 (37.5)	16.7 (-1.12;34.43)	1.8 (0.93; 3.46)	2.3 (0.92; 5.86)	0.0752	
Placebo	47	10 (21.3)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

Table 1.19.206.12.1: Total, Region, EASI 90, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	22 (22.7)	15.4 (5.48;25.24)	3.1 (1.38; 7.04)	3.7 (1.49; 9.20)	0.0035	0.2292
Placebo	94	7 (7.4)					
Asia							
Tralokinumab 300 Q2W	11	3 (27.3)	27.3 (0.95;53.59)			0.0719	
Placebo	11	0 (0.0)					
Australia							
Tralokinumab 300 Q2W	5	1 (20.0)	15.4 (-17.5;48.31)			0.4795	
Placebo	4	0 (0.0)					
Europe							
Tralokinumab 300 Q2W	33	10 (30.3)	24.7 (7.11;42.31)	5.2 (1.19;22.89)	7.3 (1.37;39.05)	0.0115	
Placebo	32	2 (6.3)					
North America							
Tralokinumab 300 Q2W	48	8 (16.7)	6.2 (-7.46;19.95)	1.6 (0.56; 4.48)	1.7 (0.52; 5.72)	0.3792	
Placebo	47	5 (10.6)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

Table 1.19.209.12.1: Total, Region, SCORAD 75, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	15 (15.5)	13.5 (5.63;21.29)	7.3 (1.72;31.34)	8.2 (1.87;36.25)	0.0012	0.3209
Placebo	94	2 (2.1)					
Asia							
Tralokinumab 300 Q2W	11	2 (18.2)	18.2 (-4.61;40.97)			0.1336	
Placebo	11	0 (0.0)					
Australia							
Tralokinumab 300 Q2W	5	0 (0.0)					
Placebo	4	0 (0.0)					
Europe							
Tralokinumab 300 Q2W	33	7 (21.2)	21.3 (7.29;35.31)			0.0066	
Placebo	32	0 (0.0)					
North America							
Tralokinumab 300 Q2W	48	6 (12.5)	8.3 (-2.74;19.26)	2.9 (0.63;13.82)	3.2 (0.61;16.83)	0.1518	
Placebo	47	2 (4.3)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.19.213.12.1: Total, Region, POEM improvement of >= 4, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	94	70 (74.5)	27.0 (13.17;40.84)	1.6 (1.22; 2.03)	3.2 (1.70; 5.92)	0.0002	0.1724
Placebo	87	41 (47.1)					
Asia							
Tralokinumab 300 Q2W	10	7 (70.0)	10.0 (-31.6;51.58)	1.2 (0.61; 2.23)	1.6 (0.24; 9.93)	0.6547	
Placebo	10	6 (60.0)					
Australia							
Tralokinumab 300 Q2W	5	5 (100)	53.8 (6.91;100.0)	2.2 (0.71; 6.57)		0.0896	
Placebo	4	2 (50.0)					
Europe							
Tralokinumab 300 Q2W	33	27 (81.8)	41.0 (18.97;63.13)	2.0 (1.27; 3.21)	6.6 (2.09;20.92)	0.0009	
Placebo	30	12 (40.0)					
North America							
Tralokinumab 300 Q2W	46	31 (67.4)	18.4 (-1.82;38.52)	1.4 (0.95; 1.98)	2.1 (0.91; 5.08)	0.0820	
Placebo	43	21 (48.8)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Including subjects with a baseline of at least 4. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA. Including subjects with a baseline score of at least 4.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
EASI Score								
Total								
Baseline	94	94	31.2 (14.47)		97	97	31.8 (13.91)	
Week 2		94	24.9 (15.33)			97	22.4 (12.46)	
Week 2 chg		94	-6.3 (10.06)	-6.41 (1.15)		97	-9.4 (9.84)	-9.32 (1.13)
LS Means (T - P) p-value								-2.91 (1.62) (-6.09, 0.27)
					0.072			
[SMD T - P]					[-0.29 (-0.58, -0.01)]			
Week 4		90	23.6 (15.77)			96	18.4 (13.04)	
Week 4 chg		90	-7.9 (12.13)	-7.94 (1.17)		96	-13.5 (11.34)	-13.35 (1.14)
LS Means (T - P) p-value								-5.42 (1.63) (-8.62, -2.21)
					<.001			
[SMD T - P]					[-0.46 (-0.75, -0.17)]			
Week 6		91	21.6 (14.67)			94	16.1 (13.84)	
Week 6 chg		91	-9.9 (11.90)	-10.06 (1.16)		94	-15.7 (13.62)	-15.62 (1.14)
LS Means (T - P) p-value								-5.56 (1.63) (-8.77, -2.35)
					<.001			
[SMD T - P]					[-0.43 (-0.73, -0.14)]			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		88	20.5 (15.07)				95	13.6 (12.57)		
Week 8 chg		88	-10.8 (12.19)	-10.89	(1.17)		95	-18.2 (12.35)	-18.12	(1.14)
LS Means (T - P) p-value									-7.23	(1.64) (-10.4, -4.01)
						<.001				
[SMD T - P]									[-0.59 (-0.89, -0.29)]	
Week 10		86	20.2 (15.71)				93	13.4 (12.32)		
Week 10 chg		86	-11.1 (12.85)	-11.31	(1.18)		93	-18.8 (12.82)	-18.63	(1.15)
LS Means (T - P) p-value									-7.33	(1.65) (-10.6, -4.09)
						<.001				
[SMD T - P]									[-0.57 (-0.87, -0.27)]	
Week 12		90	19.2 (14.92)				93	12.6 (11.83)		
Week 12 chg		90	-11.8 (14.49)	-12.20	(1.17)		93	-19.0 (14.14)	-18.64	(1.15)
LS Means (T - P) p-value									-6.44	(1.64) (-9.66, -3.22)
						<.001				
[SMD T - P]									[-0.45 (-0.74, -0.16)]	
Week 14		83	18.7 (15.04)				95	12.7 (13.33)		
Week 14 chg		83	-12.5 (14.00)	-12.71	(1.19)		95	-19.2 (13.78)	-19.01	(1.14)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								-6.31 (1.65) (-9.55, -3.06)		
						<.001				
[SMD T - P]						[-0.45 (-0.75, -0.16)]				
Week 16		87	19.5 (15.17)				95	13.2 (13.81)		
Week 16 chg		87	-11.7 (12.88)	-11.54	(1.18)		95	-18.7 (13.43)	-18.52	(1.14)
LS Means (T - P) p-value								-6.97 (1.64) (-10.2, -3.75)		
						<.001				
[SMD T - P]						[-0.53 (-0.83, -0.23)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
Asia								
Baseline	11	11	27.2 (10.38)		11	11	29.4 (11.35)	
Week 2		11	19.3 (9.26)			11	16.6 (10.24)	
Week 2 chg		11	-7.9 (8.38)	-8.22 (2.40)		11	-12.8 (9.53)	-12.38 (2.40)
LS Means (T - P) p-value								-4.16 (3.40) (-11.0, 2.68)
					0.228			
[SMD T - P]								[-0.46 (-1.31, 0.38)]
Week 4		11	18.4 (8.51)			11	13.2 (8.89)	
Week 4 chg		11	-8.8 (9.59)	-9.28 (2.40)		11	-16.2 (11.15)	-15.51 (2.40)
LS Means (T - P) p-value								-6.23 (3.40) (-13.1, 0.60)
					0.073			
[SMD T - P]								[-0.60 (-1.45, 0.26)]
Week 6		11	17.9 (11.53)			11	10.0 (6.13)	
Week 6 chg		11	-9.3 (13.33)	-10.10 (2.40)		11	-19.4 (14.49)	-18.31 (2.40)
LS Means (T - P) p-value								-8.21 (3.40) (-15.0, -1.38)
					0.019			
[SMD T - P]								[-0.59 (-1.44, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		11	14.7 (9.03)				11	8.2 (6.22)		
Week 8 chg		11	-12.5 (12.59)	-13.35	(2.40)		11	-21.1 (14.60)	-19.98	(2.40)
LS Means (T - P) p-value									-6.63	(3.40) (-13.5, 0.20)
									0.057	
[SMD T - P]									[-0.49	(-1.33, 0.36)]
Week 10		11	13.8 (8.04)				11	8.3 (6.03)		
Week 10 chg		11	-13.4 (11.92)	-14.24	(2.40)		11	-21.1 (13.93)	-19.98	(2.40)
LS Means (T - P) p-value									-5.74	(3.40) (-12.6, 1.09)
									0.098	
[SMD T - P]									[-0.44	(-1.29, 0.40)]
Week 12		11	12.5 (7.30)				11	8.7 (7.28)		
Week 12 chg		11	-14.7 (12.04)	-15.66	(2.40)		11	-20.7 (15.23)	-19.51	(2.40)
LS Means (T - P) p-value									-3.85	(3.40) (-10.7, 2.98)
									0.263	
[SMD T - P]									[-0.28	(-1.12, 0.56)]
Week 14		10	14.6 (10.52)				11	9.5 (8.19)		
Week 14 chg		10	-10.0 (12.42)	-13.82	(2.51)		11	-19.9 (15.72)	-18.57	(2.40)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								-4.75 (3.51)	(-11.8, 2.28)	
						0.181				
[SMD T - P]						[-0.33		(-1.20, 0.53)]		
Week 16		11	13.4 (7.69)				11	7.9 (6.24)		
Week 16 chg		11	-13.8 (12.70)	-14.75	(2.40)		11	-21.4 (15.08)	-20.17	(2.40)
LS Means (T - P) p-value								-5.42 (3.40)	(-12.3, 1.41)	
						0.117				
[SMD T - P]						[-0.39		(-1.23, 0.45)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Australia										
Baseline	4	4	34.3 (16.65)			5	5	45.4 (22.69)		
Week 2		4	20.2 (19.54)				5	25.1 (11.46)		
Week 2 chg		4	-14.1 (5.14)	-14.88	(5.30)		5	-20.2 (13.48)	-19.60	(4.70)
LS Means (T - P) p-value								-4.72 (7.32)	(-20.6, 11.14)	
[SMD T - P]						0.531		[-0.44 (-1.77, 0.89)]		
Week 4		4	13.0 (5.89)				5	21.5 (15.02)		
Week 4 chg		4	-21.3 (13.53)	-23.58	(5.30)		5	-23.9 (15.64)	-22.07	(4.70)
LS Means (T - P) p-value								1.51 (7.32)	(-14.3, 17.37)	
[SMD T - P]						0.839		[0.10 (-1.21, 1.42)]		
Week 6		4	13.3 (7.24)				5	18.1 (11.96)		
Week 6 chg		4	-21.0 (9.43)	-24.46	(5.30)		5	-27.3 (22.86)	-24.54	(4.70)
LS Means (T - P) p-value								-0.08 (7.32)	(-15.9, 15.78)	
[SMD T - P]						0.992		[-0.00 (-1.32, 1.31)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		4	15.8 (6.53)				5	12.4 (10.46)		
Week 8 chg		4	-18.5 (11.38)	-21.00	(5.30)		5	-32.9 (15.20)	-30.92	(4.70)
LS Means (T - P) p-value								-9.92	(7.32)	(-25.8, 5.94)
						0.199				
[SMD T - P]						[-0.72		(-2.08, 0.63)]		
Week 10		3	12.1 (5.33)				5	18.0 (10.84)		
Week 10 chg		3	-20.5 (15.81)	-23.93	(5.74)		5	-27.3 (16.57)	-25.05	(4.70)
LS Means (T - P) p-value								-1.12	(7.67)	(-17.5, 15.24)
						0.885				
[SMD T - P]						[-0.07		(-1.50, 1.36)]		
Week 12		4	14.8 (9.85)				5	16.5 (13.92)		
Week 12 chg		4	-19.5 (10.26)	-21.67	(5.30)		5	-28.8 (17.24)	-27.07	(4.70)
LS Means (T - P) p-value								-5.40	(7.32)	(-21.3, 10.46)
						0.474				
[SMD T - P]						[-0.37		(-1.69, 0.96)]		
Week 14		4	16.2 (4.84)				5	23.5 (22.94)		
Week 14 chg		4	-18.1 (12.18)	-19.89	(5.30)		5	-21.9 (21.01)	-20.48	(4.70)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								-0.59 (7.32)	(-16.4, 15.26)	
						0.937				
[SMD T - P]						[-0.03	(-1.35,	1.28)]		
Week 16		4	19.0 (10.22)				5	28.0 (24.47)		
Week 16 chg		4	-15.3 (9.69)	-16.17	(5.30)		5	-17.4 (20.36)	-16.67	(4.70)
LS Means (T - P) p-value								-0.50 (7.32)	(-16.4, 15.35)	
						0.946				
[SMD T - P]						[-0.03	(-1.35,	1.28)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Europe										
Baseline	32	32	30.0 (14.20)			33	33	32.2 (14.17)		
Week 2		32	24.7 (13.35)				33	23.1 (11.94)		
Week 2 chg		32	-5.3 (8.05)	-5.60	(1.95)		33	-9.1 (8.52)	-8.88	(1.92)
LS Means (T - P) p-value									-3.28	(2.74) (-8.69, 2.14)
						0.234				
[SMD T - P]									[-0.39 (-0.89, 0.10)]	
Week 4		32	22.7 (15.71)				32	21.0 (12.38)		
Week 4 chg		32	-7.3 (11.10)	-7.61	(1.95)		32	-11.5 (9.51)	-11.11	(1.94)
LS Means (T - P) p-value									-3.49	(2.75) (-8.94, 1.95)
						0.207				
[SMD T - P]									[-0.34 (-0.83, 0.16)]	
Week 6		32	22.1 (15.41)				31	18.4 (13.87)		
Week 6 chg		32	-7.9 (9.81)	-8.30	(1.95)		31	-13.9 (14.43)	-13.71	(1.95)
LS Means (T - P) p-value									-5.41	(2.76) (-10.9, 0.05)
						0.052				
[SMD T - P]									[-0.44 (-0.94, 0.06)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		31	21.3 (15.21)				31	15.6 (12.46)		
Week 8 chg		31	-8.8 (10.36)	-9.10	(1.96)		31	-16.7 (13.11)	-16.49	(1.95)
LS Means (T - P) p-value									-7.39	(2.77) (-12.9, -1.91)
						0.009				
[SMD T - P]						[-0.63 (-1.14, -0.12)]				
Week 10		31	19.9 (14.94)				32	16.2 (13.44)		
Week 10 chg		31	-10.1 (11.92)	-10.49	(1.96)		32	-16.4 (14.35)	-15.75	(1.94)
LS Means (T - P) p-value									-5.26	(2.77) (-10.7, 0.21)
						0.059				
[SMD T - P]						[-0.40 (-0.90, 0.10)]				
Week 12		32	19.6 (15.31)				32	16.4 (13.53)		
Week 12 chg		32	-10.4 (14.66)	-11.02	(1.95)		32	-16.2 (14.51)	-15.46	(1.94)
LS Means (T - P) p-value									-4.43	(2.75) (-9.88, 1.01)
						0.110				
[SMD T - P]						[-0.30 (-0.80, 0.19)]				
Week 14		29	18.8 (16.56)				32	13.7 (12.22)		
Week 14 chg		29	-11.5 (13.29)	-11.41	(1.99)		32	-18.8 (15.06)	-18.17	(1.94)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-6.76 (2.79)	(-12.3, -1.25)
						0.017				
[SMD T - P]						[-0.47			(-0.98, 0.04)]	
Week 16		29	19.2 (13.34)				32	14.2 (12.52)		
Week 16 chg		29	-11.1 (13.31)	-11.10	(1.99)		32	-18.3 (14.67)	-17.54	(1.94)
LS Means (T - P) p-value									-6.44 (2.79)	(-11.9, -0.93)
						0.022				
[SMD T - P]						[-0.46			(-0.97, 0.05)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
North America								
Baseline	47	47	32.7 (15.42)		48	48	30.6 (12.85)	
Week 2		47	26.8 (17.28)			48	22.9 (13.30)	
Week 2 chg		47	-5.9 (11.71)	-5.73 (1.70)		48	-7.7 (9.77)	-7.94 (1.68)
LS Means (T - P) p-value								-2.21 (2.39) (-6.93, 2.51)
								0.357
[SMD T - P]								[-0.21 (-0.61, 0.20)]
Week 4		43	26.6 (17.25)			48	17.5 (13.91)	
Week 4 chg		43	-6.8 (12.92)	-6.40 (1.74)		48	-13.2 (11.70)	-13.50 (1.68)
LS Means (T - P) p-value								-7.11 (2.43) (-11.9, -2.32)
								0.004
[SMD T - P]								[-0.58 (-1.00, -0.16)]
Week 6		44	22.8 (15.27)			47	15.9 (15.11)	
Week 6 chg		44	-10.5 (12.83)	-10.25 (1.73)		47	-14.8 (11.29)	-15.19 (1.69)
LS Means (T - P) p-value								-4.94 (2.43) (-9.73, -0.16)
								0.043
[SMD T - P]								[-0.41 (-0.83, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		42	22.0 (16.61)				48	13.7 (13.78)		
Week 8 chg		42	-11.2 (13.38)	-10.88	(1.75)		48	-17.0 (10.10)	-17.29	(1.68)
LS Means (T - P) p-value									-6.41	(2.44) (-11.2, -1.61)
						0.009				
[SMD T - P]						[-0.55 (-0.97, -0.12)]				
Week 10		41	22.8 (17.79)				45	12.1 (12.45)		
Week 10 chg		41	-10.5 (13.68)	-10.31	(1.76)		45	-19.1 (10.75)	-19.50	(1.71)
LS Means (T - P) p-value									-9.20	(2.46) (-14.0, -4.35)
						<.001				
[SMD T - P]						[-0.75 (-1.19, -0.31)]				
Week 12		43	21.1 (16.17)				45	10.5 (10.65)		
Week 12 chg		43	-11.4 (15.33)	-11.31	(1.74)		45	-19.5 (13.13)	-19.91	(1.71)
LS Means (T - P) p-value									-8.61	(2.45) (-13.4, -3.78)
						<.001				
[SMD T - P]						[-0.60 (-1.03, -0.18)]				
Week 14		40	20.0 (15.65)				47	11.6 (13.61)		
Week 14 chg		40	-13.3 (15.23)	-12.88	(1.77)		47	-19.1 (11.92)	-19.56	(1.69)

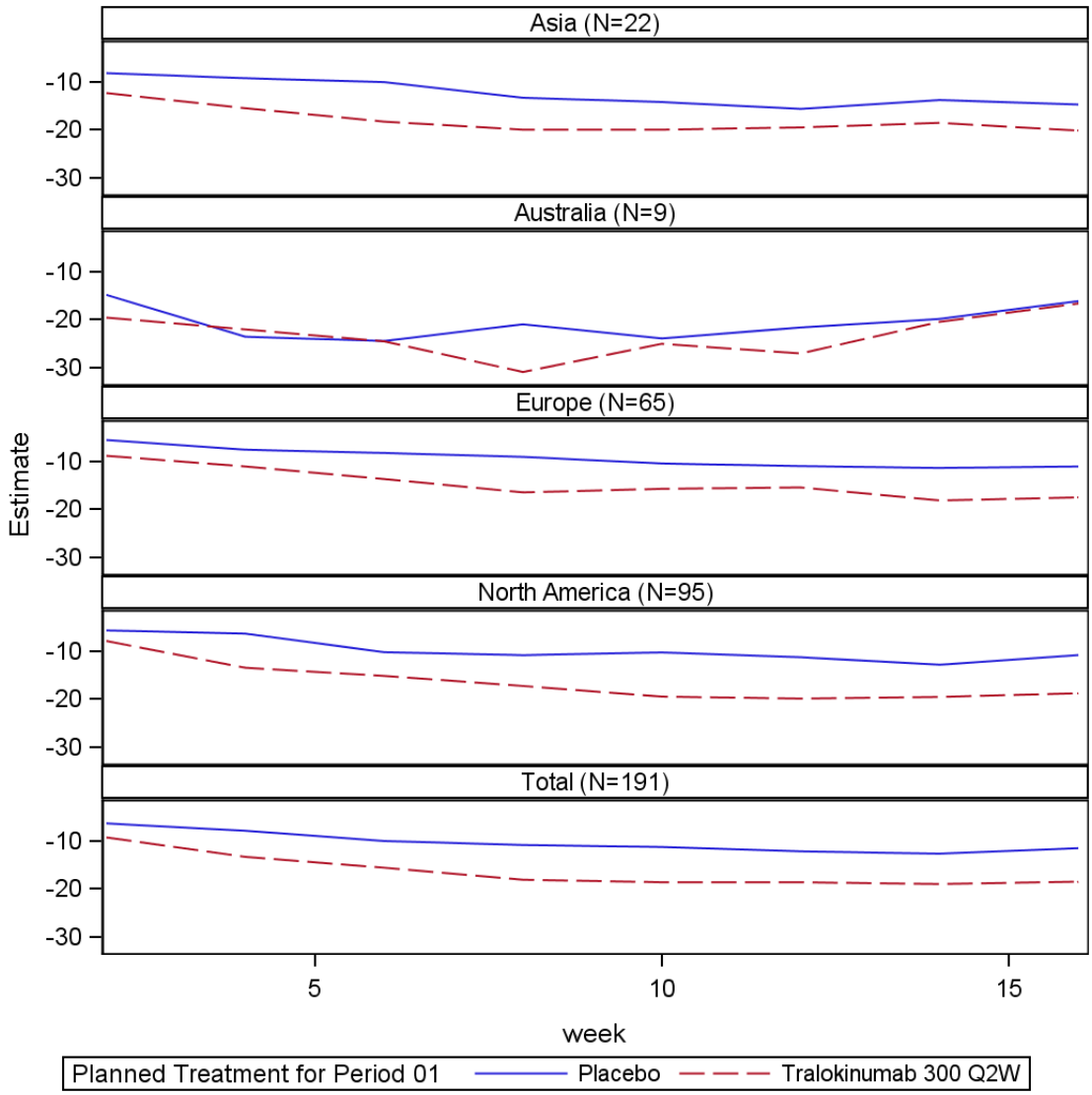
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.291.12.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								-6.69 (2.46) (-11.5, -1.85)		
						0.007				
[SMD T - P]						[-0.49 (-0.92, -0.07)]				
Week 16		43	21.3 (17.83)				47	12.2 (13.85)		
Week 16 chg		43	-11.2 (13.18)	-10.86 (1.74)			47	-18.5 (11.66)	-18.80 (1.69)	
LS Means (T - P) p-value								-7.94 (2.43) (-12.7, -3.15)		
						0.001				
[SMD T - P]						[-0.64 (-1.06, -0.22)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4655
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.19.291.12.2: Total, Region, change in EASI, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in EASI = Treatment*Week + [Baseline EASI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Interference With Sleep (eDiary)										
Total										
Baseline	94	92	6.8 (2.06)			97	96	6.8 (2.12)		
Week 1		91	6.4 (2.21)				94	6.1 (2.23)		
Week 1 chg		91	-0.4 (1.34)	-0.40	(0.23)		94	-0.7 (1.60)	-0.77	(0.23)
LS Means (T - P) p-value									-0.37	(0.32) (-1.00, 0.27)
						0.258				
[SMD T - P]						[-0.25 (-0.54, 0.04)]				
Week 2		90	6.0 (2.35)				94	5.8 (2.29)		
Week 2 chg		90	-0.8 (1.85)	-0.76	(0.23)		94	-1.1 (1.97)	-1.06	(0.23)
LS Means (T - P) p-value									-0.30	(0.32) (-0.94, 0.33)
						0.350				
[SMD T - P]						[-0.16 (-0.45, 0.13)]				
Week 3		89	5.7 (2.31)				94	5.3 (2.40)		
Week 3 chg		89	-1.1 (2.12)	-1.09	(0.23)		94	-1.5 (2.09)	-1.50	(0.23)
LS Means (T - P) p-value									-0.41	(0.32) (-1.05, 0.23)
						0.205				
[SMD T - P]						[-0.20 (-0.49, 0.09)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		89	5.5 (2.29)				91	5.2 (2.48)		
Week 4 chg		89	-1.3 (2.18)	-1.25	(0.23)		91	-1.5 (2.19)	-1.61	(0.23)
LS Means (T - P) p-value									-0.36	(0.33) (-1.00, 0.28)
						0.268				
[SMD T - P]									[-0.17 (-0.46, 0.13)]	
Week 5		85	5.1 (2.41)				94	4.9 (2.57)		
Week 5 chg		85	-1.7 (2.47)	-1.68	(0.23)		94	-1.9 (2.48)	-1.99	(0.23)
LS Means (T - P) p-value									-0.30	(0.33) (-0.95, 0.34)
						0.353				
[SMD T - P]									[-0.12 (-0.42, 0.17)]	
Week 6		86	4.9 (2.56)				92	4.9 (2.64)		
Week 6 chg		86	-1.9 (2.54)	-1.87	(0.23)		92	-1.9 (2.46)	-1.99	(0.23)
LS Means (T - P) p-value									-0.12	(0.33) (-0.76, 0.52)
						0.711				
[SMD T - P]									[-0.05 (-0.34, 0.25)]	
Week 7		82	4.8 (2.47)				91	4.7 (2.51)		
Week 7 chg		82	-2.1 (2.42)	-1.98	(0.24)		91	-2.1 (2.49)	-2.22	(0.23)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.24 (0.33)	(-0.88, 0.41)
						0.466				
[SMD T - P]						[-0.10			(-0.40, 0.20)]	
Week 8		85	4.6 (2.46)				91	4.6 (2.52)		
Week 8 chg		85	-2.2 (2.49)	-2.17	(0.23)		91	-2.3 (2.55)	-2.36	(0.23)
LS Means (T - P) p-value									-0.18 (0.33)	(-0.83, 0.46)
						0.573				
[SMD T - P]						[-0.07			(-0.37, 0.22)]	
Week 9		81	4.6 (2.26)				92	4.3 (2.55)		
Week 9 chg		81	-2.3 (2.30)	-2.17	(0.24)		92	-2.5 (2.55)	-2.59	(0.23)
LS Means (T - P) p-value									-0.42 (0.33)	(-1.07, 0.22)
						0.199				
[SMD T - P]						[-0.17			(-0.47, 0.13)]	
Week 10		83	4.4 (2.50)				89	4.2 (2.66)		
Week 10 chg		83	-2.5 (2.44)	-2.28	(0.24)		89	-2.6 (2.77)	-2.64	(0.23)
LS Means (T - P) p-value									-0.35 (0.33)	(-1.00, 0.29)
						0.281				
[SMD T - P]						[-0.14			(-0.44, 0.16)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		79	4.4 (2.41)				88	4.2 (2.62)		
Week 11 chg		79	-2.4 (2.45)	-2.26	(0.24)		88	-2.5 (2.61)	-2.71	(0.23)
LS Means (T - P) p-value									-0.46	(0.33) (-1.10, 0.19)
						0.169				
[SMD T - P]						[-0.18 (-0.48, 0.12)]				
Week 12		85	4.5 (2.40)				88	4.3 (2.65)		
Week 12 chg		85	-2.3 (2.64)	-2.23	(0.23)		88	-2.5 (2.55)	-2.66	(0.23)
LS Means (T - P) p-value									-0.43	(0.33) (-1.07, 0.22)
						0.191				
[SMD T - P]						[-0.17 (-0.46, 0.13)]				
Week 13		81	4.3 (2.44)				90	4.1 (2.57)		
Week 13 chg		81	-2.4 (2.57)	-2.31	(0.24)		90	-2.8 (2.62)	-2.83	(0.23)
LS Means (T - P) p-value									-0.52	(0.33) (-1.17, 0.12)
						0.112				
[SMD T - P]						[-0.20 (-0.50, 0.10)]				
Week 14		79	4.3 (2.60)				86	3.9 (2.63)		
Week 14 chg		79	-2.7 (2.69)	-2.36	(0.24)		86	-2.8 (2.66)	-2.90	(0.23)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.54 (0.33)	(-1.19, 0.11)
						0.105				
[SMD T - P]						[-0.20 (-0.51, 0.10)]				
Week 15	77	77	4.3 (2.43)			84	84	3.8 (2.53)		
Week 15 chg	77	77	-2.7 (2.57)	-2.39	(0.24)	84	84	-3.0 (2.64)	-3.06	(0.23)
LS Means (T - P) p-value									-0.67 (0.33)	(-1.32, -0.02)
						0.044				
[SMD T - P]						[-0.26 (-0.57, 0.05)]				
Week 16	78	78	4.6 (2.48)			88	88	3.8 (2.56)		
Week 16 chg	78	78	-2.4 (2.58)	-2.17	(0.24)	88	88	-3.0 (2.69)	-3.00	(0.23)
LS Means (T - P) p-value									-0.83 (0.33)	(-1.48, -0.18)
						0.013				
[SMD T - P]						[-0.31 (-0.62, -0.01)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Asia										
Baseline	11	11	6.8 (1.53)			11	11	5.7 (2.84)		
Week 1		11	5.7 (1.86)				10	5.0 (2.08)		
Week 1 chg		11	-1.1 (1.44)	-0.88	(0.68)		10	-0.6 (1.45)	-0.74	(0.69)
LS Means (T - P) p-value									0.14	(0.99) (-1.88, 2.16)
									0.887	
[SMD T - P]									[0.10	(-0.76, 0.95)]
Week 2		11	5.2 (2.21)				11	4.6 (2.03)		
Week 2 chg		11	-1.6 (1.74)	-1.38	(0.68)		11	-1.2 (2.16)	-1.39	(0.68)
LS Means (T - P) p-value									-0.02	(0.98) (-2.03, 1.99)
									0.986	
[SMD T - P]									[-0.01	(-0.84, 0.83)]
Week 3		11	4.4 (1.95)				11	4.3 (2.08)		
Week 3 chg		11	-2.3 (1.84)	-2.07	(0.68)		11	-1.4 (2.07)	-1.62	(0.68)
LS Means (T - P) p-value									0.45	(0.98) (-1.56, 2.47)
									0.647	
[SMD T - P]									[0.23	(-0.61, 1.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		11	4.4 (2.10)				10	4.6 (2.71)		
Week 4 chg		11	-2.4 (1.95)	-2.10	(0.68)		10	-1.0 (2.87)	-1.30	(0.69)
LS Means (T - P) p-value								0.80 (0.99) (-1.22, 2.82)		
						0.425				
[SMD T - P]						[0.33 (-0.53, 1.19)]				
Week 5		11	3.9 (2.49)				11	3.8 (2.48)		
Week 5 chg		11	-2.9 (2.39)	-2.52	(0.68)		11	-2.0 (3.31)	-2.33	(0.68)
LS Means (T - P) p-value								0.19 (0.98) (-1.82, 2.21)		
						0.845				
[SMD T - P]						[0.07 (-0.77, 0.90)]				
Week 6		11	3.8 (2.67)				11	3.6 (2.46)		
Week 6 chg		11	-3.0 (2.47)	-2.62	(0.68)		11	-2.1 (3.29)	-2.50	(0.68)
LS Means (T - P) p-value								0.12 (0.98) (-1.89, 2.13)		
						0.905				
[SMD T - P]						[0.04 (-0.80, 0.88)]				
Week 7		11	3.7 (2.33)				11	3.4 (2.20)		
Week 7 chg		11	-3.1 (2.32)	-2.57	(0.68)		11	-2.3 (3.67)	-2.79	(0.68)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.22 (0.98)	(-2.23, 1.79)
									0.823	
[SMD T - P]									[-0.07	(-0.91, 0.76)]
Week 8		11	3.6 (2.25)				11	3.0 (2.33)		
Week 8 chg		11	-3.1 (2.26)	-2.67	(0.68)		11	-2.7 (3.68)	-3.17	(0.68)
LS Means (T - P) p-value									-0.50 (0.98)	(-2.51, 1.51)
									0.615	
[SMD T - P]									[-0.16	(-1.00, 0.67)]
Week 9		11	3.7 (2.08)				11	3.2 (2.26)		
Week 9 chg		11	-3.1 (2.17)	-2.59	(0.68)		11	-2.5 (3.50)	-2.94	(0.68)
LS Means (T - P) p-value									-0.35 (0.98)	(-2.36, 1.66)
									0.725	
[SMD T - P]									[-0.12	(-0.96, 0.72)]
Week 10		11	3.8 (2.10)				11	3.0 (2.15)		
Week 10 chg		11	-3.0 (2.02)	-2.56	(0.68)		11	-2.7 (3.48)	-3.14	(0.68)
LS Means (T - P) p-value									-0.58 (0.98)	(-2.59, 1.43)
									0.559	
[SMD T - P]									[-0.20	(-1.04, 0.63)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		11	4.1 (2.24)				11	3.1 (2.24)		
Week 11 chg		11	-2.6 (1.97)	-2.25	(0.68)		11	-2.6 (3.20)	-3.00	(0.68)
LS Means (T - P) p-value								-0.76 (0.98) (-2.77, 1.25)		
						0.446				
[SMD T - P]						[-0.29 (-1.13, 0.55)]				
Week 12		11	3.8 (2.28)				11	2.9 (2.20)		
Week 12 chg		11	-3.0 (2.16)	-2.62	(0.68)		11	-2.8 (3.15)	-3.18	(0.68)
LS Means (T - P) p-value								-0.56 (0.98) (-2.57, 1.46)		
						0.575				
[SMD T - P]						[-0.21 (-1.04, 0.63)]				
Week 13		11	3.9 (2.41)				11	3.2 (2.26)		
Week 13 chg		11	-2.8 (2.21)	-2.47	(0.68)		11	-2.5 (3.09)	-2.90	(0.68)
LS Means (T - P) p-value								-0.43 (0.98) (-2.44, 1.59)		
						0.667				
[SMD T - P]						[-0.16 (-1.00, 0.68)]				
Week 14		11	4.0 (2.57)				11	3.2 (2.46)		
Week 14 chg		11	-2.7 (2.41)	-2.36	(0.68)		11	-2.5 (3.19)	-2.88	(0.68)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.52 (0.98) (-2.53, 1.49)	
						0.602				
[SMD T - P]						[-0.18 (-1.02, 0.65)]				
Week 15		11	4.1 (2.42)				11	3.3 (2.63)		
Week 15 chg		11	-2.7 (2.25)	-2.38 (0.68)			11	-2.4 (3.19)	-2.76 (0.68)	
LS Means (T - P) p-value									-0.38 (0.98) (-2.39, 1.63)	
						0.703				
[SMD T - P]						[-0.14 (-0.97, 0.70)]				
Week 16		11	3.9 (2.11)				11	3.3 (2.74)		
Week 16 chg		11	-2.9 (1.93)	-2.55 (0.68)			11	-2.5 (3.24)	-2.78 (0.68)	
LS Means (T - P) p-value									-0.23 (0.98) (-2.24, 1.78)	
						0.818				
[SMD T - P]						[-0.09 (-0.92, 0.75)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Australia										
Baseline	4	4	6.4 (2.36)			5	4	6.7 (1.13)		
Week 1		4	5.2 (1.88)				4	7.9 (1.35)		
Week 1 chg		4	-1.1 (2.25)	-1.03	(1.05)		4	1.2 (1.10)	0.98	(1.04)
LS Means (T - P) p-value								2.01	(1.50)	(-1.36, 5.38)
						0.212				
[SMD T - P]						[1.13		(-0.36, 2.63)]		
Week 2		4	3.8 (1.56)				4	7.9 (1.50)		
Week 2 chg		4	-2.5 (3.01)	-2.55	(1.05)		4	1.2 (1.81)	1.06	(1.04)
LS Means (T - P) p-value								3.61	(1.50)	(0.24, 6.98)
						0.038				
[SMD T - P]						[1.46		(-0.10, 3.01)]		
Week 3		4	4.9 (1.40)				3	7.8 (1.07)		
Week 3 chg		4	-1.4 (2.44)	-1.36	(1.05)		3	0.6 (1.08)	0.67	(1.13)
LS Means (T - P) p-value								2.03	(1.57)	(-1.42, 5.49)
						0.222				
[SMD T - P]						[1.01		(-0.58, 2.60)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		4	4.3 (1.58)				4	7.2 (1.59)		
Week 4 chg		4	-2.0 (3.06)	-2.04	(1.05)		4	0.5 (1.58)	0.31	(1.04)
LS Means (T - P) p-value								2.35	(1.50)	(-1.02, 5.72)
						0.150				
[SMD T - P]						[0.97			(-0.50, 2.43)]	
Week 5		4	3.6 (2.18)				4	5.8 (1.49)		
Week 5 chg		4	-2.7 (4.16)	-2.86	(1.05)		4	-0.8 (2.05)	-0.96	(1.04)
LS Means (T - P) p-value								1.90	(1.50)	(-1.47, 5.27)
						0.237				
[SMD T - P]						[0.58			(-0.84, 1.99)]	
Week 6		4	3.2 (1.32)				4	5.5 (1.83)		
Week 6 chg		4	-3.2 (3.58)	-3.29	(1.05)		4	-1.2 (2.35)	-1.28	(1.04)
LS Means (T - P) p-value								2.01	(1.50)	(-1.36, 5.38)
						0.212				
[SMD T - P]						[0.66			(-0.76, 2.09)]	
Week 7		2	2.3 (2.63)				4	6.5 (1.75)		
Week 7 chg		2	-2.9 (5.76)	-3.51	(1.35)		4	-0.1 (2.26)	-0.27	(1.04)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								3.23 (1.74) (-0.44, 6.91)		
						0.081				
[SMD T - P]						[0.93 (-0.85, 2.71)]				
Week 8		4	3.9 (3.24)				4	6.0 (1.83)		
Week 8 chg		4	-2.4 (4.20)	-2.44 (1.05)			4	-0.7 (2.10)	-0.87 (1.04)	
LS Means (T - P) p-value								1.57 (1.50) (-1.80, 4.94)		
						0.322				
[SMD T - P]						[0.47 (-0.93, 1.88)]				
Week 9		4	3.3 (1.31)				4	6.0 (1.67)		
Week 9 chg		4	-3.1 (2.94)	-3.09 (1.05)			4	-0.7 (1.46)	-0.85 (1.04)	
LS Means (T - P) p-value								2.25 (1.50) (-1.13, 5.62)		
						0.167				
[SMD T - P]						[0.97 (-0.50, 2.43)]				
Week 10		3	4.6 (3.69)				4	5.7 (1.78)		
Week 10 chg		3	-2.8 (4.33)	-1.48 (1.22)			4	-1.0 (1.76)	-1.16 (1.04)	
LS Means (T - P) p-value								0.32 (1.61) (-3.18, 3.82)		
						0.845				
[SMD T - P]						[0.11 (-1.39, 1.60)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		3	2.7 (1.58)				4	6.0 (2.16)		
Week 11 chg		3	-3.6 (3.18)	-2.90	(1.13)		4	-0.7 (2.10)	-0.89	(1.04)
LS Means (T - P) p-value								2.01	(1.56)	(-1.43, 5.44)
						0.224				
[SMD T - P]						[0.78		(-0.77, 2.33)]		
Week 12		4	4.6 (3.37)				4	5.5 (2.09)		
Week 12 chg		4	-1.7 (4.23)	-1.71	(1.05)		4	-1.1 (1.90)	-1.31	(1.04)
LS Means (T - P) p-value								0.40	(1.50)	(-2.97, 3.77)
						0.796				
[SMD T - P]						[0.12		(-1.27, 1.51)]		
Week 13		4	3.9 (2.92)				4	4.8 (1.43)		
Week 13 chg		4	-2.5 (3.91)	-2.46	(1.05)		4	-1.9 (1.70)	-2.09	(1.04)
LS Means (T - P) p-value								0.38	(1.50)	(-3.00, 3.75)
						0.808				
[SMD T - P]						[0.12		(-1.26, 1.51)]		
Week 14		3	4.8 (4.01)				3	5.5 (2.66)		
Week 14 chg		3	-2.7 (4.58)	-0.43	(1.43)		3	-1.7 (2.66)	-0.65	(1.29)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								-0.23 (1.61)	(-3.73, 3.28)	
						0.891				
[SMD T - P]								[-0.06 (-1.66, 1.54)]		
Week 15		3	3.8 (2.42)				2	5.5 (1.90)		
Week 15 chg		3	-2.5 (4.36)	-1.88	(1.13)		2	-1.7 (1.90)	-1.14	(1.26)
LS Means (T - P) p-value								0.75 (1.72)	(-2.90, 4.40)	
						0.669				
[SMD T - P]								[0.20 (-1.59, 1.99)]		
Week 16		3	3.8 (2.44)				3	5.7 (1.43)		
Week 16 chg		3	-2.5 (4.50)	-1.89	(1.13)		3	-1.5 (1.44)	-1.15	(1.13)
LS Means (T - P) p-value								0.74 (1.63)	(-2.79, 4.27)	
						0.657				
[SMD T - P]								[0.22 (-1.38, 1.83)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Europe										
Baseline	32	32	7.4 (1.65)			33	33	7.5 (1.63)		
Week 1		31	7.1 (1.88)				32	6.5 (1.78)		
Week 1 chg		31	-0.3 (1.12)	-0.31	(0.39)		32	-0.9 (1.57)	-0.98	(0.39)
LS Means (T - P) p-value									-0.67	(0.55) (-1.76, 0.42)
						0.228				
[SMD T - P]									[-0.49 (-0.99, 0.01)]	
Week 2		31	6.9 (2.02)				33	6.0 (2.07)		
Week 2 chg		31	-0.5 (1.59)	-0.53	(0.39)		33	-1.5 (1.87)	-1.48	(0.38)
LS Means (T - P) p-value									-0.94	(0.55) (-2.03, 0.14)
						0.088				
[SMD T - P]									[-0.54 (-1.04, -0.04)]	
Week 3		32	6.3 (2.22)				33	5.3 (2.38)		
Week 3 chg		32	-1.1 (1.86)	-1.13	(0.39)		33	-2.2 (2.27)	-2.15	(0.38)
LS Means (T - P) p-value									-1.03	(0.55) (-2.11, 0.06)
						0.063				
[SMD T - P]									[-0.49 (-0.99, 0.00)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		32	6.3 (1.71)				31	5.4 (2.29)		
Week 4 chg		32	-1.1 (1.53)	-1.14	(0.39)		31	-2.1 (2.11)	-2.19	(0.39)
LS Means (T - P) p-value									-1.06	(0.55) (-2.15, 0.03)
						0.057				
[SMD T - P]						[-0.57 (-1.08, -0.07)]				
Week 5		30	5.6 (1.96)				31	5.1 (2.50)		
Week 5 chg		30	-1.7 (1.73)	-1.74	(0.39)		31	-2.4 (2.25)	-2.49	(0.39)
LS Means (T - P) p-value									-0.75	(0.55) (-1.85, 0.35)
						0.179				
[SMD T - P]						[-0.37 (-0.88, 0.13)]				
Week 6		31	5.4 (2.42)				30	5.3 (2.58)		
Week 6 chg		31	-2.1 (2.16)	-2.06	(0.39)		30	-2.1 (2.25)	-2.33	(0.39)
LS Means (T - P) p-value									-0.27	(0.55) (-1.36, 0.83)
						0.632				
[SMD T - P]						[-0.12 (-0.62, 0.38)]				
Week 7		32	5.3 (2.32)				32	4.8 (2.51)		
Week 7 chg		32	-2.1 (2.10)	-2.13	(0.39)		32	-2.6 (2.42)	-2.70	(0.39)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.57 (0.55)	(-1.66, 0.51)
						0.297				
[SMD T - P]						[-0.25			(-0.75, 0.24)]	
Week 8		29	5.0 (2.40)				31	4.8 (2.64)		
Week 8 chg		29	-2.5 (2.27)	-2.47	(0.40)		31	-2.7 (2.57)	-2.80	(0.39)
LS Means (T - P) p-value									-0.33 (0.56)	(-1.43, 0.77)
						0.550				
[SMD T - P]						[-0.14			(-0.64, 0.37)]	
Week 9		29	5.3 (2.21)				31	4.4 (2.72)		
Week 9 chg		29	-2.1 (1.99)	-2.09	(0.40)		31	-3.1 (2.67)	-3.17	(0.39)
LS Means (T - P) p-value									-1.07 (0.56)	(-2.17, 0.03)
						0.056				
[SMD T - P]						[-0.45			(-0.96, 0.06)]	
Week 10		31	5.2 (2.48)				30	4.2 (2.82)		
Week 10 chg		31	-2.3 (2.26)	-2.26	(0.39)		30	-3.2 (2.74)	-3.15	(0.39)
LS Means (T - P) p-value									-0.90 (0.55)	(-2.00, 0.20)
						0.107				
[SMD T - P]						[-0.36			(-0.86, 0.15)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		30	4.9 (2.38)				30	4.4 (2.89)		
Week 11 chg		30	-2.5 (2.30)	-2.42	(0.39)		30	-3.0 (2.59)	-3.17	(0.39)
LS Means (T - P) p-value									-0.76	(0.56) (-1.85, 0.34)
						0.177				
[SMD T - P]						[-0.31 (-0.82, 0.20)]				
Week 12		30	5.0 (2.23)				30	4.8 (2.95)		
Week 12 chg		30	-2.3 (2.22)	-2.40	(0.39)		30	-2.6 (2.59)	-2.78	(0.39)
LS Means (T - P) p-value									-0.38	(0.56) (-1.48, 0.72)
						0.496				
[SMD T - P]						[-0.16 (-0.66, 0.35)]				
Week 13		27	5.1 (2.39)				31	4.2 (2.68)		
Week 13 chg		27	-2.3 (2.36)	-2.33	(0.40)		31	-3.2 (2.64)	-3.24	(0.39)
LS Means (T - P) p-value									-0.91	(0.56) (-2.02, 0.20)
						0.107				
[SMD T - P]						[-0.36 (-0.88, 0.16)]				
Week 14		28	5.0 (2.45)				29	4.0 (2.62)		
Week 14 chg		28	-2.5 (2.44)	-2.37	(0.40)		29	-3.4 (2.67)	-3.46	(0.39)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-1.09 (0.56)	(-2.21, 0.02)
						0.053				
[SMD T - P]						[-0.43			(-0.95, 0.10)]	
Week 15	28		4.8 (2.32)			28		3.6 (2.71)		
Week 15 chg	28		-2.6 (2.40)	-2.54	(0.40)	28		-3.8 (2.71)	-3.89	(0.40)
LS Means (T - P) p-value									-1.35 (0.56)	(-2.47, -0.24)
						0.018				
[SMD T - P]						[-0.53			(-1.06, 0.00)]	
Week 16	29		5.2 (2.33)			30		3.6 (2.60)		
Week 16 chg	29		-2.3 (2.40)	-2.21	(0.40)	30		-3.8 (2.65)	-3.79	(0.39)
LS Means (T - P) p-value									-1.59 (0.56)	(-2.69, -0.48)
						0.005				
[SMD T - P]						[-0.63			(-1.15, -0.10)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
North America										
Baseline	47	45	6.3 (2.33)			48	48	6.6 (2.20)		
Week 1		45	6.1 (2.43)				48	5.8 (2.47)		
Week 1 chg		45	-0.2 (1.33)	-0.26	(0.33)		48	-0.8 (1.61)	-0.80	(0.32)
LS Means (T - P) p-value									-0.54	(0.46) (-1.45, 0.37)
									0.241	
[SMD T - P]									[-0.37 (-0.78, 0.04)]	
Week 2		44	5.8 (2.46)				46	5.7 (2.44)		
Week 2 chg		44	-0.5 (1.84)	-0.58	(0.33)		46	-1.0 (1.92)	-0.92	(0.32)
LS Means (T - P) p-value									-0.33	(0.46) (-1.25, 0.58)
									0.474	
[SMD T - P]									[-0.18 (-0.59, 0.24)]	
Week 3		42	5.6 (2.43)				47	5.3 (2.47)		
Week 3 chg		42	-0.8 (2.29)	-0.76	(0.33)		47	-1.3 (1.90)	-1.23	(0.32)
LS Means (T - P) p-value									-0.47	(0.46) (-1.38, 0.45)
									0.313	
[SMD T - P]									[-0.22 (-0.64, 0.19)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		42	5.3 (2.61)				46	5.1 (2.60)		
Week 4 chg		42	-1.0 (2.53)	-1.02	(0.33)		46	-1.5 (2.05)	-1.45	(0.32)
LS Means (T - P) p-value									-0.43	(0.46) (-1.35, 0.48)
						0.350				
[SMD T - P]									[-0.19	(-0.61, 0.23)]
Week 5		40	5.2 (2.61)				48	4.9 (2.69)		
Week 5 chg		40	-1.3 (2.72)	-1.27	(0.34)		48	-1.7 (2.45)	-1.68	(0.32)
LS Means (T - P) p-value									-0.41	(0.46) (-1.33, 0.51)
						0.381				
[SMD T - P]									[-0.16	(-0.58, 0.26)]
Week 6		40	5.1 (2.64)				47	4.9 (2.73)		
Week 6 chg		40	-1.4 (2.68)	-1.37	(0.34)		47	-1.8 (2.45)	-1.72	(0.32)
LS Means (T - P) p-value									-0.36	(0.47) (-1.28, 0.56)
						0.443				
[SMD T - P]									[-0.14	(-0.56, 0.28)]
Week 7		37	4.9 (2.54)				44	4.8 (2.55)		
Week 7 chg		37	-1.7 (2.56)	-1.59	(0.34)		44	-1.9 (2.16)	-2.00	(0.32)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.41 (0.47)	(-1.33, 0.52)
						0.390				
[SMD T - P]						[-0.17			(-0.61, 0.27)]	
Week 8		41	4.6 (2.50)				45	4.7 (2.45)		
Week 8 chg		41	-1.8 (2.52)	-1.76	(0.34)		45	-2.0 (2.22)	-2.05	(0.32)
LS Means (T - P) p-value									-0.29 (0.47)	(-1.21, 0.63)
						0.534				
[SMD T - P]						[-0.12			(-0.55, 0.30)]	
Week 9		37	4.4 (2.30)				46	4.3 (2.52)		
Week 9 chg		37	-2.1 (2.50)	-1.98	(0.34)		46	-2.3 (2.23)	-2.33	(0.32)
LS Means (T - P) p-value									-0.35 (0.47)	(-1.27, 0.58)
						0.463				
[SMD T - P]						[-0.15			(-0.58, 0.29)]	
Week 10		38	4.0 (2.48)				44	4.4 (2.70)		
Week 10 chg		38	-2.5 (2.60)	-2.25	(0.34)		44	-2.3 (2.66)	-2.32	(0.32)
LS Means (T - P) p-value									-0.07 (0.47)	(-0.99, 0.86)
						0.886				
[SMD T - P]						[-0.03			(-0.46, 0.41)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		35	4.2 (2.51)				43	4.2 (2.50)		
Week 11 chg		35	-2.2 (2.71)	-2.09	(0.34)		43	-2.3 (2.48)	-2.52	(0.32)
LS Means (T - P) p-value									-0.43 (0.47) (-1.37, 0.50)	
						0.364				
[SMD T - P]									[-0.17 (-0.61, 0.28)]	
Week 12		40	4.2 (2.47)				43	4.1 (2.50)		
Week 12 chg		40	-2.1 (2.93)	-2.04	(0.34)		43	-2.5 (2.44)	-2.59	(0.32)
LS Means (T - P) p-value									-0.56 (0.47) (-1.48, 0.37)	
						0.237				
[SMD T - P]									[-0.21 (-0.64, 0.22)]	
Week 13		39	4.0 (2.40)				44	4.1 (2.65)		
Week 13 chg		39	-2.4 (2.75)	-2.25	(0.34)		44	-2.6 (2.58)	-2.63	(0.32)
LS Means (T - P) p-value									-0.38 (0.47) (-1.31, 0.55)	
						0.419				
[SMD T - P]									[-0.14 (-0.57, 0.29)]	
Week 14		37	3.8 (2.60)				43	3.9 (2.71)		
Week 14 chg		37	-2.8 (2.90)	-2.44	(0.34)		43	-2.7 (2.54)	-2.68	(0.32)

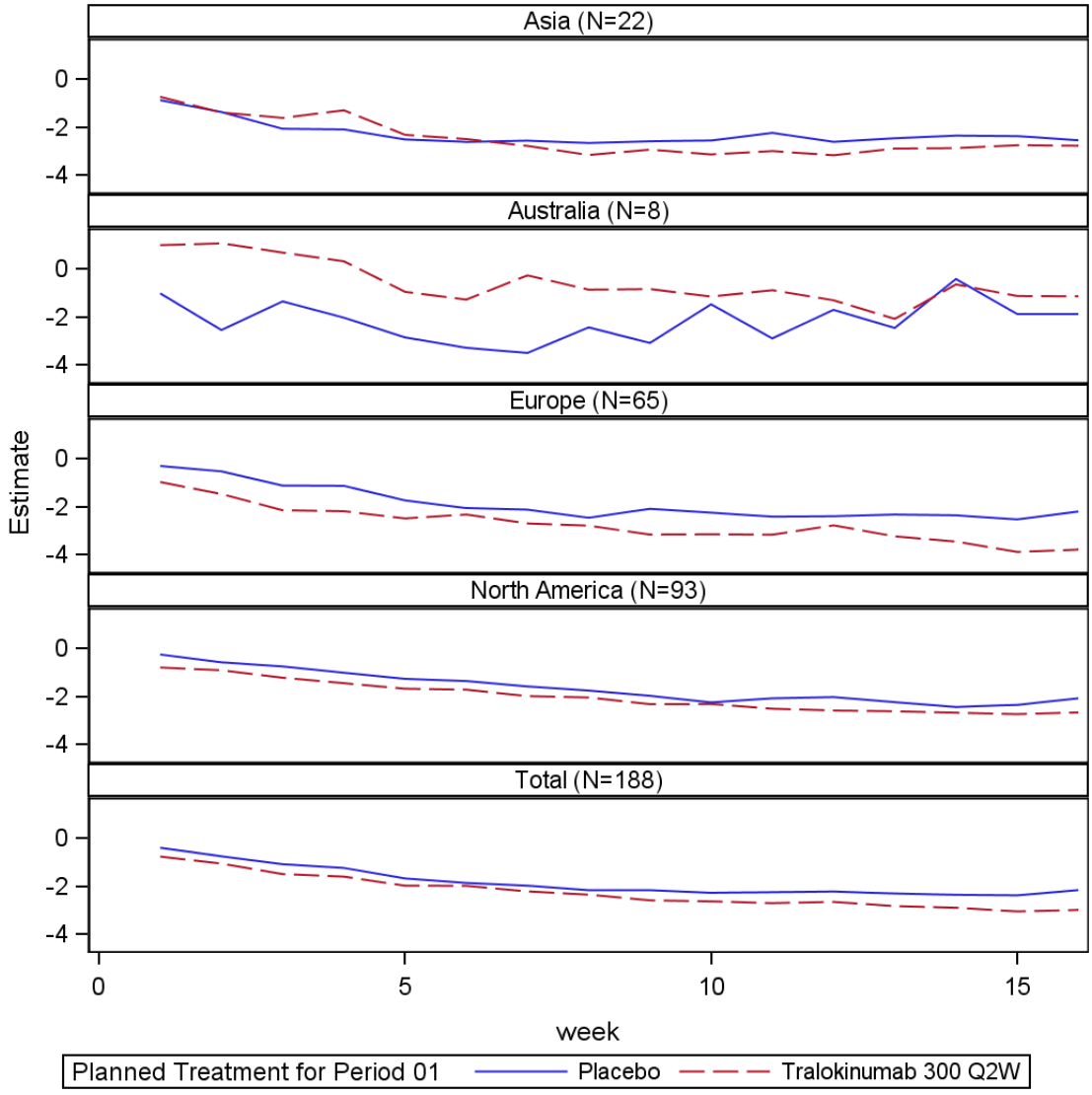
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.295.12.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.24 (0.47) (-1.17, 0.69)	
						0.612				
[SMD T - P]						[-0.09 (-0.53, 0.35)]				
Week 15	35		3.9 (2.55)			43		3.9 (2.43)		
Week 15 chg	35		-2.7 (2.74)	-2.36 (0.34)		43		-2.7 (2.41)	-2.74 (0.32)	
LS Means (T - P) p-value									-0.39 (0.47) (-1.32, 0.55)	
						0.415				
[SMD T - P]						[-0.15 (-0.60, 0.30)]				
Week 16	35		4.3 (2.68)			44		4.0 (2.54)		
Week 16 chg	35		-2.4 (2.82)	-2.09 (0.34)		44		-2.6 (2.55)	-2.67 (0.32)	
LS Means (T - P) p-value									-0.59 (0.47) (-1.52, 0.35)	
						0.215				
[SMD T - P]						[-0.22 (-0.67, 0.23)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.19.295.12.2: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
SCORAD Score										
Total										
Baseline	94	94	67.4 (14.91)			97	97	68.3 (13.71)		
Week 2		94	59.2 (18.89)				97	55.4 (15.59)		
Week 2 chg		94	-8.2 (14.01)	-8.28	(1.79)		97	-12.9 (12.97)	-12.78	(1.76)
LS Means (T - P) p-value									-4.50	(2.51) (-9.43, 0.43)
						0.073				
[SMD T - P]								[-0.33 (-0.62, -0.05)]		
Week 4		90	54.7 (20.17)				96	49.3 (16.99)		
Week 4 chg		90	-12.6 (16.38)	-12.88	(1.81)		96	-19.2 (16.02)	-18.86	(1.76)
LS Means (T - P) p-value									-5.98	(2.53) (-11.0, -1.02)
						0.018				
[SMD T - P]								[-0.37 (-0.66, -0.08)]		
Week 6		91	52.1 (20.65)				94	43.6 (19.42)		
Week 6 chg		91	-15.3 (17.61)	-15.57	(1.80)		94	-24.7 (18.93)	-24.40	(1.77)
LS Means (T - P) p-value									-8.84	(2.53) (-13.8, -3.87)
						<.001				
[SMD T - P]								[-0.48 (-0.78, -0.19)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		88	49.6 (20.33)				95	40.9 (18.23)		
Week 8 chg		88	-17.4 (17.17)	-17.65	(1.82)		95	-27.4 (17.97)	-27.17	(1.77)
LS Means (T - P) p-value									-9.52	(2.54) (-14.5, -4.54)
						<.001				
[SMD T - P]						[-0.54 (-0.84, -0.25)]				
Week 10		86	49.3 (20.83)				93	39.0 (19.16)		
Week 10 chg		86	-17.8 (19.00)	-17.91	(1.83)		93	-29.8 (18.96)	-29.52	(1.78)
LS Means (T - P) p-value									-11.62	(2.55) (-16.6, -6.60)
						<.001				
[SMD T - P]						[-0.61 (-0.91, -0.31)]				
Week 12		90	48.6 (20.94)				93	39.5 (19.84)		
Week 12 chg		90	-18.5 (18.90)	-18.67	(1.81)		93	-28.6 (20.28)	-28.16	(1.78)
LS Means (T - P) p-value									-9.50	(2.54) (-14.5, -4.51)
						<.001				
[SMD T - P]						[-0.48 (-0.78, -0.19)]				
Week 14		83	46.0 (20.48)				95	37.9 (20.73)		
Week 14 chg		83	-20.6 (18.53)	-20.64	(1.84)		95	-30.5 (20.04)	-30.11	(1.77)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-9.47 (2.56)	(-14.5, -4.45)
						<.001				
[SMD T - P]						[-0.49			(-0.79, -0.19)]	
Week 16		87	50.1 (20.98)				95	38.3 (20.94)		
Week 16 chg		87	-16.5 (18.56)	-16.36	(1.82)		95	-30.2 (21.40)	-29.74	(1.77)
LS Means (T - P) p-value									-13.37 (2.54)	(-18.4, -8.38)
						<.001				
[SMD T - P]						[-0.67			(-0.96, -0.37)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Asia										
Baseline	11	11	63.0 (15.03)			11	11	65.1 (14.43)		
Week 2		11	52.0 (15.50)				11	50.0 (15.55)		
Week 2 chg		11	-11.0 (14.23)	-11.31	(4.53)		11	-15.1 (15.09)	-14.65	(4.54)
LS Means (T - P) p-value									-3.35	(6.43) (-16.3, 9.63)
						0.605				
[SMD T - P]									[-0.23	(-1.07, 0.61)]
Week 4		11	45.6 (11.75)				11	44.1 (15.89)		
Week 4 chg		11	-17.3 (16.63)	-17.96	(4.53)		11	-21.0 (17.24)	-20.28	(4.54)
LS Means (T - P) p-value									-2.33	(6.43) (-15.3, 10.65)
						0.719				
[SMD T - P]									[-0.14	(-0.97, 0.70)]
Week 6		11	43.4 (16.69)				11	35.5 (12.29)		
Week 6 chg		11	-19.6 (21.66)	-20.49	(4.53)		11	-29.7 (21.01)	-28.51	(4.54)
LS Means (T - P) p-value									-8.01	(6.43) (-21.0, 4.96)
						0.219				
[SMD T - P]									[-0.38	(-1.22, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		11	37.6 (12.35)				11	33.4 (14.17)		
Week 8 chg		11	-25.4 (14.08)	-26.22	(4.53)		11	-31.7 (23.59)	-30.63	(4.54)
LS Means (T - P) p-value									-4.41	(6.43) (-17.4, 8.56)
						0.496				
[SMD T - P]									[-0.23	(-1.07, 0.61)]
Week 10		11	41.8 (15.70)				11	32.7 (11.97)		
Week 10 chg		11	-21.1 (12.36)	-21.79	(4.53)		11	-32.4 (21.22)	-31.61	(4.54)
LS Means (T - P) p-value									-9.83	(6.43) (-22.8, 3.15)
						0.134				
[SMD T - P]									[-0.57	(-1.42, 0.29)]
Week 12		11	36.1 (15.62)				11	32.9 (17.60)		
Week 12 chg		11	-26.9 (14.46)	-27.63	(4.53)		11	-32.3 (26.00)	-31.31	(4.54)
LS Means (T - P) p-value									-3.68	(6.43) (-16.7, 9.29)
						0.570				
[SMD T - P]									[-0.18	(-1.01, 0.66)]
Week 14		10	37.6 (18.43)				11	32.5 (14.69)		
Week 14 chg		10	-23.4 (18.81)	-25.25	(4.66)		11	-32.7 (23.52)	-31.69	(4.54)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-6.44 (6.52)	(-19.6, 6.71)
						0.329				
[SMD T - P]						[-0.30			(-1.16, 0.56)]	
Week 16		11	38.1 (13.36)				11	34.3 (15.85)		
Week 16 chg		11	-24.9 (15.43)	-25.74 (4.53)			11	-30.8 (24.00)	-29.80 (4.54)	
LS Means (T - P) p-value									-4.06 (6.43)	(-17.0, 8.91)
						0.531				
[SMD T - P]						[-0.20			(-1.04, 0.64)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Australia										
Baseline	4	4	64.0 (9.94)			5	5	73.9 (21.61)		
Week 2		4	42.7 (16.91)				5	57.4 (10.73)		
Week 2 chg		4	-21.3 (8.48)	-20.75	(7.35)		5	-16.6 (14.97)	-17.00	(6.51)
LS Means (T - P) p-value									3.75	(10.22) (-17.6, 25.12)
						0.718				
[SMD T - P]									[0.30	(-1.02, 1.62)]
Week 4		4	42.2 (10.68)				5	47.4 (11.00)		
Week 4 chg		4	-21.8 (13.87)	-23.34	(7.35)		5	-26.5 (20.69)	-25.24	(6.51)
LS Means (T - P) p-value									-1.90	(10.22) (-23.3, 19.46)
						0.854				
[SMD T - P]									[-0.11	(-1.42, 1.21)]
Week 6		4	41.8 (5.85)				5	42.6 (12.69)		
Week 6 chg		4	-22.2 (11.43)	-25.24	(7.35)		5	-31.4 (27.23)	-28.93	(6.51)
LS Means (T - P) p-value									-3.69	(10.22) (-25.1, 17.68)
						0.722				
[SMD T - P]									[-0.17	(-1.49, 1.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		4	45.5 (10.84)				5	34.4 (15.73)		
Week 8 chg		4	-18.4 (18.66)	-19.53	(7.35)		5	-39.5 (18.61)	-38.61	(6.51)
LS Means (T - P) p-value								-19.08 (10.22)	(-40.4,	2.29)
								0.077		
[SMD T - P]								[-1.02 (-2.42,	0.37)]	
Week 10		3	48.5 (16.21)				5	40.8 (10.31)		
Week 10 chg		3	-13.6 (27.43)	-17.55	(8.22)		5	-33.2 (20.63)	-31.05	(6.52)
LS Means (T - P) p-value								-13.50 (10.91)	(-36.1,	9.06)
								0.228		
[SMD T - P]								[-0.58 (-2.04,	0.88)]	
Week 12		4	41.5 (14.25)				5	39.4 (14.44)		
Week 12 chg		4	-22.4 (20.14)	-24.79	(7.35)		5	-34.5 (23.93)	-32.65	(6.51)
LS Means (T - P) p-value								-7.87 (10.22)	(-29.2,	13.50)
								0.451		
[SMD T - P]								[-0.35 (-1.68,	0.97)]	
Week 14		4	44.2 (10.82)				5	47.2 (25.45)		
Week 14 chg		4	-19.8 (20.49)	-20.52	(7.35)		5	-26.7 (24.93)	-26.14	(6.51)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								-5.62 (10.22)	(-27.0, 15.75)	
						0.589				
[SMD T - P]								[-0.24 (-1.56, 1.08)]		
Week 16		4	50.8 (18.90)				5	48.0 (24.48)		
Week 16 chg		4	-13.2 (25.70)	-12.99	(7.35)		5	-25.9 (19.80)	-26.09	(6.51)
LS Means (T - P) p-value								-13.09 (10.22)	(-34.5, 8.27)	
						0.215				
[SMD T - P]								[-0.58 (-1.92, 0.76)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Europe										
Baseline	32	32	68.7 (14.86)			33	33	69.6 (11.98)		
Week 2		32	62.9 (16.94)				33	56.5 (14.50)		
Week 2 chg		32	-5.8 (9.88)	-5.78	(3.21)		33	-13.1 (13.05)	-13.19	(3.16)
LS Means (T - P) p-value									-7.41	(4.50) (-16.3, 1.49)
						0.102				
[SMD T - P]									[-0.64 (-1.14, -0.14)]	
Week 4		32	54.9 (19.69)				32	51.2 (16.84)		
Week 4 chg		32	-13.8 (14.87)	-13.82	(3.21)		32	-18.9 (17.33)	-18.60	(3.19)
LS Means (T - P) p-value									-4.78	(4.53) (-13.7, 4.18)
						0.293				
[SMD T - P]									[-0.30 (-0.79, 0.20)]	
Week 6		32	53.3 (20.65)				31	47.6 (19.27)		
Week 6 chg		32	-15.4 (16.27)	-15.43	(3.21)		31	-22.2 (19.41)	-22.18	(3.22)
LS Means (T - P) p-value									-6.75	(4.55) (-15.7, 2.23)
						0.140				
[SMD T - P]									[-0.38 (-0.88, 0.12)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		31	52.8 (20.78)				31	44.0 (19.75)		
Week 8 chg		31	-15.7 (16.55)	-15.56	(3.23)		31	-25.7 (18.55)	-25.77	(3.22)
LS Means (T - P) p-value									-10.21	(4.57) (-19.2, -1.19)
									0.027	
[SMD T - P]									[-0.58 (-1.09, -0.07)]	
Week 10		31	49.9 (22.17)				32	43.5 (22.28)		
Week 10 chg		31	-18.7 (21.35)	-18.53	(3.23)		32	-26.7 (20.13)	-26.32	(3.19)
LS Means (T - P) p-value									-7.80	(4.55) (-16.8, 1.20)
									0.089	
[SMD T - P]									[-0.38 (-0.87, 0.12)]	
Week 12		32	50.6 (21.58)				32	45.1 (23.88)		
Week 12 chg		32	-18.0 (19.00)	-18.00	(3.21)		32	-25.1 (21.32)	-24.83	(3.19)
LS Means (T - P) p-value									-6.83	(4.53) (-15.8, 2.12)
									0.134	
[SMD T - P]									[-0.34 (-0.83, 0.16)]	
Week 14		29	47.8 (21.83)				32	40.0 (20.70)		
Week 14 chg		29	-19.6 (19.42)	-19.93	(3.29)		32	-30.1 (22.62)	-29.61	(3.19)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-9.68 (4.60)	(-18.8, -0.60)
						0.037				
[SMD T - P]						[-0.46	(-0.97,	0.05)]		
Week 16		29	51.8 (20.64)				32	40.3 (22.52)		
Week 16 chg		29	-15.6 (19.14)	-16.06	(3.29)		32	-29.9 (24.46)	-29.33	(3.19)
LS Means (T - P) p-value									-13.27 (4.60)	(-22.4, -4.19)
						0.004				
[SMD T - P]						[-0.60	(-1.11,	-0.09)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
North America								
Baseline	47	47	67.8 (15.43)		48	48	67.6 (13.94)	
Week 2		47	59.8 (20.28)			48	55.7 (16.84)	
Week 2 chg		47	-8.0 (16.18)	-7.99 (2.49)		48	-11.9 (12.50)	-11.87 (2.47)
LS Means (T - P) p-value							-3.88 (3.51)	(-10.8, 3.05)
							0.270	
[SMD T - P]							[-0.27 (-0.67, 0.14)]	
Week 4		43	58.2 (22.04)			48	49.4 (17.98)	
Week 4 chg		43	-9.7 (17.37)	-9.98 (2.55)		48	-18.1 (14.60)	-18.11 (2.47)
LS Means (T - P) p-value							-8.13 (3.55)	(-15.1, -1.13)
							0.023	
[SMD T - P]							[-0.51 (-0.93, -0.09)]	
Week 6		44	54.4 (21.96)			47	43.0 (21.14)	
Week 6 chg		44	-13.5 (18.10)	-13.79 (2.54)		47	-24.5 (17.41)	-24.35 (2.48)
LS Means (T - P) p-value							-10.56 (3.55)	(-17.6, -3.56)
							0.003	
[SMD T - P]							[-0.60 (-1.02, -0.17)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		42	50.7 (21.60)				48	41.3 (18.11)		
Week 8 chg		42	-16.5 (18.20)	-16.82	(2.56)		48	-26.2 (15.99)	-26.22	(2.47)
LS Means (T - P) p-value									-9.40	(3.56) (-16.4, -2.37)
									0.009	
[SMD T - P]									[-0.55 (-0.97, -0.13)]	
Week 10		41	50.9 (21.45)				45	37.1 (18.62)		
Week 10 chg		41	-16.7 (18.51)	-16.49	(2.58)		45	-31.0 (17.71)	-31.20	(2.50)
LS Means (T - P) p-value									-14.71	(3.59) (-21.8, -7.62)
									<.001	
[SMD T - P]									[-0.81 (-1.25, -0.37)]	
Week 12		43	50.9 (21.41)				45	37.1 (17.10)		
Week 12 chg		43	-16.3 (19.67)	-16.39	(2.55)		45	-29.6 (17.79)	-29.50	(2.50)
LS Means (T - P) p-value									-13.12	(3.58) (-20.2, -6.06)
									<.001	
[SMD T - P]									[-0.70 (-1.13, -0.27)]	
Week 14		40	47.0 (20.75)				47	36.8 (21.57)		
Week 14 chg		40	-20.7 (18.30)	-20.32	(2.59)		47	-30.7 (17.28)	-30.55	(2.48)

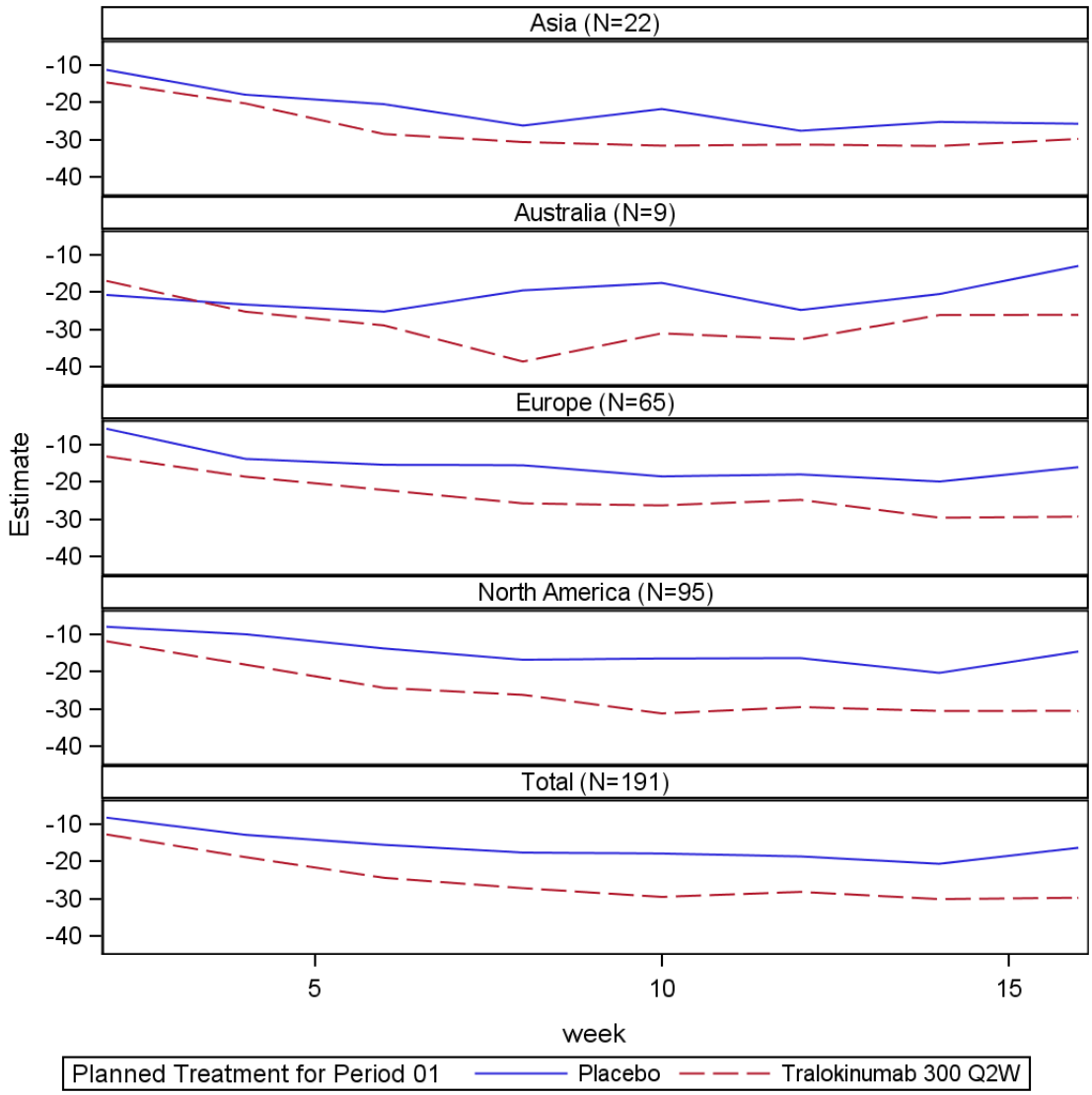
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.297.12.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								-10.22 (3.59) (-17.3, -3.15)		
						0.005				
[SMD T - P]						[-0.58 (-1.01, -0.15)]				
Week 16		43	52.0 (22.48)				47	36.8 (20.70)		
Week 16 chg		43	-15.3 (18.32)	-14.63 (2.55)			47	-30.7 (19.27)	-30.51 (2.48)	
LS Means (T - P) p-value								-15.88 (3.56) (-22.9, -8.86)		
						<.001				
[SMD T - P]						[-0.84 (-1.28, -0.41)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8117
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.19.297.12.2: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
POEM Total										
Total										
Baseline	94	87	20.8 (5.59)			97	94	20.1 (5.83)		
Week 2		86	18.1 (6.90)				93	15.7 (6.02)		
Week 2 chg		86	-2.6 (6.14)	-2.47	(0.68)		93	-4.4 (5.26)	-4.56	(0.65)
LS Means (T - P) p-value									-2.09	(0.94) (-3.95, -0.23)
						0.027				
[SMD T - P]						[-0.37 (-0.66, -0.07)]				
Week 4		82	16.4 (6.70)				91	13.8 (6.32)		
Week 4 chg		82	-4.1 (6.82)	-4.21	(0.69)		91	-6.3 (6.66)	-6.45	(0.66)
LS Means (T - P) p-value									-2.24	(0.95) (-4.11, -0.36)
						0.019				
[SMD T - P]						[-0.33 (-0.63, -0.03)]				
Week 6		82	16.1 (7.75)				91	12.8 (6.65)		
Week 6 chg		82	-4.7 (7.86)	-4.56	(0.69)		91	-7.3 (6.81)	-7.44	(0.66)
LS Means (T - P) p-value									-2.88	(0.95) (-4.76, -1.00)
						0.003				
[SMD T - P]						[-0.39 (-0.69, -0.09)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		82	14.9 (7.61)				91	11.7 (6.15)		
Week 8 chg		82	-5.8 (7.71)	-5.62	(0.69)		91	-8.4 (6.83)	-8.63	(0.66)
LS Means (T - P) p-value								-3.00 (0.95)	(-4.88, -1.13)	
						0.002				
[SMD T - P]								[-0.41 (-0.72, -0.11)]		
Week 12		83	15.8 (7.32)				88	11.8 (6.80)		
Week 12 chg		83	-4.8 (7.40)	-4.68	(0.69)		88	-8.3 (7.29)	-8.34	(0.66)
LS Means (T - P) p-value								-3.67 (0.96)	(-5.55, -1.79)	
						<.001				
[SMD T - P]								[-0.50 (-0.80, -0.20)]		
Week 16		83	16.1 (7.33)				92	11.4 (6.80)		
Week 16 chg		83	-4.6 (8.00)	-4.34	(0.69)		92	-8.7 (7.18)	-8.78	(0.66)
LS Means (T - P) p-value								-4.44 (0.95)	(-6.31, -2.57)	
						<.001				
[SMD T - P]								[-0.59 (-0.89, -0.28)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Asia										
Baseline	11	10	21.2 (5.81)			11	10	18.5 (5.36)		
Week 2		10	19.6 (7.21)				10	13.7 (3.80)		
Week 2 chg		10	-1.6 (5.17)	-1.01	(1.80)		10	-4.8 (6.07)	-5.39	(1.80)
LS Means (T - P) p-value									-4.38	(2.59) (-9.63, 0.88)
						0.100				
[SMD T - P]									[-0.78 (-1.69, 0.13)]	
Week 4		10	15.8 (6.16)				9	12.6 (3.36)		
Week 4 chg		10	-5.4 (6.42)	-4.56	(1.80)		9	-6.4 (5.90)	-7.34	(1.85)
LS Means (T - P) p-value									-2.79	(2.62) (-8.08, 2.51)
						0.293				
[SMD T - P]									[-0.45 (-1.36, 0.46)]	
Week 6		10	15.4 (6.47)				10	9.1 (5.34)		
Week 6 chg		10	-5.8 (7.39)	-4.71	(1.80)		10	-9.4 (7.73)	-10.50	(1.80)
LS Means (T - P) p-value									-5.79	(2.59) (-11.0, -0.54)
						0.032				
[SMD T - P]									[-0.77 (-1.67, 0.14)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		10	14.9 (6.14)				10	10.6 (4.72)		
Week 8 chg		10	-6.3 (7.20)	-5.03	(1.80)		10	-7.9 (8.31)	-9.18	(1.80)
LS Means (T - P) p-value									-4.15	(2.59) (-9.41, 1.10)
						0.118				
[SMD T - P]						[-0.53 (-1.43, 0.36)]				
Week 12		9	14.6 (7.84)				10	11.4 (4.30)		
Week 12 chg		9	-6.2 (4.68)	-5.53	(1.85)		10	-7.1 (8.70)	-7.96	(1.80)
LS Means (T - P) p-value									-2.42	(2.62) (-7.72, 2.87)
						0.360				
[SMD T - P]						[-0.34 (-1.25, 0.57)]				
Week 16		10	14.5 (5.44)				10	11.2 (4.92)		
Week 16 chg		10	-6.7 (6.17)	-5.44	(1.80)		10	-7.3 (8.69)	-8.57	(1.80)
LS Means (T - P) p-value									-3.13	(2.59) (-8.38, 2.12)
						0.235				
[SMD T - P]						[-0.42 (-1.30, 0.47)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Australia										
Baseline	4	4	25.8 (2.63)			5	5	25.2 (2.17)		
Week 2		4	16.5 (11.24)				5	18.0 (5.70)		
Week 2 chg		4	-9.3 (9.29)	-8.94	(4.37)		5	-7.2 (7.40)	-7.47	(3.90)
LS Means (T - P) p-value									1.47	(5.89) (-11.6, 14.58)
						0.808				
[SMD T - P]								[0.18 (-1.14, 1.50)]		
Week 4		4	17.0 (9.20)				4	14.0 (5.66)		
Week 4 chg		4	-8.8 (6.75)	-8.43	(4.37)		4	-10.8 (7.63)	-11.75	(4.15)
LS Means (T - P) p-value									-3.32	(6.09) (-16.7, 10.05)
						0.597				
[SMD T - P]								[-0.46 (-1.86, 0.94)]		
Week 6		4	15.8 (9.98)				5	12.4 (5.68)		
Week 6 chg		4	-10.0 (7.62)	-9.64	(4.37)		5	-12.8 (7.66)	-13.11	(3.90)
LS Means (T - P) p-value									-3.47	(5.89) (-16.6, 9.64)
						0.569				
[SMD T - P]								[-0.45 (-1.78, 0.88)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		4	18.5 (10.97)				5	9.6 (3.51)		
Week 8 chg		4	-7.3 (9.50)	-6.92	(4.37)		5	-15.6 (5.32)	-15.89	(3.90)
LS Means (T - P) p-value								-8.97 (5.89)	(-22.1,	4.14)
						0.159				
[SMD T - P]						[-1.21	(-2.64,	0.22)]		
Week 12		4	17.8 (10.63)				5	10.8 (6.87)		
Week 12 chg		4	-8.0 (9.97)	-7.20	(4.37)		5	-14.4 (8.85)	-14.99	(3.90)
LS Means (T - P) p-value								-7.78 (5.89)	(-20.9,	5.33)
						0.216				
[SMD T - P]						[-0.83	(-2.20,	0.54)]		
Week 16		4	18.8 (11.93)				5	13.4 (5.68)		
Week 16 chg		4	-7.0 (11.02)	-6.49	(4.37)		5	-11.8 (7.22)	-12.20	(3.90)
LS Means (T - P) p-value								-5.72 (5.89)	(-18.8,	7.39)
						0.354				
[SMD T - P]						[-0.63	(-1.98,	0.71)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
Europe								
Baseline	32	30	20.9 (4.58)		33	33	19.7 (6.11)	
Week 2		30	18.7 (5.90)			32	15.0 (5.74)	
Week 2 chg		30	-2.3 (5.25)	-2.02 (1.08)		32	-4.5 (5.06)	-4.81 (1.04)
LS Means (T - P) p-value								-2.79 (1.51) (-5.78, 0.19)
					0.066			
[SMD T - P]								[-0.54 (-1.05, -0.04)]
Week 4		30	16.2 (6.33)			32	12.5 (5.96)	
Week 4 chg		30	-4.7 (6.69)	-4.23 (1.08)		32	-7.0 (7.49)	-7.38 (1.04)
LS Means (T - P) p-value								-3.15 (1.51) (-6.14, -0.16)
					0.039			
[SMD T - P]								[-0.44 (-0.95, 0.06)]
Week 6		30	14.5 (7.02)			31	12.3 (5.54)	
Week 6 chg		30	-6.4 (7.46)	-6.09 (1.08)		31	-7.3 (5.21)	-7.63 (1.05)
LS Means (T - P) p-value								-1.53 (1.52) (-4.53, 1.47)
					0.314			
[SMD T - P]								[-0.24 (-0.74, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		29	14.7 (7.61)				31	11.7 (5.78)		
Week 8 chg		29	-6.2 (8.42)	-5.93	(1.09)		31	-7.8 (5.73)	-8.19	(1.05)
LS Means (T - P) p-value									-2.26	(1.53) (-5.27, 0.76)
									0.141	
[SMD T - P]									[-0.32 (-0.83, 0.19)]	
Week 12		30	15.3 (7.13)				32	11.9 (6.71)		
Week 12 chg		30	-5.6 (7.21)	-5.36	(1.08)		32	-7.7 (6.01)	-7.81	(1.04)
LS Means (T - P) p-value									-2.45	(1.51) (-5.44, 0.53)
									0.107	
[SMD T - P]									[-0.37 (-0.87, 0.13)]	
Week 16		29	16.9 (6.81)				32	10.6 (6.37)		
Week 16 chg		29	-4.1 (6.93)	-3.88	(1.09)		32	-9.0 (5.64)	-9.13	(1.04)
LS Means (T - P) p-value									-5.25	(1.52) (-8.26, -2.25)
									<.001	
[SMD T - P]									[-0.83 (-1.36, -0.31)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
North America								
Baseline	47	43	20.1 (6.23)		48	46	20.3 (5.83)	
Week 2		42	17.6 (7.21)			46	16.3 (6.60)	
Week 2 chg		42	-2.4 (6.46)	-2.45 (1.01)		46	-4.0 (5.07)	-3.97 (0.98)
LS Means (T - P) p-value								-1.52 (1.41) (-4.30, 1.26)
								0.281
[SMD T - P]								[-0.26 (-0.68, 0.16)]
Week 4		38	16.7 (7.11)			46	15.0 (6.94)	
Week 4 chg		38	-2.8 (6.94)	-3.53 (1.05)		46	-5.3 (6.07)	-5.20 (0.98)
LS Means (T - P) p-value								-1.67 (1.43) (-4.50, 1.15)
								0.243
[SMD T - P]								[-0.26 (-0.69, 0.17)]
Week 6		38	17.6 (8.37)			45	14.0 (7.47)	
Week 6 chg		38	-2.6 (7.94)	-2.67 (1.04)		45	-6.2 (7.29)	-6.16 (0.98)
LS Means (T - P) p-value								-3.48 (1.43) (-6.31, -0.66)
								0.016
[SMD T - P]								[-0.46 (-0.90, -0.02)]

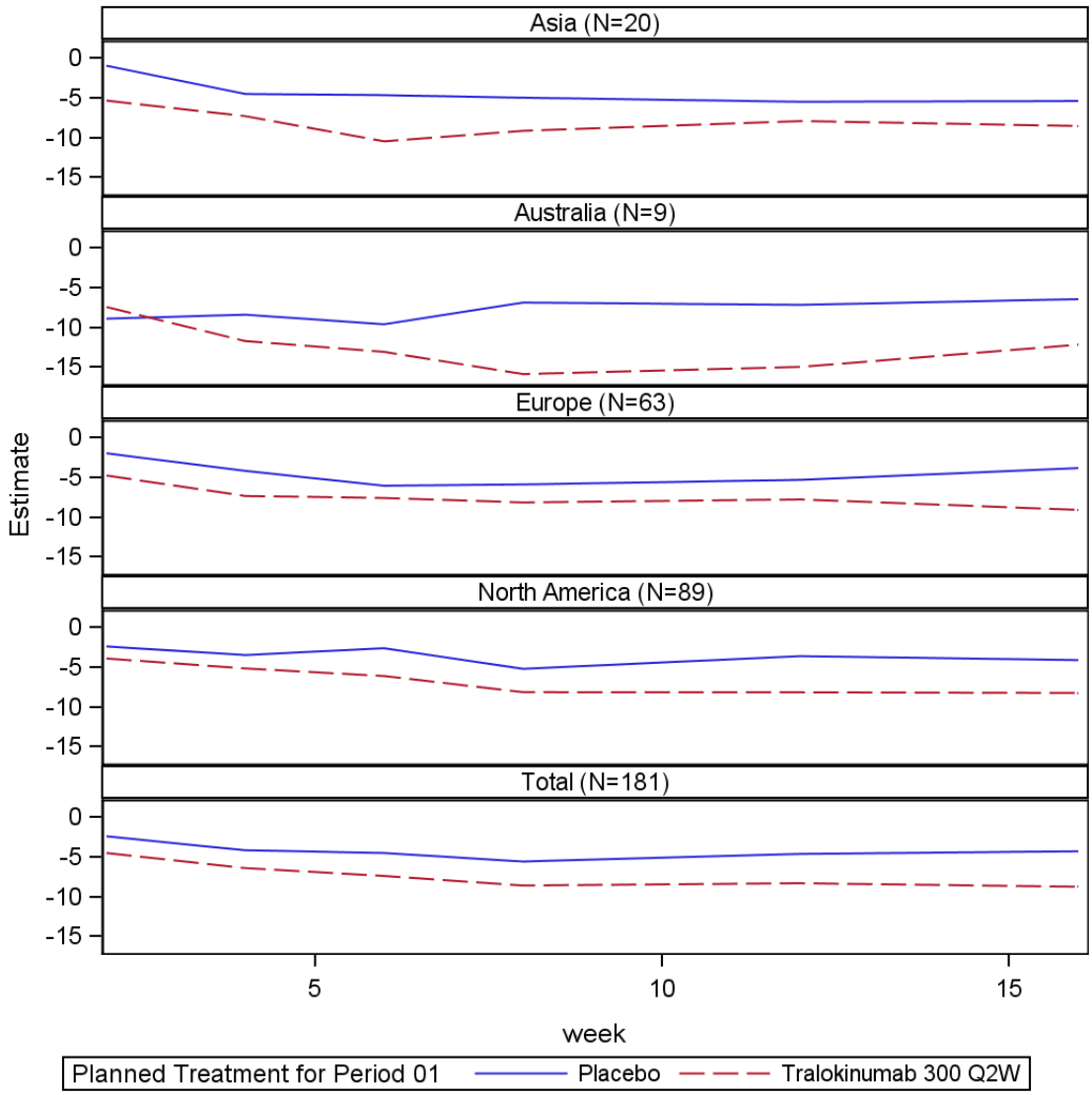
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.300.12.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		39	14.7 (7.81)				45	12.1 (6.92)		
Week 8 chg		39	-5.2 (7.36)	-5.25	(1.04)		45	-8.1 (7.07)	-8.18	(0.98)
LS Means (T - P) p-value									-2.93	(1.43) (-5.75, -0.11)
									0.041	
[SMD T - P]									[-0.41 (-0.84, 0.03)]	
Week 12		40	16.4 (7.23)				41	11.9 (7.51)		
Week 12 chg		40	-3.5 (7.77)	-3.67	(1.03)		41	-8.3 (7.58)	-8.20	(1.00)
LS Means (T - P) p-value									-4.53	(1.44) (-7.37, -1.69)
									0.002	
[SMD T - P]									[-0.59 (-1.04, -0.15)]	
Week 16		40	15.7 (7.75)				45	11.9 (7.61)		
Week 16 chg		40	-4.1 (8.93)	-4.16	(1.03)		45	-8.4 (7.90)	-8.29	(0.98)
LS Means (T - P) p-value									-4.13	(1.42) (-6.93, -1.32)
									0.004	
[SMD T - P]									[-0.49 (-0.92, -0.06)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4854
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.19.300.12.2: Total, Region, change in POEM, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in POEM = Treatment*Week + [Baseline POEM]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.480.12.1: Total, Region, CDLQI 0/1, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	97	14 (14.4)	7.4 (-1.41;16.24)	2.0 (0.85; 4.81)	2.2 (0.84; 5.70)	0.1060	0.2570
Placebo	94	7 (7.4)					
Asia							
Tralokinumab 300 Q2W	11	3 (27.3)	18.2 (-12.5;48.89)	3.0 (0.38;23.68)	4.0 (0.32;50.76)	0.2819	
Placebo	11	1 (9.1)					
Australia							
Tralokinumab 300 Q2W	5	0 (0.0)	-23.1 (-65.3;19.15)	0.0 (Not estimable)	0.0 (Not estimable)	0.3173	
Placebo	4	1 (25.0)					
Europe							
Tralokinumab 300 Q2W	33	5 (15.2)	12.9 (-0.72;26.45)	5.4 (0.66;44.01)	6.6 (0.68;64.42)	0.0749	
Placebo	32	1 (3.1)					
North America							
Tralokinumab 300 Q2W	48	6 (12.5)	4.0 (-8.34;16.34)	1.5 (0.43; 5.03)	1.5 (0.40; 5.81)	0.5299	
Placebo	47	4 (8.5)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. Setting missing data in dataset to non-responders. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
CDLQI Score										
Total										
Baseline	94	89	13.3 (6.04)			97	94	13.4 (7.26)		
Week 2		88	9.9 (5.59)				93	9.1 (5.75)		
Week 2 chg		88	-3.4 (5.37)	-3.41	(0.50)		93	-4.2 (5.37)	-4.29	(0.49)
LS Means (T - P) p-value								-0.88 (0.70) (-2.25, 0.49)		
						0.206				
[SMD T - P]								[-0.16 (-0.46, 0.13)]		
Week 4		84	9.3 (5.98)				91	7.6 (5.56)		
Week 4 chg		84	-3.9 (6.29)	-3.97	(0.51)		91	-5.7 (6.06)	-5.75	(0.49)
LS Means (T - P) p-value								-1.78 (0.70) (-3.17, -0.40)		
						0.012				
[SMD T - P]								[-0.29 (-0.59, 0.01)]		
Week 6		84	8.7 (5.91)				91	7.2 (5.56)		
Week 6 chg		84	-4.9 (6.38)	-4.69	(0.51)		91	-6.1 (6.16)	-6.07	(0.49)
LS Means (T - P) p-value								-1.39 (0.70) (-2.77, -0.00)		
						0.050				
[SMD T - P]								[-0.22 (-0.52, 0.08)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		84	7.1 (5.06)				92	6.6 (5.01)		
Week 8 chg		84	-6.4 (5.85)	-6.24	(0.51)		92	-6.7 (6.09)	-6.69	(0.49)
LS Means (T - P) p-value								-0.45 (0.70) (-1.83, 0.94)		
						0.525				
[SMD T - P]								[-0.07 (-0.37, 0.22)]		
Week 12		85	7.9 (5.33)				87	6.4 (5.42)		
Week 12 chg		85	-5.3 (6.44)	-5.36	(0.50)		87	-6.9 (6.56)	-6.84	(0.49)
LS Means (T - P) p-value								-1.48 (0.71) (-2.87, -0.09)		
						0.037				
[SMD T - P]								[-0.23 (-0.53, 0.07)]		
Week 16		84	8.3 (5.27)				92	6.1 (5.47)		
Week 16 chg		84	-5.0 (6.57)	-4.98	(0.51)		92	-7.2 (6.90)	-7.19	(0.49)
LS Means (T - P) p-value								-2.21 (0.70) (-3.59, -0.83)		
						0.002				
[SMD T - P]								[-0.33 (-0.63, -0.03)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Asia										
Baseline	11	11	12.6 (6.86)			11	10	9.3 (5.21)		
Week 2		11	7.5 (5.41)				10	5.2 (3.26)		
Week 2 chg		11	-5.2 (5.13)	-4.34	(1.11)		10	-4.1 (3.21)	-4.90	(1.16)
LS Means (T - P) p-value									-0.56	(1.64) (-3.92, 2.81)
						0.738				
[SMD T - P]						[-0.13 (-0.99, 0.73)]				
Week 4		11	6.6 (6.22)				9	3.6 (2.30)		
Week 4 chg		11	-6.0 (5.88)	-5.01	(1.11)		9	-5.1 (4.23)	-6.65	(1.19)
LS Means (T - P) p-value									-1.64	(1.67) (-5.05, 1.77)
						0.334				
[SMD T - P]						[-0.31 (-1.20, 0.57)]				
Week 6		11	6.1 (5.66)				10	2.6 (1.65)		
Week 6 chg		11	-6.5 (6.62)	-5.24	(1.11)		10	-6.7 (5.42)	-7.94	(1.16)
LS Means (T - P) p-value									-2.70	(1.64) (-6.07, 0.67)
						0.112				
[SMD T - P]						[-0.44 (-1.31, 0.42)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		11	5.6 (3.93)				10	2.9 (2.18)		
Week 8 chg		11	-7.0 (5.73)	-5.60	(1.11)		10	-6.4 (5.80)	-7.72	(1.16)
LS Means (T - P) p-value									-2.12	(1.64) (-5.49, 1.24)
									0.207	
[SMD T - P]									[-0.37 (-1.23, 0.50)]	
Week 12		10	5.8 (4.98)				10	2.9 (2.08)		
Week 12 chg		10	-5.8 (5.29)	-4.93	(1.12)		10	-6.4 (6.00)	-7.54	(1.16)
LS Means (T - P) p-value									-2.61	(1.65) (-5.98, 0.76)
									0.124	
[SMD T - P]									[-0.46 (-1.35, 0.43)]	
Week 16		11	5.5 (3.62)				10	2.7 (1.83)		
Week 16 chg		11	-7.2 (5.46)	-5.76	(1.11)		10	-6.6 (5.87)	-7.94	(1.16)
LS Means (T - P) p-value									-2.17	(1.64) (-5.54, 1.19)
									0.197	
[SMD T - P]									[-0.38 (-1.25, 0.48)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Australia										
Baseline	4	4	19.3 (6.95)			5	5	18.2 (7.05)		
Week 2		4	7.8 (4.99)				5	11.0 (5.24)		
Week 2 chg		4	-11.5 (3.42)	-10.69	(2.84)		5	-7.2 (5.85)	-7.88	(2.54)
LS Means (T - P) p-value									2.81	(3.83) (-5.84, 11.47)
						0.481				
[SMD T - P]									[0.57	(-0.77, 1.91)]
Week 4		4	8.3 (6.40)				4	11.0 (8.21)		
Week 4 chg		4	-11.0 (4.08)	-10.21	(2.84)		4	-8.0 (9.20)	-8.86	(2.66)
LS Means (T - P) p-value									1.36	(3.91) (-7.38, 10.10)
						0.736				
[SMD T - P]									[0.19	(-1.20, 1.58)]
Week 6		4	9.5 (6.19)				5	8.6 (6.02)		
Week 6 chg		4	-9.8 (5.32)	-8.87	(2.84)		5	-9.6 (8.11)	-10.36	(2.54)
LS Means (T - P) p-value									-1.49	(3.83) (-10.1, 7.16)
						0.706				
[SMD T - P]									[-0.21	(-1.53, 1.11)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
Week 8		4 14.0 (9.02)			5 7.2 (7.33)	
Week 8 chg		4 -5.3 (10.44)	-4.30 (2.84)		5 -11.0 (8.72)	-11.82 (2.54)
LS Means (T - P) p-value					-7.52 (3.83)	(-16.2, 1.13)
				0.081		
[SMD T - P]					[-0.79 (-2.16, 0.57)]	
Week 12		4 10.8 (7.09)			5 7.2 (6.87)	
Week 12 chg		4 -8.5 (9.81)	-7.47 (2.84)		5 -11.0 (9.22)	-11.91 (2.54)
LS Means (T - P) p-value					-4.45 (3.83)	(-13.1, 4.21)
				0.275		
[SMD T - P]					[-0.47 (-1.80, 0.86)]	
Week 16		4 10.3 (7.46)			5 8.6 (6.88)	
Week 16 chg		4 -9.0 (10.68)	-8.01 (2.84)		5 -9.6 (7.86)	-10.47 (2.54)
LS Means (T - P) p-value					-2.46 (3.83)	(-11.1, 6.19)
				0.536		
[SMD T - P]					[-0.27 (-1.59, 1.05)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Europe										
Baseline	32	31	15.0 (5.62)			33	33	14.5 (7.85)		
Week 2		31	12.3 (5.53)				32	9.8 (6.39)		
Week 2 chg		31	-2.7 (5.18)	-2.57	(0.89)		32	-4.5 (5.87)	-4.78	(0.87)
LS Means (T - P) p-value									-2.21	(1.25) (-4.67, 0.26)
						0.079				
[SMD T - P]									[-0.40 (-0.90, 0.10)]	
Week 4		31	11.3 (5.59)				32	7.9 (5.46)		
Week 4 chg		31	-3.7 (6.20)	-3.50	(0.89)		32	-6.5 (6.54)	-6.56	(0.87)
LS Means (T - P) p-value									-3.07	(1.25) (-5.53, -0.60)
						0.015				
[SMD T - P]									[-0.48 (-0.98, 0.02)]	
Week 6		31	9.5 (6.06)				31	8.2 (5.64)		
Week 6 chg		31	-5.5 (6.82)	-5.28	(0.89)		31	-6.0 (6.26)	-6.14	(0.88)
LS Means (T - P) p-value									-0.86	(1.25) (-3.34, 1.62)
						0.493				
[SMD T - P]									[-0.13 (-0.63, 0.37)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		30	8.0 (4.50)				31	7.8 (5.38)		
Week 8 chg		30	-7.4 (6.05)	-7.00	(0.90)		31	-6.5 (5.89)	-6.60	(0.88)
LS Means (T - P) p-value									0.40	(1.26) (-2.09, 2.89)
									0.752	
[SMD T - P]									[0.07	(-0.44, 0.57)]
Week 12		31	8.5 (6.05)				32	7.1 (6.31)		
Week 12 chg		31	-6.5 (6.42)	-6.32	(0.89)		32	-7.3 (6.49)	-7.32	(0.87)
LS Means (T - P) p-value									-1.00	(1.25) (-3.46, 1.47)
									0.426	
[SMD T - P]									[-0.15	(-0.65, 0.34)]
Week 16		29	9.8 (6.00)				32	5.9 (5.44)		
Week 16 chg		29	-5.6 (6.80)	-5.32	(0.91)		32	-8.4 (6.65)	-8.54	(0.87)
LS Means (T - P) p-value									-3.23	(1.26) (-5.72, -0.73)
									0.012	
[SMD T - P]									[-0.48	(-0.99, 0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
North America								
Baseline	47	43	11.8 (5.59)		48	46	13.0 (6.92)	
Week 2		42	9.0 (5.25)			46	9.2 (5.56)	
Week 2 chg		42	-2.7 (5.11)	-3.01 (0.71)		46	-3.8 (5.38)	-3.47 (0.68)
LS Means (T - P) p-value								-0.46 (0.99) (-2.41, 1.49)
					0.643			
[SMD T - P]								[-0.09 (-0.51, 0.33)]
Week 4		38	8.6 (5.92)			46	7.9 (5.61)	
Week 4 chg		38	-2.8 (6.23)	-3.35 (0.73)		46	-5.1 (5.82)	-4.74 (0.68)
LS Means (T - P) p-value								-1.39 (1.01) (-3.38, 0.59)
					0.168			
[SMD T - P]								[-0.23 (-0.66, 0.20)]
Week 6		38	8.6 (5.84)			45	7.4 (5.65)	
Week 6 chg		38	-3.4 (5.77)	-3.47 (0.73)		45	-5.6 (6.11)	-5.30 (0.69)
LS Means (T - P) p-value								-1.83 (1.01) (-3.81, 0.16)
					0.071			
[SMD T - P]								[-0.31 (-0.74, 0.13)]

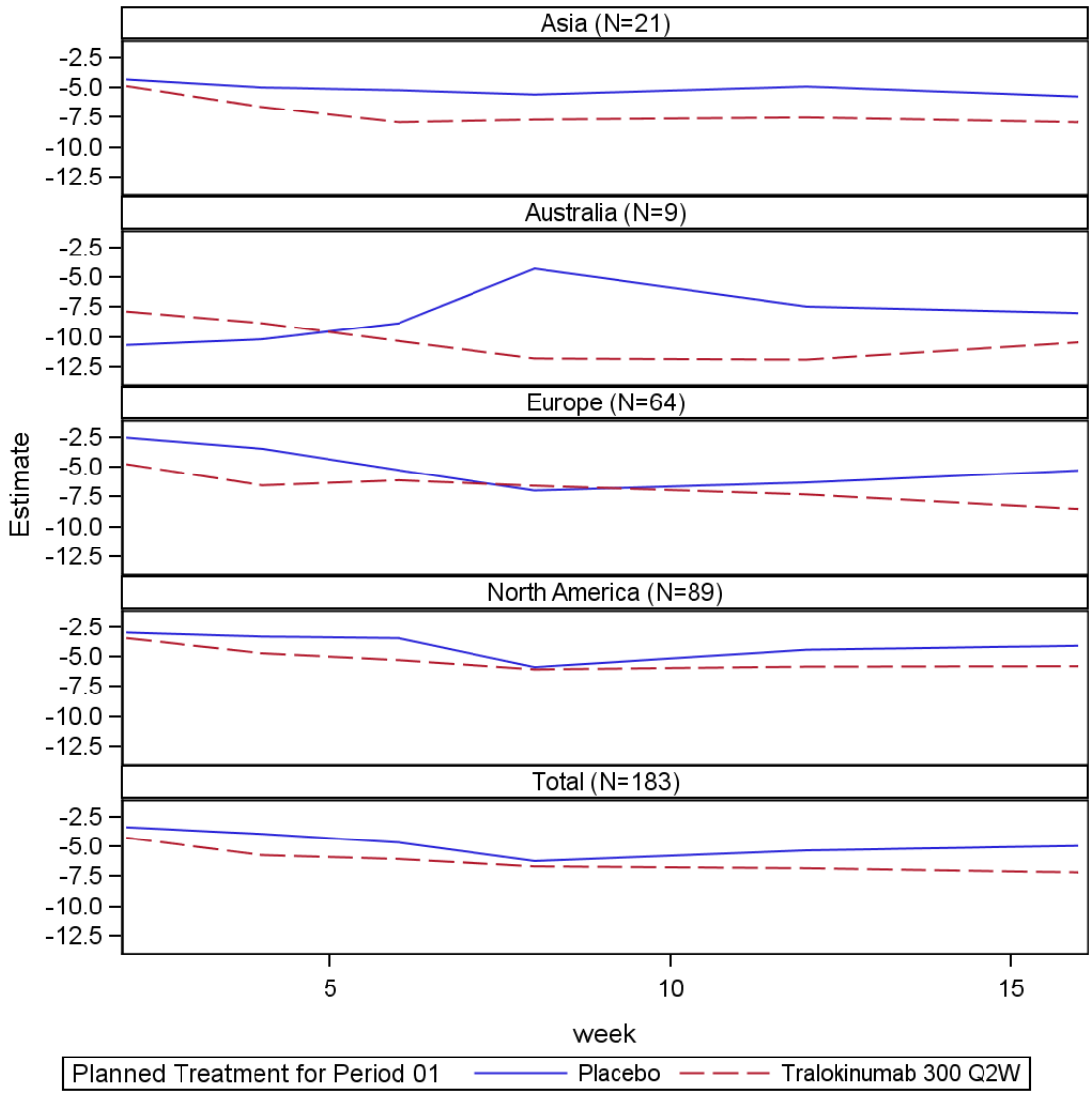
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.482.12.1: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 8		39	6.1 (4.76)				46	6.5 (4.65)		
Week 8 chg		39	-5.6 (5.27)	-5.89	(0.73)		46	-6.5 (6.02)	-6.08	(0.68)
LS Means (T - P) p-value								-0.19 (1.00)	(-2.17,	1.79)
						0.851				
[SMD T - P]						[-0.03	(-0.46,	0.39)]		
Week 12		40	7.7 (4.60)				40	6.5 (4.87)		
Week 12 chg		40	-4.0 (6.30)	-4.44	(0.72)		40	-6.2 (6.45)	-5.84	(0.71)
LS Means (T - P) p-value								-1.40 (1.02)	(-3.40,	0.60)
						0.170				
[SMD T - P]						[-0.22	(-0.66,	0.22)]		
Week 16		40	7.9 (4.61)				45	6.7 (5.67)		
Week 16 chg		40	-3.7 (6.10)	-4.11	(0.72)		45	-6.3 (7.20)	-5.80	(0.69)
LS Means (T - P) p-value								-1.70 (1.00)	(-3.67,	0.28)
						0.092				
[SMD T - P]						[-0.25	(-0.68,	0.17)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.19.482.12.2: Total, Region, change in CDLQI, Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.483.12.1: Total, Region, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	96	32 (33.3)	15.7 (3.43;27.88)	1.9 (1.11; 3.21)	2.4 (1.17; 4.76)	0.0141	0.0618
Placebo	90	16 (17.8)					
Asia							
Tralokinumab 300 Q2W	11	5 (45.5)	36.4 (1.88;70.85)	5.0 (0.68;36.90)	7.7 (0.72;81.37)	0.0675	
Placebo	11	1 (9.1)					
Australia							
Tralokinumab 300 Q2W	4	0 (0.0)	-42.9 (-96.3;10.58)	0.0 (Not estimable)	0.0 (Not estimable)	0.1824	
Placebo	4	2 (50.0)					
Europe							
Tralokinumab 300 Q2W	33	16 (48.5)	25.0 (3.00;47.08)	2.1 (1.02; 4.35)	3.3 (1.09; 9.98)	0.0336	
Placebo	32	7 (21.9)					
North America							
Tralokinumab 300 Q2W	48	11 (22.9)	8.8 (-6.98;24.52)	1.6 (0.66; 4.04)	1.8 (0.61; 5.43)	0.2878	
Placebo	43	6 (14.0)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Including subjects with a baseline of at least 4. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA. Including subjects with a baseline score of at least 4.

09MAR22 12:46 LP0162-Payer /p_bin_eff1/T_t_reg4_g83_hp_w16.txt

Table 1.19.484.12.1: Total, Region, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1334 300mg, Week 16

Treatment	N	Responders n (%)	Difference in percentage (95% CI)	Relative risk (95% CI)	Odds ratio estimate (95% CI)	p-value (OR)*	p-value (interaction) #
Total							
Tralokinumab 300 Q2W	96	38 (39.6)	9.0 (-4.61;22.61)	1.3 (0.87; 1.93)	1.5 (0.81; 2.74)	0.2017	0.1767
Placebo	91	28 (30.8)					
Asia							
Tralokinumab 300 Q2W	11	5 (45.5)	18.2 (-21.0;57.37)	1.7 (0.53; 5.28)	2.3 (0.37;13.56)	0.3944	
Placebo	11	3 (27.3)					
Australia							
Tralokinumab 300 Q2W	4	0 (0.0)	-42.9 (-96.3;10.58)	0.0 (Not estimable)	0.0 (Not estimable)	0.1824	
Placebo	4	2 (50.0)					
Europe							
Tralokinumab 300 Q2W	33	17 (51.5)	16.6 (-7.27;40.39)	1.5 (0.82; 2.68)	2.0 (0.73; 5.38)	0.1843	
Placebo	32	11 (34.4)					
North America							
Tralokinumab 300 Q2W	48	16 (33.3)	5.7 (-13.0;24.39)	1.2 (0.65; 2.25)	1.3 (0.53; 3.22)	0.5562	
Placebo	44	12 (27.3)					

Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Including subjects with a baseline of at least 3. *: Cochran-Mantel-Haenszel test. The diff in %, relative risk, and OR are estimated in Cochran-Mantel-Haenszel analysis. #: Type 1 test for treatment and subgroup interaction in model treatment studyid subgroup treatment*subgroup Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA. Including subjects with a baseline score of at least 3.

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Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Adolescent Pruritus NRS (eDiary)										
Total										
Baseline	94	92	7.5 (1.65)			97	96	7.8 (1.53)		
Week 1		90	7.0 (1.77)				94	7.2 (1.70)		
Week 1 chg		90	-0.5 (1.08)	-0.51	(0.22)		94	-0.7 (1.65)	-0.66	(0.21)
LS Means (T - P) p-value									-0.15	(0.30) (-0.75, 0.44)
						0.612				
[SMD T - P]									[-0.11 (-0.40, 0.18)]	
Week 2		91	6.8 (1.89)				94	6.7 (1.97)		
Week 2 chg		91	-0.7 (1.52)	-0.71	(0.22)		94	-1.1 (1.84)	-1.11	(0.21)
LS Means (T - P) p-value									-0.40	(0.30) (-1.00, 0.19)
						0.184				
[SMD T - P]									[-0.24 (-0.53, 0.05)]	
Week 3		89	6.5 (1.89)				94	6.2 (2.18)		
Week 3 chg		89	-1.0 (1.74)	-1.06	(0.22)		94	-1.6 (2.02)	-1.51	(0.21)
LS Means (T - P) p-value									-0.45	(0.30) (-1.05, 0.15)
						0.138				
[SMD T - P]									[-0.24 (-0.53, 0.05)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		89	6.3 (1.97)				91	6.1 (2.24)		
Week 4 chg		89	-1.2 (1.96)	-1.22	(0.22)		91	-1.7 (1.95)	-1.70	(0.21)
LS Means (T - P) p-value									-0.48	(0.30) (-1.08, 0.11)
									0.112	
[SMD T - P]									[-0.25 (-0.54, 0.05)]	
Week 5		85	6.0 (1.99)				94	5.8 (2.26)		
Week 5 chg		85	-1.5 (1.98)	-1.63	(0.22)		94	-2.1 (2.14)	-2.05	(0.21)
LS Means (T - P) p-value									-0.43	(0.30) (-1.03, 0.17)
									0.163	
[SMD T - P]									[-0.21 (-0.50, 0.09)]	
Week 6		86	5.8 (2.23)				92	5.8 (2.30)		
Week 6 chg		86	-1.7 (2.26)	-1.77	(0.22)		92	-2.0 (2.19)	-2.05	(0.21)
LS Means (T - P) p-value									-0.27	(0.30) (-0.87, 0.33)
									0.371	
[SMD T - P]									[-0.12 (-0.42, 0.17)]	
Week 7		82	5.8 (1.97)				91	5.5 (2.21)		
Week 7 chg		82	-1.8 (2.02)	-1.84	(0.22)		91	-2.2 (2.09)	-2.30	(0.21)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.45 (0.31)	(-1.06, 0.15)
						0.139				
[SMD T - P]						[-0.22 (-0.52, 0.08)]				
Week 8		85	5.5 (2.20)				91	5.4 (2.31)		
Week 8 chg		85	-2.0 (2.20)	-2.04	(0.22)		91	-2.5 (2.26)	-2.45	(0.21)
LS Means (T - P) p-value									-0.41 (0.31)	(-1.01, 0.19)
						0.178				
[SMD T - P]						[-0.19 (-0.48, 0.11)]				
Week 9		81	5.6 (2.08)				92	5.1 (2.37)		
Week 9 chg		81	-2.0 (1.98)	-1.99	(0.22)		92	-2.7 (2.42)	-2.73	(0.21)
LS Means (T - P) p-value									-0.75 (0.31)	(-1.35, -0.14)
						0.015				
[SMD T - P]						[-0.34 (-0.64, -0.04)]				
Week 10		83	5.4 (2.33)				89	5.0 (2.47)		
Week 10 chg		83	-2.1 (2.29)	-2.08	(0.22)		89	-2.9 (2.55)	-2.77	(0.21)
LS Means (T - P) p-value									-0.70 (0.31)	(-1.30, -0.09)
						0.024				
[SMD T - P]						[-0.29 (-0.59, 0.01)]				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		79	5.4 (2.30)				88	5.0 (2.33)		
Week 11 chg		79	-2.1 (2.31)	-2.13	(0.22)		88	-2.7 (2.29)	-2.79	(0.21)
LS Means (T - P) p-value									-0.65	(0.31) (-1.26, -0.05)
						0.034				
[SMD T - P]						[-0.29	(-0.59,	0.02)]		
Week 12		85	5.4 (2.34)				88	5.0 (2.33)		
Week 12 chg		85	-2.0 (2.39)	-2.12	(0.22)		88	-2.7 (2.38)	-2.78	(0.21)
LS Means (T - P) p-value									-0.65	(0.31) (-1.25, -0.05)
						0.034				
[SMD T - P]						[-0.27	(-0.57,	0.03)]		
Week 13		81	5.3 (2.37)				90	5.0 (2.35)		
Week 13 chg		81	-2.2 (2.47)	-2.20	(0.22)		90	-2.8 (2.34)	-2.83	(0.21)
LS Means (T - P) p-value									-0.63	(0.31) (-1.23, -0.02)
						0.043				
[SMD T - P]						[-0.26	(-0.56,	0.04)]		
Week 14		79	5.2 (2.44)				86	4.8 (2.42)		
Week 14 chg		79	-2.4 (2.55)	-2.29	(0.22)		86	-3.0 (2.42)	-2.95	(0.21)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.66 (0.31)	(-1.27, -0.05)
						0.033				
[SMD T - P]						[-0.27			(-0.57, 0.04)]	
Week 15	77	77	5.2 (2.26)			84	84	4.8 (2.43)		
Week 15 chg	77	77	-2.4 (2.41)	-2.32	(0.22)	84	84	-2.9 (2.43)	-2.97	(0.22)
LS Means (T - P) p-value									-0.65 (0.31)	(-1.26, -0.04)
						0.038				
[SMD T - P]						[-0.27			(-0.58, 0.04)]	
Week 16	78	78	5.5 (2.26)			88	88	4.8 (2.48)		
Week 16 chg	78	78	-2.2 (2.35)	-2.09	(0.22)	88	88	-2.9 (2.46)	-2.96	(0.21)
LS Means (T - P) p-value									-0.87 (0.31)	(-1.48, -0.27)
						0.005				
[SMD T - P]						[-0.36			(-0.67, -0.05)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Asia										
Baseline	11	11	7.6 (1.17)			11	11	7.5 (1.70)		
Week 1		11	6.3 (1.77)				10	7.0 (1.08)		
Week 1 chg		11	-1.3 (0.86)	-1.27	(0.54)		10	-0.4 (1.84)	-0.48	(0.56)
LS Means (T - P) p-value									0.78	(0.78) (-0.78, 2.35)
[SMD T - P]									0.318	[0.56 (-0.32, 1.43)]
Week 2		11	6.2 (1.62)				11	5.8 (1.78)		
Week 2 chg		11	-1.4 (1.34)	-1.35	(0.54)		11	-1.7 (2.28)	-1.75	(0.54)
LS Means (T - P) p-value									-0.40	(0.77) (-1.95, 1.15)
[SMD T - P]									0.608	[-0.21 (-1.05, 0.63)]
Week 3		11	5.9 (1.32)				11	5.6 (1.80)		
Week 3 chg		11	-1.8 (1.30)	-1.70	(0.54)		11	-1.8 (2.44)	-1.91	(0.54)
LS Means (T - P) p-value									-0.21	(0.77) (-1.76, 1.35)
[SMD T - P]									0.791	[-0.10 (-0.94, 0.73)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		11	5.6 (1.74)				10	5.5 (2.18)		
Week 4 chg		11	-2.1 (1.91)	-2.00	(0.54)		10	-2.0 (2.55)	-2.08	(0.56)
LS Means (T - P) p-value								-0.08 (0.78) (-1.65, 1.48)		
						0.916				
[SMD T - P]						[-0.04 (-0.89, 0.82)]				
Week 5		11	5.2 (1.49)				11	4.8 (1.98)		
Week 5 chg		11	-2.5 (1.86)	-2.38	(0.54)		11	-2.6 (2.65)	-2.73	(0.54)
LS Means (T - P) p-value								-0.36 (0.77) (-1.91, 1.19)		
						0.645				
[SMD T - P]						[-0.16 (-0.99, 0.68)]				
Week 6		11	5.4 (2.15)				11	4.5 (2.03)		
Week 6 chg		11	-2.3 (2.31)	-2.17	(0.54)		11	-3.0 (2.82)	-3.05	(0.54)
LS Means (T - P) p-value								-0.88 (0.77) (-2.43, 0.67)		
						0.259				
[SMD T - P]						[-0.34 (-1.18, 0.50)]				
Week 7		11	4.9 (1.87)				11	4.2 (1.99)		
Week 7 chg		11	-2.8 (1.99)	-2.65	(0.54)		11	-3.2 (2.98)	-3.34	(0.54)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.69 (0.77)	(-2.24, 0.86)
[SMD T - P]						0.377			[-0.27 (-1.11, 0.57)]	
Week 8		11	5.1 (1.64)				11	4.1 (2.03)		
Week 8 chg		11	-2.6 (1.58)	-2.46 (0.54)			11	-3.3 (3.15)	-3.43 (0.54)	
LS Means (T - P) p-value									-0.97 (0.77)	(-2.52, 0.59)
[SMD T - P]						0.216			[-0.39 (-1.23, 0.46)]	
Week 9		11	4.8 (1.87)				11	3.7 (1.97)		
Week 9 chg		11	-2.8 (1.66)	-2.74 (0.54)			11	-3.8 (2.98)	-3.90 (0.54)	
LS Means (T - P) p-value									-1.15 (0.77)	(-2.71, 0.40)
[SMD T - P]						0.141			[-0.48 (-1.33, 0.37)]	
Week 10		11	4.6 (1.81)				11	3.8 (1.68)		
Week 10 chg		11	-3.1 (1.57)	-2.97 (0.54)			11	-3.7 (2.87)	-3.80 (0.54)	
LS Means (T - P) p-value									-0.83 (0.77)	(-2.38, 0.72)
[SMD T - P]						0.288			[-0.36 (-1.20, 0.48)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		11	5.1 (1.94)				11	3.6 (1.50)		
Week 11 chg		11	-2.5 (1.52)	-2.42	(0.54)		11	-3.8 (2.44)	-3.91	(0.54)
LS Means (T - P) p-value								-1.48 (0.77) (-3.03, 0.07)		
						0.061				
[SMD T - P]						[-0.73 (-1.59, 0.13)]				
Week 12		11	4.7 (1.98)				11	3.9 (1.66)		
Week 12 chg		11	-2.9 (1.54)	-2.83	(0.54)		11	-3.6 (2.69)	-3.64	(0.54)
LS Means (T - P) p-value								-0.81 (0.77) (-2.36, 0.74)		
						0.298				
[SMD T - P]						[-0.37 (-1.21, 0.47)]				
Week 13		11	5.0 (2.11)				11	4.0 (1.92)		
Week 13 chg		11	-2.6 (1.51)	-2.52	(0.54)		11	-3.5 (2.91)	-3.54	(0.54)
LS Means (T - P) p-value								-1.01 (0.77) (-2.57, 0.54)		
						0.194				
[SMD T - P]						[-0.44 (-1.28, 0.41)]				
Week 14		11	5.1 (1.84)				11	4.0 (2.08)		
Week 14 chg		11	-2.6 (1.48)	-2.49	(0.54)		11	-3.4 (2.99)	-3.51	(0.54)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-1.02 (0.77)	(-2.57, 0.54)
						0.194				
[SMD T - P]						[-0.43			(-1.28, 0.41)]	
Week 15		11	5.0 (1.75)				11	4.4 (2.22)		
Week 15 chg		11	-2.6 (1.65)	-2.55	(0.54)		11	-3.1 (3.13)	-3.19	(0.54)
LS Means (T - P) p-value									-0.64 (0.77)	(-2.19, 0.91)
						0.408				
[SMD T - P]						[-0.26			(-1.10, 0.58)]	
Week 16		11	5.3 (1.50)				11	4.4 (2.21)		
Week 16 chg		11	-2.3 (1.31)	-2.24	(0.54)		11	-3.1 (2.98)	-3.17	(0.54)
LS Means (T - P) p-value									-0.93 (0.77)	(-2.48, 0.62)
						0.233				
[SMD T - P]						[-0.40			(-1.25, 0.44)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
Australia								
Baseline	4	4	7.2 (2.00)		5	4	7.7 (1.49)	
Week 1		4	6.0 (1.71)			4	8.2 (1.26)	
Week 1 chg		4	-1.2 (1.85)	-1.15 (1.03)		4	0.5 (1.07)	0.32 (1.02)
LS Means (T - P) p-value								1.47 (1.48) (-1.82, 4.75)
					0.344			
[SMD T - P]					[0.97 (-0.50, 2.43)]			
Week 2		4	4.6 (1.83)			4	7.9 (1.50)	
Week 2 chg		4	-2.6 (2.13)	-2.49 (1.03)		4	0.3 (0.72)	0.10 (1.02)
LS Means (T - P) p-value								2.59 (1.48) (-0.70, 5.88)
					0.110			
[SMD T - P]					[1.63 (0.03, 3.23)]			
Week 3		4	5.3 (1.14)			3	7.5 (1.86)	
Week 3 chg		4	-1.9 (1.58)	-1.82 (1.03)		3	-0.6 (0.46)	-0.74 (1.11)
LS Means (T - P) p-value								1.07 (1.55) (-2.31, 4.45)
					0.503			
[SMD T - P]					[0.85 (-0.71, 2.42)]			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		4	4.3 (0.94)				4	7.2 (1.44)		
Week 4 chg		4	-2.9 (2.40)	-2.90	(1.03)		4	-0.4 (0.50)	-0.57	(1.02)
LS Means (T - P) p-value								2.33 (1.48) (-0.96, 5.62)		
						0.145				
[SMD T - P]						[1.34 (-0.19, 2.88)]				
Week 5		4	4.4 (1.59)				4	6.6 (1.74)		
Week 5 chg		4	-2.8 (3.39)	-2.96	(1.03)		4	-1.0 (1.11)	-1.12	(1.02)
LS Means (T - P) p-value								1.84 (1.48) (-1.45, 5.13)		
						0.241				
[SMD T - P]						[0.73 (-0.70, 2.16)]				
Week 6		4	3.6 (1.11)				4	6.5 (1.62)		
Week 6 chg		4	-3.5 (3.09)	-3.67	(1.03)		4	-1.2 (1.04)	-1.28	(1.02)
LS Means (T - P) p-value								2.39 (1.48) (-0.90, 5.67)		
						0.137				
[SMD T - P]						[1.04 (-0.44, 2.51)]				
Week 7		2	3.3 (2.22)				4	6.3 (1.61)		
Week 7 chg		2	-3.3 (5.10)	-3.40	(1.28)		4	-1.4 (1.52)	-1.41	(1.02)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								1.99 (1.67)	(-1.56, 5.54)	
						0.251				
[SMD T - P]						[0.69			(-1.05, 2.44)]	
Week 8		4	4.6 (2.84)				4	5.6 (1.65)		
Week 8 chg		4	-2.6 (4.00)	-2.70	(1.03)		4	-2.1 (0.88)	-2.19	(1.02)
LS Means (T - P) p-value								0.50 (1.48)	(-2.78, 3.79)	
						0.740				
[SMD T - P]						[0.17			(-1.21, 1.56)]	
Week 9		4	4.3 (1.66)				4	6.1 (2.19)		
Week 9 chg		4	-2.9 (2.93)	-2.90	(1.03)		4	-1.6 (1.06)	-1.74	(1.02)
LS Means (T - P) p-value								1.16 (1.48)	(-2.13, 4.44)	
						0.451				
[SMD T - P]						[0.53			(-0.88, 1.94)]	
Week 10		3	5.5 (3.31)				4	5.8 (2.03)		
Week 10 chg		3	-2.6 (4.28)	-1.66	(1.13)		4	-1.9 (0.88)	-1.94	(1.03)
LS Means (T - P) p-value								-0.28 (1.53)	(-3.63, 3.07)	
						0.856				
[SMD T - P]						[-0.10			(-1.60, 1.40)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		3	3.0 (1.71)				4	5.9 (2.33)		
Week 11 chg		3	-4.3 (2.90)	-3.56	(1.11)		4	-1.8 (1.44)	-1.93	(1.02)
LS Means (T - P) p-value								1.63 (1.53) (-1.72, 4.97)		
						0.310				
[SMD T - P]						[0.76 (-0.79, 2.31)]				
Week 12		4	4.8 (3.29)				4	5.9 (2.15)		
Week 12 chg		4	-2.4 (4.30)	-2.42	(1.03)		4	-1.8 (0.91)	-1.90	(1.02)
LS Means (T - P) p-value								0.52 (1.48) (-2.77, 3.80)		
						0.733				
[SMD T - P]						[0.17 (-1.22, 1.56)]				
Week 13		4	4.9 (2.64)				4	5.5 (1.57)		
Week 13 chg		4	-2.3 (4.11)	-2.48	(1.03)		4	-2.2 (0.63)	-2.28	(1.02)
LS Means (T - P) p-value								0.20 (1.48) (-3.08, 3.49)		
						0.893				
[SMD T - P]						[0.07 (-1.32, 1.46)]				
Week 14		3	5.0 (3.87)				3	6.3 (2.53)		
Week 14 chg		3	-3.1 (4.82)	-2.07	(1.14)		3	-1.8 (1.12)	-1.46	(1.14)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value								0.61 (1.57)	(-2.78, 4.01)	
						0.702				
[SMD T - P]						[0.18		(-1.43, 1.78)]		
Week 15		3	4.2 (2.86)				2	6.1 (2.51)		
Week 15 chg		3	-3.1 (4.95)	-2.53	(1.11)		2	-2.1 (0.49)	-1.44	(1.25)
LS Means (T - P) p-value								1.09 (1.69)	(-2.49, 4.67)	
						0.529				
[SMD T - P]						[0.27		(-1.53, 2.07)]		
Week 16		3	4.3 (2.96)				3	6.3 (2.16)		
Week 16 chg		3	-3.0 (5.05)	-2.39	(1.11)		3	-1.8 (0.78)	-1.38	(1.11)
LS Means (T - P) p-value								1.02 (1.60)	(-2.42, 4.46)	
						0.534				
[SMD T - P]						[0.28		(-1.33, 1.89)]		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean (se)
Europe								
Baseline	32	32	7.8 (1.48)		33	33	7.9 (1.34)	
Week 1		31	7.5 (1.69)			32	7.0 (1.66)	
Week 1 chg		31	-0.4 (1.09)	-0.43 (0.37)		32	-0.9 (1.66)	-0.94 (0.36)
LS Means (T - P) p-value								-0.51 (0.52) (-1.53, 0.52)
								0.328
[SMD T - P]								[-0.36 (-0.86, 0.14)]
Week 2		31	7.3 (1.71)			33	6.6 (1.94)	
Week 2 chg		31	-0.5 (1.44)	-0.57 (0.37)		33	-1.4 (1.77)	-1.36 (0.36)
LS Means (T - P) p-value								-0.79 (0.52) (-1.81, 0.23)
								0.127
[SMD T - P]								[-0.49 (-0.99, 0.01)]
Week 3		32	6.7 (1.92)			33	5.9 (2.11)	
Week 3 chg		32	-1.1 (1.68)	-1.17 (0.37)		33	-2.0 (2.05)	-1.99 (0.36)
LS Means (T - P) p-value								-0.82 (0.51) (-1.84, 0.20)
								0.112
[SMD T - P]								[-0.44 (-0.93, 0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		32	6.7 (1.66)				31	6.1 (1.99)		
Week 4 chg		32	-1.1 (1.44)	-1.13	(0.37)		31	-1.9 (1.91)	-1.98	(0.37)
LS Means (T - P) p-value									-0.85	(0.52) (-1.87, 0.18)
									0.105	
[SMD T - P]									[-0.50 (-1.00, 0.00)]	
Week 5		30	6.1 (1.94)				31	5.8 (2.26)		
Week 5 chg		30	-1.7 (1.59)	-1.69	(0.37)		31	-2.2 (1.97)	-2.27	(0.37)
LS Means (T - P) p-value									-0.58	(0.52) (-1.61, 0.45)
									0.266	
[SMD T - P]									[-0.33 (-0.83, 0.18)]	
Week 6		31	5.9 (2.40)				30	5.8 (2.26)		
Week 6 chg		31	-2.0 (2.12)	-1.99	(0.37)		30	-2.1 (2.04)	-2.33	(0.37)
LS Means (T - P) p-value									-0.33	(0.52) (-1.36, 0.70)
									0.523	
[SMD T - P]									[-0.16 (-0.66, 0.34)]	
Week 7		32	5.9 (2.06)				32	5.5 (2.20)		
Week 7 chg		32	-1.9 (1.95)	-1.93	(0.37)		32	-2.5 (2.05)	-2.53	(0.36)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.60 (0.52) (-1.62, 0.42)	
[SMD T - P]						0.248			[-0.30 (-0.79, 0.19)]	
Week 8		29	5.5 (2.39)				31	5.5 (2.48)		
Week 8 chg		29	-2.4 (2.28)	-2.36 (0.37)			31	-2.5 (2.25)	-2.57 (0.37)	
LS Means (T - P) p-value									-0.21 (0.52) (-1.25, 0.82)	
[SMD T - P]						0.684			[-0.09 (-0.60, 0.41)]	
Week 9		29	5.9 (2.21)				31	5.0 (2.38)		
Week 9 chg		29	-1.9 (2.01)	-1.99 (0.37)			31	-2.9 (2.38)	-2.98 (0.37)	
LS Means (T - P) p-value									-1.00 (0.52) (-2.03, 0.04)	
[SMD T - P]						0.059			[-0.45 (-0.96, 0.06)]	
Week 10		31	5.8 (2.32)				30	4.9 (2.44)		
Week 10 chg		31	-2.1 (2.21)	-2.06 (0.37)			30	-3.0 (2.60)	-2.97 (0.37)	
LS Means (T - P) p-value									-0.91 (0.52) (-1.94, 0.12)	
[SMD T - P]						0.083			[-0.38 (-0.88, 0.13)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		30	5.5 (2.24)				30	5.0 (2.61)		
Week 11 chg		30	-2.3 (2.20)	-2.27	(0.37)		30	-2.8 (2.46)	-3.03	(0.37)
LS Means (T - P) p-value									-0.76	(0.52) (-1.80, 0.27)
						0.147				
[SMD T - P]						[-0.33 (-0.84, 0.18)]				
Week 12		30	5.6 (2.20)				30	5.2 (2.59)		
Week 12 chg		30	-2.1 (2.13)	-2.27	(0.37)		30	-2.7 (2.47)	-2.86	(0.37)
LS Means (T - P) p-value									-0.60	(0.52) (-1.63, 0.44)
						0.257				
[SMD T - P]						[-0.26 (-0.77, 0.25)]				
Week 13		27	5.8 (2.34)				31	4.8 (2.56)		
Week 13 chg		27	-2.1 (2.29)	-2.14	(0.38)		31	-3.1 (2.60)	-3.05	(0.37)
LS Means (T - P) p-value									-0.91	(0.53) (-1.95, 0.14)
						0.088				
[SMD T - P]						[-0.37 (-0.89, 0.15)]				
Week 14		28	5.7 (2.21)				29	4.6 (2.55)		
Week 14 chg		28	-2.2 (2.13)	-2.13	(0.38)		29	-3.2 (2.49)	-3.26	(0.37)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-1.13 (0.53)	(-2.17, -0.08)
									0.034	
[SMD T - P]									[-0.49 (-1.01, 0.04)]	
Week 15		28	5.6 (2.03)				28	4.5 (2.57)		
Week 15 chg		28	-2.3 (2.06)	-2.24	(0.38)		28	-3.4 (2.51)	-3.52	(0.37)
LS Means (T - P) p-value									-1.29 (0.53)	(-2.33, -0.24)
									0.017	
[SMD T - P]									[-0.56 (-1.09, -0.03)]	
Week 16		29	5.9 (2.07)				30	4.1 (2.52)		
Week 16 chg		29	-1.9 (2.02)	-1.90	(0.37)		30	-3.8 (2.57)	-3.76	(0.37)
LS Means (T - P) p-value									-1.86 (0.53)	(-2.90, -0.82)
									<.001	
[SMD T - P]									[-0.80 (-1.33, -0.27)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
North America										
Baseline	47	45	7.2 (1.84)			48	48	7.9 (1.65)		
Week 1		44	7.0 (1.78)				48	7.2 (1.86)		
Week 1 chg		44	-0.2 (0.93)	-0.31	(0.31)		48	-0.7 (1.63)	-0.59	(0.30)
LS Means (T - P) p-value									-0.29	(0.44) (-1.15, 0.58)
						0.512				
[SMD T - P]									[-0.21	(-0.62, 0.20)]
Week 2		45	6.9 (1.95)				46	6.9 (2.02)		
Week 2 chg		45	-0.4 (1.44)	-0.48	(0.31)		46	-1.0 (1.81)	-0.92	(0.30)
LS Means (T - P) p-value									-0.45	(0.44) (-1.31, 0.42)
						0.309				
[SMD T - P]									[-0.27	(-0.69, 0.14)]
Week 3		42	6.6 (2.02)				47	6.5 (2.30)		
Week 3 chg		42	-0.7 (1.84)	-0.72	(0.32)		47	-1.3 (1.93)	-1.20	(0.30)
LS Means (T - P) p-value									-0.49	(0.44) (-1.35, 0.38)
						0.271				
[SMD T - P]									[-0.26	(-0.68, 0.16)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 4		42	6.4 (2.17)				46	6.2 (2.48)		
Week 4 chg		42	-0.8 (2.16)	-0.91	(0.32)		46	-1.6 (1.92)	-1.55	(0.30)
LS Means (T - P) p-value									-0.64	(0.44) (-1.51, 0.23)
						0.148				
[SMD T - P]									[-0.31 (-0.73, 0.11)]	
Week 5		40	6.2 (2.09)				48	5.9 (2.35)		
Week 5 chg		40	-1.1 (2.05)	-1.24	(0.32)		48	-2.0 (2.19)	-1.84	(0.30)
LS Means (T - P) p-value									-0.60	(0.44) (-1.47, 0.27)
						0.174				
[SMD T - P]									[-0.28 (-0.70, 0.14)]	
Week 6		40	6.1 (2.11)				47	6.0 (2.38)		
Week 6 chg		40	-1.2 (2.19)	-1.32	(0.32)		47	-1.8 (2.17)	-1.71	(0.30)
LS Means (T - P) p-value									-0.38	(0.44) (-1.25, 0.49)
						0.386				
[SMD T - P]									[-0.18 (-0.60, 0.25)]	
Week 7		37	6.0 (1.81)				44	5.9 (2.24)		
Week 7 chg		37	-1.3 (1.86)	-1.43	(0.32)		44	-1.9 (1.84)	-2.00	(0.31)

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.57 (0.45)	(-1.45, 0.31)
						0.204				
[SMD T - P]						[-0.31			(-0.75, 0.13)]	
Week 8		41	5.8 (2.17)				45	5.6 (2.27)		
Week 8 chg		41	-1.5 (2.05)	-1.62	(0.32)		45	-2.3 (2.12)	-2.19	(0.30)
LS Means (T - P) p-value									-0.56 (0.44)	(-1.44, 0.31)
						0.207				
[SMD T - P]						[-0.27			(-0.69, 0.16)]	
Week 9		37	5.7 (2.03)				46	5.4 (2.40)		
Week 9 chg		37	-1.6 (1.92)	-1.68	(0.32)		46	-2.5 (2.34)	-2.40	(0.30)
LS Means (T - P) p-value									-0.72 (0.45)	(-1.60, 0.16)
						0.107				
[SMD T - P]						[-0.33			(-0.77, 0.10)]	
Week 10		38	5.4 (2.43)				44	5.3 (2.63)		
Week 10 chg		38	-1.9 (2.37)	-1.86	(0.32)		44	-2.7 (2.55)	-2.50	(0.31)
LS Means (T - P) p-value									-0.64 (0.45)	(-1.52, 0.25)
						0.156				
[SMD T - P]						[-0.26			(-0.69, 0.18)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
Week 11		35	5.5 (2.45)				43	5.3 (2.22)		
Week 11 chg		35	-1.7 (2.50)	-1.85	(0.33)		43	-2.4 (2.13)	-2.44	(0.31)
LS Means (T - P) p-value								-0.59 (0.45) (-1.48, 0.30)		
						0.190				
[SMD T - P]								[-0.26 (-0.71, 0.19)]		
Week 12		40	5.5 (2.47)				43	5.2 (2.29)		
Week 12 chg		40	-1.7 (2.54)	-1.81	(0.32)		43	-2.7 (2.33)	-2.60	(0.31)
LS Means (T - P) p-value								-0.78 (0.45) (-1.66, 0.10)		
						0.080				
[SMD T - P]								[-0.32 (-0.76, 0.11)]		
Week 13		39	5.0 (2.46)				44	5.3 (2.33)		
Week 13 chg		39	-2.1 (2.70)	-2.16	(0.32)		44	-2.5 (2.09)	-2.57	(0.30)
LS Means (T - P) p-value								-0.41 (0.45) (-1.29, 0.47)		
						0.363				
[SMD T - P]								[-0.17 (-0.60, 0.26)]		
Week 14		37	4.9 (2.67)				43	5.0 (2.42)		
Week 14 chg		37	-2.4 (2.95)	-2.39	(0.32)		43	-2.7 (2.29)	-2.74	(0.31)

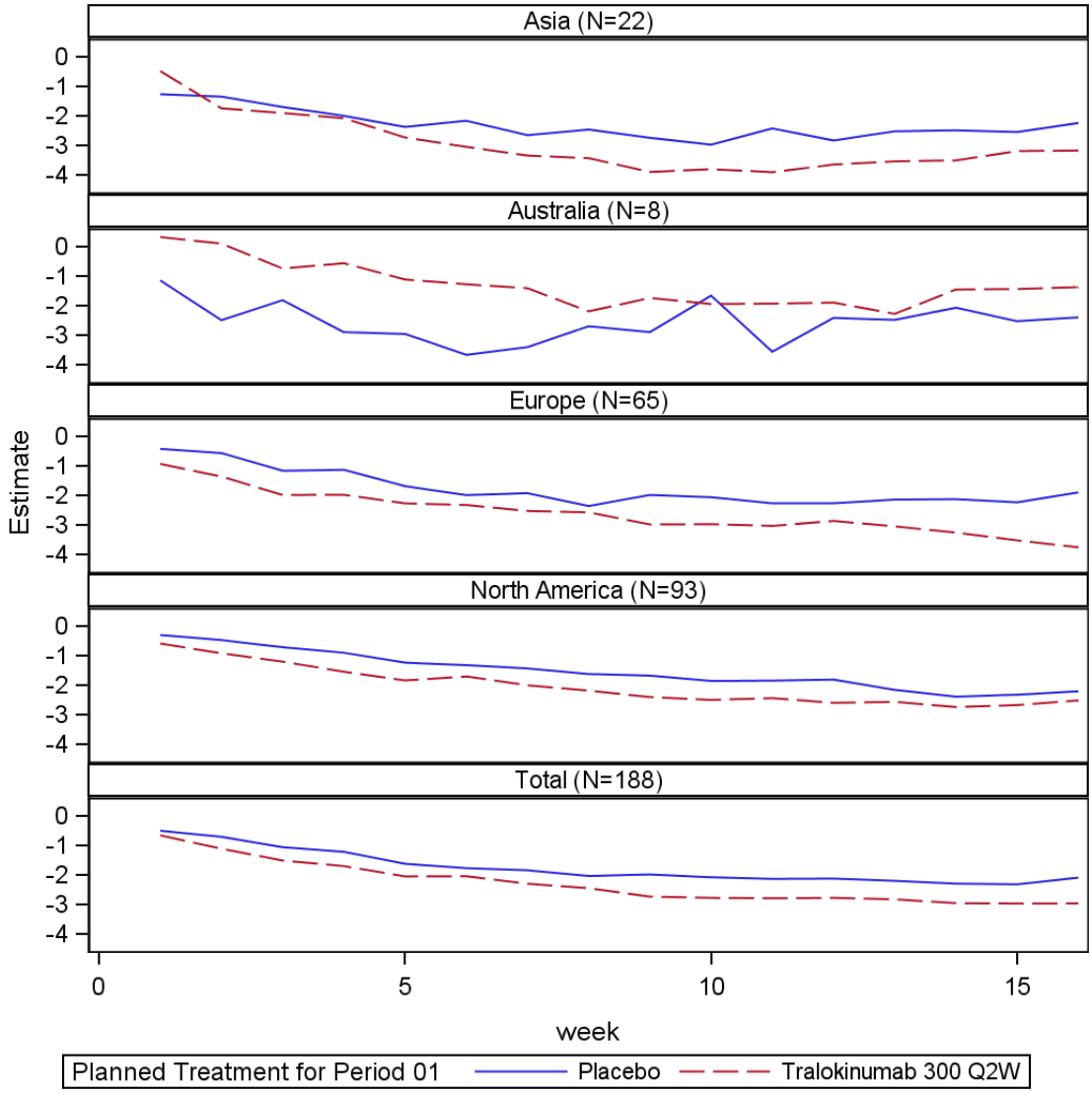
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Table 1.19.485.12.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16

Subgroup/visit	Placebo N	Placebo Raw n	Placebo Raw mean (sd)	Placebo Least Squares mean	Placebo Least Squares (se)	Tralokinumab 300 Q2W N	Tralokinumab 300 Q2W Raw n	Tralokinumab 300 Q2W Raw mean (sd)	Tralokinumab 300 Q2W Least Squares mean	Tralokinumab 300 Q2W Least Squares (se)
LS Means (T - P) p-value									-0.35 (0.45)	(-1.23, 0.53)
									0.436	
[SMD T - P]									[-0.13 (-0.57, 0.31)]	
Week 15		35	5.0 (2.56)				43	5.1 (2.41)		
Week 15 chg		35	-2.4 (2.70)	-2.32	(0.33)		43	-2.6 (2.22)	-2.67	(0.31)
LS Means (T - P) p-value									-0.35 (0.45)	(-1.24, 0.54)
									0.439	
[SMD T - P]									[-0.14 (-0.59, 0.30)]	
Week 16		35	5.2 (2.55)				44	5.3 (2.45)		
Week 16 chg		35	-2.3 (2.65)	-2.21	(0.33)		44	-2.4 (2.19)	-2.51	(0.30)
LS Means (T - P) p-value									-0.31 (0.45)	(-1.19, 0.58)
									0.496	
[SMD T - P]									[-0.13 (-0.57, 0.32)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8199
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Figure 1.19.485.12.2: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1334 300mg, Week 16



Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in NRS = Treatment*Week + [Baseline NRS]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. The repeated measurements from baseline and up to analysis point are modelled in a mixed effects repeated measurement model. In case of no post-baseline assessments before initiation of rescue medication, the change to the first planned visit will be imputed as 0. N: Number of subjects, n: number of subjects with measurements at visit. Including Region, baseline IGA, interaction between treatment and visit as fixed effects and interaction between baseline measurement and treatment as covariate. Repeated measures within subjects are modelled using a compound symmetry covariance model.

Tralokinumab

Subgruppenanalysen der Sicherheitsendpunkte: IGA

LEO Pharma A/S

Table of Contents

Statistical appendix

Table 1.7.601.12.1: Total, Disease severity (IGA), Any TEAE, LP0162-1334 300mg

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% CI Lower	Upper	p-value (interaction) #
Total								
Tralokinumab 300 Q2W	97	29.48	63 (64.9)	130	440.96	371.3	523.7	0.2409
Placebo	94	27.93	58 (61.7)	134	479.72	405.0	568.2	
Moderate [IGA=3]								
Tralokinumab 300 Q2W	49	14.70	33 (67.3)	59	401.40	311.0	518.1	
Placebo	51	15.15	29 (56.9)	57	376.29	290.3	487.8	
Severe [IGA=4]								
Tralokinumab 300 Q2W	48	14.78	30 (62.5)	71	480.30	380.6	606.1	
Placebo	43	12.78	29 (67.4)	77	602.28	481.7	753.0	

The number of subjects and percentage of subjects with at least one adverse event is summarised. The rate is calculated as the number of experienced adverse events (multiple occurrences are counted more than once) divided by the total exposed period and presented as events per 100 patient years. The exposure period corresponds to the treatment emergent period, from treatment start and up to 7 days after last trial medication or last follow up visit, whichever comes first. 95% CI limits are calculated in the poisson model where treatment and IGA strata are included as fixed effects. N: Number of subjects exposed, n: Number of subjects with an event, %: Percent of exposed subjects with an event, e: Number of events. TEAE: Treatment emergent adverse events

Table 1.7.607.12.1: Total, Disease severity (IGA), Death, LP0162-1334 300mg

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)		95% CI Lower	Upper	p-value (interaction) #
Total									
Tralokinumab 300 Q2W	97	29.48	0 (0.0)	0	0.00	*	0.0	-	1.0000
Placebo	94	27.93	0 (0.0)	0	0.00	*	0.0	-	
Moderate [IGA=3]									
Tralokinumab 300 Q2W	49	14.70	0 (0.0)	0	0.00	*	0.0	-	
Placebo	51	15.15	0 (0.0)	0	0.00	*	0.0	-	
Severe [IGA=4]									
Tralokinumab 300 Q2W	48	14.78	0 (0.0)	0	0.00	*	0.0	-	
Placebo	43	12.78	0 (0.0)	0	0.00	*	0.0	-	

*: The statistical model did not converge, the confidence interval is not estimable.
The number of subjects and percentage of subjects with at least one adverse event is summarised. The rate is calculated as the number of experienced adverse events (multiple occurrences are counted more than once) divided by the total exposed period and presented as events per 100 patient years. The exposure period corresponds to the treatment emergent period, from treatment start and up to 7 days after last trial medication or last follow up visit, whichever comes first. 95% CI limits are calculated in the poisson model where treatment and IGA strata are included as fixed effects. N: Number of subjects exposed, n: Number of subjects with an event, %: Percent of exposed subjects with an event, e: Number of events.

Table 1.7.701.12.1: Total, Disease severity (IGA), Any TEAE, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC Preferred term Subgroup	Test for inter-action	CMH p-value	RR 95%CI	OR 95%CI	RD 95%CI	Placebo n	(%)	E	Tralokinumab 300 Q2W n	(%)	E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Moderate [IGA=3]						51	15.1		49	14.7	
Severe [IGA=4]						43	12.8		48	14.8	
Any system organ class											
Any preferred term											
Total	0.2940	0.6720	1.05 (0.84, 1.30)	1.14 (0.63, 2.05)	3.0 (-11, 16.7)	58	(61.7)	134	63	(64.9)	130
Moderate [IGA=3]		0.2988	1.18 (0.86, 1.62)	1.54 (0.68, 3.48)	10.2 (-8.8, 29.1)	29	(56.9)	57	33	(67.3)	59
Severe [IGA=4]		0.6286	0.93 (0.68, 1.26)	0.80 (0.34, 1.92)	-4.9 (-24, 14.6)	29	(67.4)	77	30	(62.5)	71

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.7.703.12.1: Total, Disease severity (IGA), Any TEAE causing permanent discontinuation, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.7.708.12.1: Total, Disease severity (IGA), Any TE SAE, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Moderate [IGA=3]						51	15.1		49	14.7	
Severe [IGA=4]						43	12.8		48	14.8	
Any system organ class											
Any preferred term											
Total	0.1969	0.0918	0.20 (0.02, 1.63)	0.20 (0.02, 1.68)	-4.3 (-9.4, 0.72)	5	(5.3)	5	1	(1.0)	1
Moderate [IGA=3]		0.5776	0.51 (0.05, 5.78)	0.51 (0.05, 5.80)	-1.9 (-8.7, 4.81)	2	(3.9)	2	1	(2.0)	1
Severe [IGA=4]		0.0681	0.00 (not est.)	0.00 (not est.)	-7.0 (-15, 0.65)	3	(7.0)	3	0	(0.0)	0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.7.710.12.1: Total, Disease severity (IGA), Any TE SAE causing permanent discontinuation, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.7.711.12.1: Total, Disease severity (IGA), Any TEAE by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Moderate [IGA=3]						51	15.1		49	14.7	
Severe [IGA=4]						43	12.8		48	14.8	
Any system organ class											
Any preferred term											
Total	0.2940	0.6720	1.05 (0.84, 1.30)	1.14 (0.63, 2.05)	3.0 (-11, 16.7)	58	(61.7)	134	63	(64.9)	130
Moderate [IGA=3]		0.2988	1.18 (0.86, 1.62)	1.54 (0.68, 3.48)	10.2 (-8.8, 29.1)	29	(56.9)	57	33	(67.3)	59
Severe [IGA=4]		0.6286	0.93 (0.68, 1.26)	0.80 (0.34, 1.92)	-4.9 (-24, 14.6)	29	(67.4)	77	30	(62.5)	71
General disorders and administration site conditions											
Any											
Total	0.1929	0.2062	1.91 (0.68, 5.37)	1.95 (0.66, 5.77)	5.0 (-2.8, 12.8)	5	(5.3)	7	10	(10.3)	13
Infections and infestations											
Any											
Total	0.0947	0.5510	1.12 (0.77, 1.63)	1.20 (0.66, 2.18)	4.2 (-9.4, 17.7)	32	(34.0)	47	37	(38.1)	50
Upper respiratory tract infection											
Total	Not est.	0.0819	2.53 (0.86, 7.51)	2.78 (0.85, 9.13)	6.8 (-.71, 14.3)	4	(4.3)	5	11	(11.3)	11
Viral upper respiratory tract infection											
Total	0.4708	0.3102	1.53 (0.67, 3.49)	1.65 (0.63, 4.32)	4.5 (-4.1, 13.0)	8	(8.5)	10	12	(12.4)	16
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.9491	0.5397	0.78 (0.36, 1.71)	0.75 (0.30, 1.86)	-2.8 (-12, 6.09)	12	(12.8)	17	10	(10.3)	12

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.7.711.12.1: Total, Disease severity (IGA), Any TEAE by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Skin and subcutaneous tissue disorders											
Any											
Total	0.0208	0.2615	0.67 (0.33, 1.35)	0.63 (0.28, 1.41)	-5.9 (-16, 4.25)	17	(18.1)	24	12	(12.4)	13
Dermatitis atopic											
Total	0.0084	0.2092	0.57 (0.22, 1.42)	0.55 (0.21, 1.44)	-5.5 (-14, 3.14)	12	(12.8)	16	7	(7.2)	7

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.7.712.12.1: Total, Disease severity (IGA), Any TESAE by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Moderate [IGA=3]						51	15.1		49	14.7	
Severe [IGA=4]						43	12.8		48	14.8	
Any system organ class											
Any preferred term											
Total	0.1969	0.0918	0.20 (0.02, 1.63)	0.20 (0.02, 1.68)	-4.3 (-9.4, 0.72)	5	(5.3)	5	1	(1.0)	1
Moderate [IGA=3]		0.5776	0.51 (0.05, 5.78)	0.51 (0.05, 5.80)	-1.9 (-8.7, 4.81)	2	(3.9)	2	1	(2.0)	1
Severe [IGA=4]		0.0681	0.00 (not est.)	0.00 (not est.)	-7.0 (-15, 0.65)	3	(7.0)	3	0	(0.0)	0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.7.713.12.1: Total, Disease severity (IGA), Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.7.714.12.1: Total, Disease severity (IGA), Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n (%)	Placebo E	Tralokinumab 300 Q2W n (%)	Tralokinumab 300 Q2W E
Analysis set									
N, Exposure(years)									
Total						94 27.9		97 29.5	
Moderate [IGA=3]						51 15.1		49 14.7	
Severe [IGA=4]						43 12.8		48 14.8	
Any system organ class									
Any preferred term									
Total	0.5205	0.4317	1.92 (0.38, 9.74)	2.05 (0.35, 12.0)	2.0 (-2.8, 6.76)	2 (2.1)	3	4 (4.1)	4
Moderate [IGA=3]		1.0000	1.00 (0.08, 12.6)	1.00 (0.05, 20.8)	0.0 (-5.1, 5.08)	1 (2.0)	1	1 (2.0)	1
Severe [IGA=4]		0.3404	2.80 (0.31, 25.3)	2.96 (0.30, 29.0)	4.1 (-4.1, 12.4)	1 (2.3)	2	3 (6.3)	3
Eye disorders									
Any									
Total	0.9640	0.9830	0.98 (0.15, 6.27)	0.98 (0.13, 7.49)	-0.0 (-4.0, 3.93)	2 (2.1)	3	2 (2.1)	2
Conjunctivitis allergic									
Total	0.9640	0.9830	0.98 (0.15, 6.27)	0.98 (0.13, 7.49)	-0.0 (-4.0, 3.93)	2 (2.1)	3	2 (2.1)	2
Infections and infestations									
Any									
Total	Not est.	0.1703			2.0 (-.79, 4.82)	0 (0.0)	0	2 (2.1)	2
Keratitis viral									
Total	Not est.	0.3375			1.0 (-.99, 3.00)	0 (0.0)	0	1 (1.0)	1
Conjunctivitis bacterial									
Total	Not est.	0.3375			1.0 (-.99, 3.00)	0 (0.0)	0	1 (1.0)	1

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.7.715.12.1: Total, Disease severity (IGA), Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.7.716.12.1: Total, Disease severity (IGA), Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Moderate [IGA=3]						51	15.1		49	14.7	
Severe [IGA=4]						43	12.8		48	14.8	
Any system organ class											
Any preferred term											
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1 (1.1)		1	0 (0.0)		0
Moderate [IGA=3]		0.3173	0.00 (not est.)	0.00 (not est.)	-2.0 (-5.9, 1.85)	1 (2.0)		1	0 (0.0)		0
Infections and infestations											
Any											
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1 (1.1)		1	0 (0.0)		0
Eczema herpeticum											
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1 (1.1)		1	0 (0.0)		0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.7.717.12.1: Total, Disease severity (IGA), Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.7.718.12.1: Total, Disease severity (IGA), Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.7.719.12.1: Total, Disease severity (IGA), Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.7.720.12.1: Total, Disease severity (IGA), Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n (%)	Placebo E	Tralokinumab 300 Q2W n (%)	Tralokinumab 300 Q2W E
Analysis set									
N, Exposure(years)									
Total						94 27.9		97 29.5	
Moderate [IGA=3]						51 15.1		49 14.7	
Severe [IGA=4]						43 12.8		48 14.8	
Any system organ class									
Any preferred term									
Total	0.9758	0.9829	1.02 (0.15, 7.10)	1.02 (0.14, 7.41)	0.0 (-4.0, 4.12)	2 (2.1)	2	2 (2.1)	3
Moderate [IGA=3]		0.9757	1.04 (0.07, 15.7)	1.05 (0.06, 17.8)	0.1 (-5.4, 5.54)	1 (2.0)	1	1 (2.0)	1
Severe [IGA=4]		1.0000	1.00 (0.06, 16.0)	1.00 (0.06, 16.0)	0.0 (-6.1, 6.12)	1 (2.3)	1	1 (2.1)	2
Infections and infestations									
Any									
Total	0.9758	0.9829	1.02 (0.15, 7.10)	1.02 (0.14, 7.41)	0.0 (-4.0, 4.12)	2 (2.1)	2	2 (2.1)	3
Staphylococcal skin infection									
Total	Not est.	0.3276	0.00 (not est.)	0.00 (not est.)	-1.0 (-3.1, 1.02)	1 (1.1)	1	0 (0.0)	0
Impetigo									
Total	Not est.	0.3070			1.1 (-.98, 3.13)	0 (0.0)	0	1 (1.0)	1
Skin infection									
Total	Not est.	0.3173			1.1 (-.98, 3.09)	0 (0.0)	0	1 (1.0)	2
Erysipelas									
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1 (1.1)	1	0 (0.0)	0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.7.721.12.1: Total, Disease severity (IGA), Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Moderate [IGA=3]					51	15.1		49	14.7	
Severe [IGA=4]					43	12.8		48	14.8	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.7.722.12.1: Total, Disease severity (IGA), Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Moderate [IGA=3]						51	15.1		49	14.7	
Severe [IGA=4]						43	12.8		48	14.8	
Any system organ class											
Any preferred term											
Total	0.0878	0.3953	1.11 (0.87, 1.40)	1.29 (0.72, 2.30)	6.0 (-7.9, 19.9)	53	(56.4)	117	61	(62.9)	123
Moderate [IGA=3]		0.0698	1.36 (0.97, 1.92)	2.14 (0.94, 4.86)	17.8 (-.98, 36.7)	25	(49.0)	46	33	(67.3)	58
Severe [IGA=4]		0.4994	0.89 (0.64, 1.24)	0.74 (0.32, 1.75)	-6.9 (-27, 12.9)	28	(65.1)	71	28	(58.3)	65

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.7.723.12.1: Total, Disease severity (IGA), Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Moderate [IGA=3]						51	15.1		49	14.7	
Severe [IGA=4]						43	12.8		48	14.8	
Any system organ class											
Any preferred term											
Total	0.2803	0.1778	0.25 (0.03, 2.24)	0.25 (0.03, 2.26)	-3.2 (-7.7, 1.43)	4	(4.3)	4	1	(1.0)	1
Moderate [IGA=3]		0.5776	0.51 (0.05, 5.78)	0.51 (0.05, 5.80)	-1.9 (-8.7, 4.81)	2	(3.9)	2	1	(2.0)	1
Severe [IGA=4]		0.1487	0.00 (not est.)	0.00 (not est.)	-4.5 (-11, 1.70)	2	(4.7)	2	0	(0.0)	0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Tralokinumab

Subgruppenanalysen der Sicherheitsendpunkte: Region

LEO Pharma A/S

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Statistical appendix

Table 1.19.601.12.1: Total, Region, Any TEAE, LP0162-1334 300mg

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% CI Lower	Upper	p-value (interaction) #
Total								
Tralokinumab 300 Q2W	97	29.48	63 (64.9)	130	440.96	362.7	513.5	0.8649
Placebo	94	27.93	58 (61.7)	134	479.72	401.8	564.5	
Asia								
Tralokinumab 300 Q2W	11	3.38	7 (63.6)	11	325.57	165.1	559.5	
Placebo	11	3.38	8 (72.7)	14	413.76	223.8	666.5	
Australia								
Tralokinumab 300 Q2W	5	1.54	4 (80.0)	8	519.79	224.9	995.2	
Placebo	4	1.31	3 (75.0)	10	761.04	289.3	1233	
Europe								
Tralokinumab 300 Q2W	33	9.95	20 (60.6)	42	422.31	296.2	550.1	
Placebo	32	9.60	18 (56.3)	46	479.24	357.4	638.5	
North America								
Tralokinumab 300 Q2W	48	14.62	32 (66.7)	69	472.02	363.7	586.3	
Placebo	47	13.64	29 (61.7)	64	469.32	363.4	594.6	

The number of subjects and percentage of subjects with at least one adverse event is summarised. The rate is calculated as the number of experienced adverse events (multiple occurrences are counted more than once) divided by the total exposed period and presented as events per 100 patient years. The exposure period corresponds to the treatment emergent period, from treatment start and up to 7 days after last trial medication or last follow up visit, whichever comes first. 95% CI limits are calculated in the poisson model where treatment and IGA strata are included as fixed effects. N: Number of subjects exposed, n: Number of subjects with an event, %: Percent of exposed subjects with an event, e: Number of events. TEAE: Treatment emergent adverse events

Table 1.19.607.12.1: Total, Region, Death, LP0162-1334 300mg

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)		95% CI Lower	Upper	p-value (interaction) #
Total									
Tralokinumab 300 Q2W	97	29.48	0 (0.0)	0	0.00	*	0.0	-	1.0000
Placebo	94	27.93	0 (0.0)	0	0.00	*	0.0	-	
Asia									
Tralokinumab 300 Q2W	11	3.38	0 (0.0)	0	0.00	*	0.0	-	
Placebo	11	3.38	0 (0.0)	0	0.00	*	0.0	-	
Australia									
Tralokinumab 300 Q2W	5	1.54	0 (0.0)	0	0.00	*	0.0	-	
Placebo	4	1.31	0 (0.0)	0	0.00	*	0.0	-	
Europe									
Tralokinumab 300 Q2W	33	9.95	0 (0.0)	0	0.00	*	0.0	-	
Placebo	32	9.60	0 (0.0)	0	0.00	*	0.0	-	
North America									
Tralokinumab 300 Q2W	48	14.62	0 (0.0)	0	0.00	*	0.0	-	
Placebo	47	13.64	0 (0.0)	0	0.00	*	0.0	-	

*: The statistical model did not converge, the confidence interval is not estimable.
The number of subjects and percentage of subjects with at least one adverse event is summarised. The rate is calculated as the number of experienced adverse events (multiple occurrences are counted more than once) divided by the total exposed period and presented as events per 100 patient years. The exposure period corresponds to the treatment emergent period, from treatment start and up to 7 days after last trial medication or last follow up visit, whichever comes first. 95% CI limits are calculated in the poisson model where treatment and IGA strata are included as fixed effects. N: Number of subjects exposed, n: Number of subjects with an event, %: Percent of exposed subjects with an event, e: Number of events.

Table 1.19.701.12.1: Total, Region, Any TEAE, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	0.9367	0.6720	1.05 (0.84, 1.30)	1.14 (0.63, 2.05)	3.0 (-11, 16.7)	58	(61.7)	134	63	(64.9)	130
Asia		0.6409	0.88 (0.51, 1.50)	0.62 (0.09, 4.25)	-9.1 (-46, 27.3)	8	(72.7)	14	7	(63.6)	11
Australia		0.8084	1.11 (0.40, 3.12)	1.33 (0.11, 16.7)	7.7 (-61, 76.4)	3	(75.0)	10	4	(80.0)	8
Europe		0.7616	1.07 (0.71, 1.61)	1.17 (0.43, 3.15)	3.8 (-20, 27.8)	18	(56.3)	46	20	(60.6)	42
North America		0.6280	1.08 (0.80, 1.46)	1.23 (0.53, 2.84)	4.8 (-15, 24.2)	29	(61.7)	64	32	(66.7)	69

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.19.703.12.1: Total, Region, Any TEAE causing permanent discontinuation, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.19.708.12.1: Total, Region, Any TE SAE, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	Not est.	0.0918	0.20 (0.02, 1.63)	0.20 (0.02, 1.68)	-4.3 (-9.4, 0.72)	5	(5.3)	5	1	(1.0)	1
Asia		0.3173			9.1 (-7.9, 26.1)	0	(0.0)	0	1	(9.1)	1
Australia		0.3173	0.00 (not est.)	0.00 (not est.)	-23 (-65, 19.2)	1	(25.0)	1	0	(0.0)	0
Europe		0.2636	0.00 (not est.)	0.00 (not est.)	-3.4 (-9.8, 2.88)	1	(3.1)	1	0	(0.0)	0
North America		0.0810	0.00 (not est.)	0.00 (not est.)	-6.3 (-13, 0.64)	3	(6.4)	3	0	(0.0)	0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.19.710.12.1: Total, Region, Any TE SAE causing permanent discontinuation, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.19.711.12.1: Total, Region, Any TEAE by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH RR p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	0.9367	0.6720	1.05 (0.84, 1.30)	1.14 (0.63, 2.05)	3.0 (-11, 16.7)	58	(61.7)	134	63	(64.9)	130
Asia		0.6409	0.88 (0.51, 1.50)	0.62 (0.09, 4.25)	-9.1 (-46, 27.3)	8	(72.7)	14	7	(63.6)	11
Australia		0.8084	1.11 (0.40, 3.12)	1.33 (0.11, 16.7)	7.7 (-61, 76.4)	3	(75.0)	10	4	(80.0)	8
Europe		0.7616	1.07 (0.71, 1.61)	1.17 (0.43, 3.15)	3.8 (-20, 27.8)	18	(56.3)	46	20	(60.6)	42
North America		0.6280	1.08 (0.80, 1.46)	1.23 (0.53, 2.84)	4.8 (-15, 24.2)	29	(61.7)	64	32	(66.7)	69
General disorders and administration site conditions											
Any											
Total	0.0100	0.2062	1.91 (0.68, 5.37)	1.95 (0.66, 5.77)	5.0 (-2.8, 12.8)	5	(5.3)	7	10	(10.3)	13
Infections and infestations											
Any											
Total	0.7033	0.5510	1.12 (0.77, 1.63)	1.20 (0.66, 2.18)	4.2 (-9.4, 17.7)	32	(34.0)	47	37	(38.1)	50
Viral upper respiratory tract infection											
Total	0.9373	0.3102	1.53 (0.67, 3.49)	1.65 (0.63, 4.32)	4.5 (-4.1, 13.0)	8	(8.5)	10	12	(12.4)	16
Upper respiratory tract infection											
Total	0.8764	0.0819	2.53 (0.86, 7.51)	2.78 (0.85, 9.13)	6.8 (-.71, 14.3)	4	(4.3)	5	11	(11.3)	11

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.19.711.12.1: Total, Region, Any TEAE by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.4881	0.5397	0.78 (0.36, 1.71)	0.75 (0.30, 1.86)	-2.8 (-12, 6.09)	12	(12.8)	17	10	(10.3)	12
Skin and subcutaneous tissue disorders											
Any											
Total	0.6481	0.2615	0.67 (0.33, 1.35)	0.63 (0.28, 1.41)	-5.9 (-16, 4.25)	17	(18.1)	24	12	(12.4)	13
Dermatitis atopic											
Total	0.9839	0.2092	0.57 (0.22, 1.42)	0.55 (0.21, 1.44)	-5.5 (-14, 3.14)	12	(12.8)	16	7	(7.2)	7

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events

Table 1.19.712.12.1: Total, Region, Any TESAE by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	Not est.	0.0918	0.20 (0.02, 1.63)	0.20 (0.02, 1.68)	-4.3 (-9.4, 0.72)	5	(5.3)	5	1	(1.0)	1
Asia		0.3173			9.1 (-7.9, 26.1)	0	(0.0)	0	1	(9.1)	1
Australia		0.3173	0.00 (not est.)	0.00 (not est.)	-23 (-65, 19.2)	1	(25.0)	1	0	(0.0)	0
Europe		0.2636	0.00 (not est.)	0.00 (not est.)	-3.4 (-9.8, 2.88)	1	(3.1)	1	0	(0.0)	0
North America		0.0810	0.00 (not est.)	0.00 (not est.)	-6.3 (-13, 0.64)	3	(6.4)	3	0	(0.0)	0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.19.713.12.1: Total, Region, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events

Table 1.19.714.12.1: Total, Region, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	0.5945	0.4317	1.92 (0.38, 9.74)	2.05 (0.35, 12.0)	2.0 (-2.8, 6.76)	2	(2.1)	3	4	(4.1)	4
Asia		1.0000	1.00 (0.08, 12.6)	1.00 (0.05, 20.8)	0.0 (-23, 23.0)	1	(9.1)	1	1	(9.1)	1
Australia		0.3173			23.1 (-14, 60.0)	0	(0.0)	0	1	(20.0)	1
North America		0.6053	1.84 (0.18, 19.0)	1.91 (0.16, 22.6)	1.8 (-5.0, 8.72)	1	(2.1)	2	2	(4.2)	2
Eye disorders											
Any											
Total	Not est.	0.9830	0.98 (0.15, 6.27)	0.98 (0.13, 7.49)	-0.0 (-4.0, 3.93)	2	(2.1)	3	2	(2.1)	2
Conjunctivitis allergic											
Total	Not est.	0.9830	0.98 (0.15, 6.27)	0.98 (0.13, 7.49)	-0.0 (-4.0, 3.93)	2	(2.1)	3	2	(2.1)	2
Infections and infestations											
Any											
Total	Not est.	0.1703			2.0 (-.79, 4.82)	0	(0.0)	0	2	(2.1)	2
Keratitis viral											
Total	Not est.	0.3375			1.0 (-.99, 3.00)	0	(0.0)	0	1	(1.0)	1
Conjunctivitis bacterial											

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.19.714.12.1: Total, Region, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total	Not est.	0.3375			1.0 (-.99, 3.00)	0	(0.0)	0	1	(1.0)	1

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.19.715.12.1: Total, Region, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.19.716.12.1: Total, Region, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1 (1.1)		1	0 (0.0)		0
Asia		0.3173	0.00 (not est.)	0.00 (not est.)	-9.1 (-26, 7.90)	1 (9.1)		1	0 (0.0)		0
Infections and infestations											
Any											
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1 (1.1)		1	0 (0.0)		0
Eczema herpeticum											
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1 (1.1)		1	0 (0.0)		0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.19.717.12.1: Total, Region, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.19.718.12.1: Total, Region, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.19.719.12.1: Total, Region, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.19.720.12.1: Total, Region, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	0.2605	0.9829	1.02 (0.15, 7.10)	1.02 (0.14, 7.41)	0.0 (-4.0, 4.12)	2	(2.1)	2	2	(2.1)	3
Asia		0.3173	0.00 (not est.)	0.00 (not est.)	-9.1 (-26, 7.90)	1	(9.1)	1	0	(0.0)	0
Australia		0.3173			23.1 (-14, 60.0)	0	(0.0)	0	1	(20.0)	2
North America		0.9757	1.04 (0.07, 15.7)	1.05 (0.06, 17.8)	0.1 (-5.6, 5.81)	1	(2.1)	1	1	(2.1)	1
Infections and infestations											
Any											
Total	0.2605	0.9829	1.02 (0.15, 7.10)	1.02 (0.14, 7.41)	0.0 (-4.0, 4.12)	2	(2.1)	2	2	(2.1)	3
Impetigo											
Total	Not est.	0.3070			1.1 (-.98, 3.13)	0	(0.0)	0	1	(1.0)	1
Staphylococcal skin infection											
Total	Not est.	0.3276	0.00 (not est.)	0.00 (not est.)	-1.0 (-3.1, 1.02)	1	(1.1)	1	0	(0.0)	0
Erysipelas											
Total	Not est.	0.3173	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.1, 1.01)	1	(1.1)	1	0	(0.0)	0
Skin infection											
Total	Not est.	0.3173			1.1 (-.98, 3.09)	0	(0.0)	0	1	(1.0)	2

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAESI: Treatment emergent adverse events of special interest

Table 1.19.721.12.1: Total, Region, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	CMH ChiSq p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Total					94	27.9		97	29.5	
Asia					11	3.4		11	3.4	
Australia					4	1.3		5	1.5	
Europe					32	9.6		33	9.9	
North America					47	13.6		48	14.6	

There is no system organ class meeting the criteria of at least 1 for intervention and 1 for control arm

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.19.722.12.1: Total, Region, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	0.6280	0.3953	1.11 (0.87, 1.40)	1.29 (0.72, 2.30)	6.0 (-7.9, 19.9)	53	(56.4)	117	61	(62.9)	123
Asia		0.3450	0.75 (0.41, 1.36)	0.38 (0.05, 2.74)	-18 (-54, 17.9)	8	(72.7)	10	6	(54.5)	9
Australia		0.8084	1.11 (0.40, 3.12)	1.33 (0.11, 16.7)	7.7 (-61, 76.4)	3	(75.0)	10	4	(80.0)	8
Europe		0.3127	1.26 (0.80, 1.99)	1.68 (0.62, 4.55)	12.6 (-11, 36.5)	15	(46.9)	39	20	(60.6)	39
North America		0.4857	1.12 (0.81, 1.55)	1.34 (0.59, 3.05)	7.1 (-13, 26.8)	27	(57.4)	58	31	(64.6)	67

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TEAE: Treatment emergent adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.19.723.12.1: Total, Region, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1334 300mg, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo n	Placebo (%)	Placebo E	Tralokinumab 300 Q2W n	Tralokinumab 300 Q2W (%)	Tralokinumab 300 Q2W E
Analysis set											
N, Exposure(years)											
Total						94	27.9		97	29.5	
Asia						11	3.4		11	3.4	
Australia						4	1.3		5	1.5	
Europe						32	9.6		33	9.9	
North America						47	13.6		48	14.6	
Any system organ class											
Any preferred term											
Total	Not est.	0.1778	0.25 (0.03, 2.24)	0.25 (0.03, 2.26)	-3.2 (-7.7, 1.43)	4	(4.3)	4	1	(1.0)	1
Asia		0.3173			9.1 (-7.9, 26.1)	0	(0.0)	0	1	(9.1)	1
Australia		0.3173	0.00 (not est.)	0.00 (not est.)	-23 (-65, 19.2)	1	(25.0)	1	0	(0.0)	0
North America		0.0810	0.00 (not est.)	0.00 (not est.)	-6.3 (-13, 0.64)	3	(6.4)	3	0	(0.0)	0

The number of subjects, percentage of subjects and number of events are summarised by preferred term and subgroup. All system organ class and preferred terms with a Chi-square treatment comparisons with p-values below 0.05 are included. Only subgroups with sufficient number of subjects and events are included.N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. Chi-square test does not include continuity corrections or zero cell corrections. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.